

## **Transcript**

# HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

October 21, 2020, 9:30 a.m. - 12:15 p.m. ET

**VIRTUAL** 

HealthIT.gov

@ONC\_HealthIT

## **Speakers**

Name	Organization	Role
Carolyn Petersen	Individual	Chair
Robert Wah	Individual	Chair
Michael Adcock	Magnolia Health	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
Jim Jirjis	Clinical Services Group of Hospital Corporation of America (HCA)	Member
John Kansky	Indiana Health Information Exchange	Member
Ken 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
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Denise Webb	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative

James Ellzy	Defense Health Agency,	Federal Representative
Cacc	Department of Defense	
	Centers for Disease Control	Federal Representative
Adi V. Gundlapalli	and Prevention	
•	Department of Veterans	
Jonathan Nebeker	Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and	Federal Representative
	Medicaid Services	'
	National Institute of Standards	
Ram Sriram	and Technology	Federal Representative
Alex Mugge	Centers for Medicare &	Federal Representative
33	Medicaid Services	'
Donald Rucker	Office of the National	National Coordinator
	Coordinator for Health	
	Information Technology	
Steve Posnack	Office of the National	Deputy National Coordinator
	Coordinator for Health	. ,
	Information Technology	
Elise Sweeney Anthony	Office of the National	Executive Director, Office of
	Coordinator for Health	Policy
	Information Technology	
Andrew Gettinger	Office of the National	Chief Clinical Officer
	Coordinator for Health	
	Information Technology	
Thomas Mason	Office of the National	Chief Medical Officer
	Coordinator for Health	
	Information Technology	
Seth Pazinski	Office of the National	Director, Office of Planning,
	Coordinator for Health	Evaluation, and Analysis
	Information Technology	
Talisha Searcy	Office of the National	Deputy Director, Technical
	Coordinator for Health	Strategy and Analysis Division
	Information Technology	
Avinash Shanbhag	Office of the National	Acting Executive Director, Office
	Coordinator for Health	of Technology
	Information Technology	
Lauren Richie	Office of the National	Designated Federal Officer
	Coordinator for Health	
	Information Technology	
Alix Goss	Imprado Consulting, a division of	Presenter
	DynaVet Solutions	





#### **Robert Wah**

Who is there?

#### Lauren Richie

I'm sorry. Can you - can you hear me?

#### **Robert Wah**

Yeah.

#### Lauren Richie

Okay. Great.

#### **Robert Wah**

And now we sound great.

#### Lauren Richie

Great. Sorry about that. Good morning, everyone. Welcome to another HITAC meeting. I want to thank our HITAC members and those from the public that have joined us today. I hope you all are enjoying the fall season so far. Just a few reminders before we get started for our HITAC members. We'll ask you to state your name before speaking. And for those that are on Adobe to please use the raised hand feature. And if you are only on the phone, you can just send us a note through the chat feature or just pipe up over the phone and we'll get you into the queue for any comments you may have. And with that, I will get us started with roll call starting with our co-chairs. Carolyn Petersen?

#### **Carolyn Petersen**

Good morning.

#### Lauren Richie

Robert Wah?

#### **Robert Wah**

Good morning. Present.

#### Lauren Richie

Michael Adcock?

### **Michael Adcock**

Good morning.

#### Lauren Richie

Christina Caraballo?

#### **Christina Caraballo**

Good morning.



### **Lauren Richie**

Tina Esposito?

#### **Tina Esposito**

Present.

#### Lauren Richie

Cynthia Fisher?

#### **Cynthia Fisher**

Present.

#### **Lauren Richie**

Valerie Grey?

#### Valerie Grey

Good morning.

#### Lauren Richie

Anil Jain?

#### **Anil Jain**

Good morning.

#### **Lauren Richie**

Jim Jirjis?

#### Jim Jirjis

Good morning.

#### **Lauren Richie**

John Kansky?

#### John Kansky

Good morning.

#### Lauren Richie

Good morning. Ken Kawamoto?

#### Ken Kawamoto

Present.

#### **Lauren Richie**

Steven Lane?



#### ONC

#### **Steven Lane**

Good morning.

#### **Lauren Richie**

Good morning. Les Lenert?

#### **Leslie Lenert**

Present.

#### **Lauren Richie**

Great. Arien Malec? Not yet. Okay. Clem McDonald? Not yet. Okay. Aaron Miri?

#### **Aaron Miri**

Good morning.

#### **Lauren Richie**

Good morning. Brett Oliver?

#### **Brett Oliver**

Good morning.

#### **Lauren Richie**

Terry O'Malley?

#### **Terrence O'Malley**

Good morning.

#### **Lauren Richie**

Jim Pantelas?

#### James Pantelas

Present.

#### **Lauren Richie**

Raj Ratwani?

#### Raj Ratwani

Good morning.

#### Lauren Richie

Steve Ready?

#### **Steve Ready**

Good morning.



### Lauren Richie

Abby Sears? Okay. Alexis Snyder?

#### Alexis Snyder

Good morning.

#### Lauren Richie

Sasha TerMaat?

#### Sasha TerMaat

Good morning.

#### Lauren Richie

Andy Truscott?

#### **Andrew Truscott**

Present.

#### **Lauren Richie**

Sheryl Turney?

#### **Sheryl Turney**

I'm here. Good morning.

#### **Lauren Richie**

Denise Webb?

#### **Denise Webb**

Good morning.

#### **Lauren Richie**

From CMS, Alex Mugge?

#### Alex Mugge

Good morning.

#### Lauren Richie

Okay, great. James Ellzy?

#### James Ellzy

Good morning.

#### **Lauren Richie**

Ram Sriram?



#### **Ram Sriram**

Good morning.

#### Lauren Richie

Adi Gundlapalli? Or Laura Conn, perhaps? Okay. Jonathan Nebeker?

#### Jonathan Nebeker

Hello.

#### Lauren Richie

Great. Amy Abernethy? Okay. Not yet. All right. Then in addition to our members are our ONC leadership team. We are joined by our National Coordinator Donald Rucker, our Deputy National Coordinator, Steve Posnack, Executive Director of Office of Policy, Elise Sweeney Anthony, Executive Director of Office of Technology, Avinash Shanbhag, Director of Office of Strategic Planning and Coordination, Seth Pazinski, our Chief Clinical Officer. Dr. Andy Gettinger, and I believe that it all. Apologies if I missed anyone. But at this point, I will turn it over to Dr. Rucker for a few opening remarks.

#### Michelle Schreiber

Hello, hi. Excuse me. This is Michelle Schreiber from CMS. I don't think you called my name.

#### **Lauren Richie**

Apologies. Hi, Michelle. Thank you.

#### Michelle Schreiber

Thank you.

#### **Lauren Richie**

Is there anyone else I may have missed during roll call?

#### Talisha Searcy

Hi, Lauren. This is Talisha Searcy with ONC. I'm on the call as well.

#### Lauren Richie

Thank you. Anyone else?

#### **Tom Mason**

Hey, Lauren. This is Tom Mason.

#### Lauren Richie

Hi, Tom. Anyone else? Great. Okay. Dr. Rucker, the floor is yours.

#### Welcome Remarks (00:04:38)

#### Robert Wah

It looks like he may have gotten disconnected, Lauren.

#### Lauren Richie



Oh, sorry. Okay. While we are waiting for Dr. Rucker to rejoin I will turn it over to Robert and Carolyn.

#### **Robert Wah**

Thanks, Lauren. Until Don comes on, we'll go ahead and review the agenda today. As you can see, we have three major topics.

#### **Donald Rucker**

I'm on. I'm on, Robert. Robert.

#### **Robert Wah**

Hey, Don.

#### **Donald Rucker**

Yeah, hi. Sorry. Between the computer and phone... So, first of all, I'd like to join Robert and Lauren in thanking everybody for participating. We are at ONC doing a lot of work with COVID. No surprise to anybody. One of the other things that we have on the agenda and for today is the Intersection of the Clinical Administrative Data Task Force. So, the report for that. This is a, as folks know, a long-standing project to really look at ways to integrate clinical and financial data. That is one of the missing links here, I think, in American healthcare in terms of having American healthcare be responsive to the vast resources invested – if that is the right word. Probably not. Spend would be a more accurate word – in all of that.

A couple other – a couple of other things. We started a program to really strengthen an opportunity that we have seen with the state and local health information exchanges during the COVID fight. They have some extraordinary abilities to do patient-level identification overall potential parties who are affecting patient care. Not just classic EMR uses like doctors and hospitals, but things like nursing homes, group homes, shelters. Eventually, schools and jails. And they are very good for figuring out things like spot outbreaks of the infection, for getting information about patients over the entirety of their care pattern no matter where that was to do, for example, things like risk factor calculation. There is some interesting technology with machine learning and with just modern data science that can make these things even more valuable.

To explore those, we have a grant program that our department of acronyms – that's probably Steve Posnack, truth be told, it's a one-man department – is calling strengthening technical advancement and readiness of public health agencies via health information exchange. Or the STAR HIE Program. So, we're pleased to announce that the Georgia Health Information Network, Health Current out in Arizona, Health Share Exchange of south – southeastern Pennsylvania, the Kansas Health Information Network, and the Texas Health Services Authorities were awarded grants for that cutting-edge work. So, we're very pleased with that. We see that as potentially the modern way to switch from the 100 plus year tradition of mandated reporting in public health to move to a more modern exchange oriented concept where operational data that is part of care is really used under all of the legal and privacy strictures to provide the data for Public Health Authority.

This is obviously a work in progress, but very exciting. In a somewhat related data note, we've extended the deadline for the USCDI ONDEC submission. That's our program to update the USCDI as time goes on. So, that's been extended to October 23.

#### Clem McDonald



Communication problems. So...

#### **Donald Rucker**

Okay. That sounds like Clem. Okay. And I'd like to announce on the membership-side that we have, as folks know, the high-tech membership is sort of a complicated rolling process of multiple constituencies. So, members and renewals and reappointments sort of come in overtime. But Ken Kawamoto, Sheryl Turney, and Alexis Snyder were reappointed for a second term. We appreciate their work. We would like to thank two HITAC members who will complete their service at the end of this year, Christina Caraballo and Tina Esposito.

Christina has done great work on the USCDI Task Force and the Annual Report Workgroup. Tina's worked on the USCDI Task Force and the ISP. We wish them well and hope they can participate as members of the public. We are anticipating appointing new HITAC co-chairs at our next and final meeting on November 10. So, just I know we have had a bunch of interest in that. And so, now let me turn it over to Robert and Carolyn. Thank you.

#### Review of Agenda and Approval of September 9, 2020 Meeting Minutes (00:10:29)

#### **Robert Wah**

Thank you, Don. And good morning, everyone. And welcome to our October meeting of the committee. It's great to be with you all. And as Lauren said, I hope everyone is enjoying the change of seasons to fall. A busy time for most folks. Just to quickly review the agenda, we have three major presentations today. One is the ONC objectives and benchmarks. And then we'll hear from the HITAC Annual Report Workgroup. And then we'll go into the Intersection of Clinical and Administrative Data Task Force, as Dr. Rucker talked about. There are grant recommendations that were sent out early. It's a fairly large file. I hope everyone had a chance to review that.

As always, we have a public comment scheduled for 12:00. We'll work to try to keep that promise to the public to make that space available for the public comment period. And so, the last thing we need to do before we proceed is review our September 9, 2020 meeting minutes. I will call for any amendments or changes to those minutes. Does anyone have any questions, problems, issues with the September 9, 2020 minutes? Hearing none, we just need to vote approval of those. All of those in favor of approving the September 9, 2020 minutes please signify by saying, "Aye."

#### 

Aye.

#### Robert Wah

All of those opposed say no. Any abstentions? Okay. So, we've approved our meeting minutes and with that, I'll turn it over to Carolyn for her welcoming remarks and we'll get going with the meeting. Thank you.

#### **Carolyn Petersen**

Thanks, Robert. Good morning, everyone. It's hard to believe it has already been a month since our last meeting. But I know the working groups and task forces have been hard at work preparing some really good presentations for us today. And I think we're all particularly interested in diving into the Intersection of Clinical and Administrative Data Task Force Draft Recommendations and the Report. So, with that, I will

not hold us up any further. We'll move on to the presentations about ONC objectives and benchmarks. Thank you.

#### **ONC Objectives and Benchmarks Presentation (00:12:47)**

#### **Elise Sweeney Anthony**

Thank you, thank you, thank you. I appreciate that, Carolyn. And good morning, everyone. My name is Elise Sweeney Anthony, Executive Director, Office of Policy. Presenting with me today would be Seth Pazinski, who leads our Strategic Planning and Coordination Division, and Talisha Searcy, who is the Deputy Director for the Technical Strategy and Analysis Division. Today we're going to be talking about the objectives and benchmarks and measurements as it relates to our work here at ONC. One of the things that we're going to be asking at the end of the presentation is for the HITAC members' feedback regarding two areas in particular. But, of course, we welcome all of your feedback. But the two areas would be the proposed measurement concepts for increasing active exchange and use across stakeholders and also the focus areas for ONC measurement activity.

So, we're going to be going through a fair amount today in terms of the objectives and benchmarks, and then a discussion of the measurement as well. And we welcome your feedback on it all. So, moving to the next slide. So, here you can see the Cures Act requirements. So, there are several things that the Cures Act asks the secretary and ONC to work on. Many of them the HITAC has already engaged in the rules, for example. Looking at TEFCA as another example. And then the objectives and measures are another piece of the puzzle in terms of implementation of the Cures Ac. And specifically what the national coordinator in collaboration with the secretary is charged to do in support of the HITAC's work.

So, to just take a look at the language on your left, "The national coordinator, in collaboration with the secretary, shall establish and update as appropriate objectives and benchmarks for advancing and measuring the advancement of the priority target areas." So, as we look at the HITAC Annual Report, or as the HITAC looks at the HITAC Annual Report, ONC sets the objectives and benchmarks used in the development of that report. The ONC objectives and benchmarks also align with the draft strategic plan that ONC, as well as our federal partners, have been working on as well. So, as we go through the activities we are going to talk about in the objectives and the benchmarks, many of them will look familiar to you.

HITAC has provided direct recommendations on many of these. So, you'll be familiar with many of them. And if there's any that you are not or have questions about, please do let us know stat so we can talk a little bit more about that. As I said before, these – the objectives and the benchmarks are going to help inform the HITAC Annual Report and the development thereof related to the target areas. And just as a reminder, the target areas that are laid out in the Cures Act, the priority target areas are patient access, inoperability, and privacy and security. So again, we look forward to your feedback. I'm going to turn it over to Seth Pazinski to start talking about the objectives and benchmarks. And then Talisha will come in and talk about the measurement as well. Seth.

#### Seth Pazinski

All right. Thanks, Elise, and hi everyone. I am Seth Pazinski with ONC we can move on to the next slide. So, in the October 2019 meeting of the HITAC, we presented two objectives in some areas for focusing on benchmarking progress through the end of the fiscal year 2020, which just wrapped up in September. So, we also communicated the same objectives in the draft 2020-2025 Federal Health IT Strategic Plan. That

was out for public comment earlier this year and we appreciate your feedback that was provided during the February HITAC meeting earlier in the year. So, the two objectives are to advance the development and use of health IT capabilities and to establish expectations for data sharing.

In the draft of the Federal Health IT Strategic Plan, we also aligned these two objectives to the goal of connecting healthcare with health data. And so, ONC intends to focus on three areas for our benchmarking progress against these objectives. So, we can go to the next slide. So, today we're going to provide some updated plans. So, through – over the next two years, so through September of 2022 in the three areas of standards, certification, and exchange. And in each of these areas, the next series of slides that I will just walk through fairly briefly will take a look back at progress from 2018 until today. And then we'll take a look ahead at the next two years of expected work in these three areas.

So, I'll start with a look back on the standards progress. So, we can go to the next slide. So, for both standards and certification you will notice, as Elise mentioned, much of the history in these areas is tied to the developed of the ONC Cures Act Final Rule, including the variety of HITAC recommendations related to the different pieces of the role. So, this slide focuses on the standard activity for the US Core Data for Interoperability Version 1 Standard and the standards version and the intimate process. Both of those were established in the ONC Final Rule. And also, I wanted to note just for the HITAC members and for the public, there are two upcoming deadlines for public feedback related to these two areas.

Don mentioned the first one, which is the USCDI opportunity to submit new data elements and classes, is due this Friday, October 23. And the second one is related to the standard version advancement process as well as ONC's annual process for the Interoperability Standard Advisory. And feedback for those two areas is due on November 9. We can go to the next slide. So, progress related to the FHIR Standard included the release of the HL7 FHIR release for Standard, which was developed in the ONC Cures Act Final Rule. And we'll next take a look at what we're anticipating in work in these standard areas over the next couple of years. We can go to the next slide.

So, we'll experience over the next couple of years the beginning of annual cycles related to the Standard Version Advancement Process as well as the Annual Cycle for the USCDI Versioning Standard. From a FHIR perspective, we are anticipating the release of HL7's FHIR release 5 as well as a variety of resources to support the use of FHIR. In addition to these standard activities, we have also begun to work on some standard support for public health as part of the H adjuster response to COVID-19. We can go to the next slide. So, ONC recently awarded some work to address standard gaps in opportunities as part of the COVID-19 response as well as to support other public health emergencies. So, these include investments to support standard development organizations to develop lab standards as well as to build innovative HIE services that benefit public health agencies. And Dr. Rucker talked about that in his opening remarks with the STAR HIE Program.

So, now I will transition to talk about certification. We can go to the next slide. So again, here the progress is largely about completing the various aspects and getting information from HITAC to inform the Cures Act Rule and the certification program requirements and criteria requirements that went into the Final Rule. And thanks again for HITAC's contributions in this area. As folks experienced, we had about 70 Task Force meetings in about 100 days to inform the Final Rule. So, thanks again for all of the great work and I appreciate the input into the Final Rule. We can transition into the implementation of these certification criteria with the next slide. So, looking ahead at implantation of the Rule over the next couple of years from

a certification perspective, this could include the start of compliance requirements related to conditions and certification for things like information blocking, and APIs, and assurances, and communications.

As well as for first – the first real-world testing plan and first attestation for conditions and maintenance of certification coming due. So, I did want to pause here just to acknowledge the significance of the work in this space. I think it – just in preparing these slides, I'm six slides deep in various points along a long path here – but it is worth highlighting that the technical requirements here and the data sharing expectation requirements that are set through the certification program are really about trying to drive improvements in data access exchange and use for multiple stakeholders. As well as creating the opportunity for the app economies to support various stakeholders' needs including patients, and physicians, and hospitals, and provider and players, and more innovation in choice within healthcare.

And so, we will get into some of these more outcome-focused concepts as we talk about the measurement concepts later in the presentation. So, with that, I will transition to the next slide, which is focused on the last area of exchange. So, to look back here, this is largely focused on the Trusted Exchange Framework and Common Agreement and the progress of implementing that program. Again, this highlights some of the HITAC recommendations at various points to inform this work. So, along with the conditions and maintenance of certification, the task addresses that second objective about establishing expectations for data sharing. And the ONC and the Recognized Coordinating Entity, who is the guarantee from ONC, are continuing to develop the Draft Common Agreement.

We can transition to the next slide. So, as we look ahead to building the progress to date, we anticipate releasing the first 60-day public comment period, the Common Agreement Draft Version 1 as well as a qualified health information network technical framework. That's a mouthful. QTF to draft 2 for public comment and then ultimately completing the final versions of the Trusted Exchange Framework Common Agreement and QTF. And so, we can go to the next and last slide for me. So, to recap, there are three areas that we are focusing on. Standard certification exchanges that are aimed at driving progress against ONC objectives, but also in – related to progress on the three priority target areas that Elise mentioned that identify for HITAC and the Cures Act.

So, this is really the opportunity for the HITAC, both through the Annual Report and any other feedback that you have today, just to consider how these activities can contribute to improvements related to Patient Access, Interoperability, and Privacy and Security. The HITAC is a part of the FY20 Annual Report Process. It's considering public health as an additional target area. So, just as a reminder on that, potential future work on that would be coming from ONC and charges to the HITAC to potentially draft work-related in the prior – the public health priority target area. So, with that, I will now turn it over to Talisha Searcy who is just going to update us on measurement activities for ONC and ask for some feedback. Talisha.

#### Talisha Searcy

Thanks. Thank you so much, Seth. So, again, my name is Talisha Searcy. And I am excited to have the opportunity to talk to you all today. As Seth mentioned, there has been a lot of work that has been happening in terms of finalization of ONC's Cures Act Final Rule. But there has also been a lot of work in terms of continuing to try to understand the possibilities for measurement as it relates to various survey activities as well as as it relates to trying to identify ways in which our newly established programs might help us to better assess what is happening in terms of interoperability. Particularly as it relates to access exchange

ONC

and use. I want to thank the members of the HITAC that were able to participate in the interoperability and measurement workshop that occurred last month.

Steven Lane was able to participate in that meeting and we hope to continue to have collaborative workgroups. Specifically designed to help us in tackling some of the hard issues as it relates to measurement. So, as Seth mentioned, we have been doing a lot of work in terms of finalization of the Rule. And it has provided us with an opportunity to take a step back to really reassess the framework that we have for measuring. What are our intended outcomes in all the work that we are doing under the Rule? How could we perhaps identify new measures and new data sources that might help us to better understand the impacts of our work? So, what you see right now are – is a very, very draft and preliminary – a list of potential measure concepts.

And I want to walk through the initial ideas with you all today. But more importantly, I would like to get your feedback in terms of some of the key outcomes that ONC should focus on, as well as some potential data sources and methods we should consider. So, what we are thinking about is four intermediate outcomes to focus our measurement efforts around. The first is how our work leads to increased standardization complement in the quality of electronic health information. And that relates to a lot of the work that we are doing around FHIR, USCDI. The ultimate goal of ensuring that the data is standard and complete and right. So, that is one of the outcomes that we are considering.

Also, a lot of the work they're doing right now is designed to foster a more robust app economy. So, a lot of - sorry. My dog just barked. A lot of the work that we are doing around the FHIR API work, a lot of the efforts that are in the Rule, ultimately, we should see manifest in terms of the app economy and patients' access to that information. So, we wanted to kind of confirm with you all that that is an outcome we should focus on. Additionally, a lot of the work that we are doing is around enhancing the technical capabilities and requirements to make electronic health information more readily available. Seth mentioned earlier aspects of information blocking. Some of the access stations that are required under the Rule are designed to make sure that data is available, and everyone understands that data needs to move.

So, we are interested in figuring out ways to identifying measures that could help us with seeing whether or not that is being realized. And then lastly, in terms of the intermediate outcomes, a lot of the work under the TEFCA is designed to simplify and increase the scale of electronic health information exchange. And so, one of the things that we are trying to see is, "Are we seeing end-users have to make fewer connections to various health information exchange networks? And are we seeing an increase in exchange as a result of that?" And so, the hope is that through moving these four intermediate outcomes, we should start to see an increase in interoperability across various stakeholders.

Another point that we would like to get your thoughts about is interoperability. We typically measure that from a perspective of access, exchange, and use of electronic information across the various stakeholder groups that are listed here on this slide. But there are opportunities for us to rethink that as well. So, I would like to go to the next slide so we can talk a little bit about a couple of the questions that we have for you all. And would love to get your feedback. One around the intermediate outcomes. Are these the right measurement concepts? Are we missing anything? What should we prioritize? There are a number of different vehicles that we can try to take and some may have data that is more readily and more feasible to obtain. And others, not so much. Especially as it relates to things like standards.

Are there some priority concepts and use cases that you all think makes more sense for us? And then also, in terms of timing. I mentioned feasibility. The things that we should measure now versus later. And then I also mentioned a little bit about interoperability across the very stakeholders. One, should we focus on access exchange and use? Are there different aspects of interoperability that we should focus more on? What stakeholders should we be measured across? The list of stakeholders on the previous slide is a lot more comprehensive, but are there some priority groups within that set that you all think are important? And then lastly, should we be measuring the same set of outcomes across those stakeholders? Different stakeholders have different needs. And so, is there some prioritization we should do there?

And then lastly, and perhaps the most important, data collection methods. Are there data sources and methods that we should consider that are available or that we should try to obtain in order to flush out, not only the measurement framework or the concepts for measurement but the actual measures and ways in which we can affect them over time? So, I know that this is a long list of questions, but I would like to go back to the prior slide if that is okay. And then, open the floor for comments and thoughts in terms of some of the outcomes that we have list – intermediate outcomes specifically. Are we missing anything? Are there some areas that we should prioritize? And then we can move to interoperability as well as some of the stakeholder thoughts. With that, I will pause to see if folks have any immediate ideas or thoughts that they would like to share.

#### Lauren Richie

So, we have a number of hands in the queue. Okay. We will start with Steven Lane.

#### Steven Lane

Yes. Thank you very much. I think that it is important to look in addition to access exchange and use also in outcomes. And Dr. Nebeker did comment on that in the public comment. I think though we do have a lot of experience with access and exchange. And as that increases throughout the implementation of the rules, I think we have an opportunity to focus on use and outcomes. And I would suggest that use is something that is a huge challenge. Certainly, for clinicians being able to fully utilize efficiently the data that we are already receiving, getting that to integrate into our systems automatically, to integrate into the workflow is a current challenge.

I would argue that for all of these stakeholders on the right, that we do some deep analysis looking at use and outcomes. And figure out what the appropriate dimensions of those measures should be. It is clearly going to be different for each of the stakeholder groups. And I think that we will be able to talk about this in a much more meaningful way if we have a list of key uses. Anywhere from 3-30 and then associated outcomes that we might be able to look at. I think then we will be able to start looking more deeply into those areas.

#### **Robert Wah**

Thank you. Next up I think is John Kansky.

#### John Kansky

Thank you, Robert. I had a comment on the fourth bullet in the intermediate outcomes with – to simplify and increase the scale of electronic health information exchange. And acknowledging that we are talking about health information exchange, the verb, which is accomplished in many different ways. So, well, it is hard to argue with the goal of simplifying and increasing the scale. I think perhaps, focusing on increasing the scale

and quality of electronic health information exchange. Because right now, in terms of national interoperability, we are doing a much better job of increasing the scale.

But the quality of the information exchange is still an area that needs work. And then, parsing words a little bit, focusing on the word simplify. It is hard to argue that simplifying is not a good idea. The nuance here is that, like in many ecosystems in business and healthcare, there is a diversity of approaches that is occurring at the same time, and that diversity is both a strength and a complicating factor. So, as we seek to simplify, we have to be careful not to do that in a way that does not tolerate diversity of approaches to exchanging information. Thank you.

#### **Robert Wah**

Thanks, John. Next is Anil Jain.

#### **Anil Jain**

Yeah. So, I think – and I am not sure whether this was sort of covered in a different way. But I think intermediate outcomes around the unintended consequences. So, both looking at burden as well as looking at issues around privacy, and wording it in such a way that we don't sort of increase those unintended consequences by measuring that intermediate outcome of retaining privacy and find some verbiage that would get at some of the burdens. I – the fourth bullet around simplify is great, but I think we need to think about burden as well.

#### **Robert Wah**

Thanks, Anil. Next is Alexis Snyder.

#### Alexis Snyder

Hi. Good morning. First, let me agree with Anil on the burden piece. I think that's a really important piece in that fourth bullet as well. I wanted to speak to the completeness and the quality piece. And really coming down to the accuracy of the electronic health record. And that while patients and caregivers alike need more transparency and more access to their health information to support their care, a big piece I think that is missing that needs to be measured and improved upon are ways to actually – to easily correct mistakes. In that EHR for the patient and/or caregiver that's involved in the care. Because if that information is not correct, and often it is not, it certainly affects the quality, the safety of the outcomes for the patient. And it could have real implications and poor experience in care and poor outcomes.

And I think that is something that we need to look at and find ways to make sure that the quality and the accuracy is in that completeness in that first bullet. And then, as far as the use piece, I am really glad to see caregivers listed as a stakeholder and not just the individuals because caregivers do play a very important role in patient care for many folks. And so, I think that that is a great piece there. And on that use side, a way to measure the use of what is being exchanged and how often or how from the patient and caregivers side. Because I do think that that gets greatly affected by two pieces. One, again, the accuracy of the information that is in the EHR. So, the apprehension of patients and caregivers alike to share that information when it may not be the most accurate picture and affects the outcomes.

So, I think you will see if you were able to measure that, that where information – where patients and caregivers are filling out, the information is inaccurate. They are sharing a lot less. The interoperability goes down and they would like to actually just control it themselves and be able to share the pieces across the

system on their own rather than through an electronic exchange to make sure that the most accurate information is getting to the next provider and the next place. And I think the other piece of that lens to work that is already being done over privacy concerns. So, again, I think that the use piece is very important. So, for me, it comes down to the quality and the accuracy that then affects the use.

#### **Robert Wah**

Thank you. Next is Jonathan Nebeker.

#### Jonathan Nebeker

All right. So - can you hear me?

#### **Robert Wah**

Yes.

#### Jonathan Nebeker

Okay. So, the – I always type my – and there's a bunch of other comments in the public chat that are sort of reinforcing this point. So, you have spoken about a measurement framework. And since we are in healthcare, a common framework that we use is DOM and BOM and it deals with structure processes and outcomes. And my – back to the previous slide, I don't know whether ONC is attempting to get at activities or processes to get to these what I would call results and maybe not outcomes. Or, whether there is a result that we are trying to get to and we are trying to measure the result. And s, I hope you can address that question.

The – what I would classify these as in more standard measurement frameworks, as – if we take out the verbs and get just to the nouns, these are about structure. They are not about outcomes. Outcomes being service outcomes for like how we did at the park? Can I call up and get an appointment on time? Or health-related outcomes that relate to comfort, function, dignity. And there is also a revenue outcome in that framework or consequent cost of avoidance outcome. So, I do hope we can get to a – kind of a standard. And there are many different frameworks or variations on DOM and BOM. And so, I hope we can get to a common language in the framework that's the standard so people can understand it more easily.

The – however, given that these – I would classify as structure results, the government has a nice history in health IT of targeting structure changes with a lot of the HITAC recommendations and a lot of the ONC activity over the last – over the years. Not so much recently, fortunately. And there's a lot of entailed perversity with unintended negative outcomes associated with the government targeting structure without clearly targeting outcomes. That is the experience of people. So, at a minimum, I would hope that we could talk about the outcomes and figure out how the structure is related to processes and outcomes. So we don't get ourselves into trouble again.

Finally, ONC has fantastic leadership. Especially recently in this area. We have the federal IT strategic plan that provides a wonderful framework for getting at all that you are talking about here and I just talked about. And you know, Dr. Ellzy and I have had the privilege of working on the VA DOD or maybe DOD VA Interoperability Modernization Plan that is based on the federal — on ONC's Federal Health IT Strategic Plan. And I think it's another iteration or like maybe version 2 of that plan applied to a scope of interoperability. I think it's a model. We are not there yet. But we are getting to be what maybe is a model

for addressing some of these points. And so, those are some comments, but also the question, "Are we trying to get out activities or results that are promoting structure?"

#### **Talisha Searcy**

Hi. This is - I've got a question.

#### **Robert Wah**

Sorry. Who is this?

#### **Talisha Searcy**

This is Talisha Searcy.

#### **Robert Wah**

Oh, yeah. Go ahead.

#### **Talisha Searcy**

Yeah. So, I think, ideally, we would like to link to activities as well. So, you are absolutely correct in that we would like to link some of the measures from the ONC specific activities to tie to these intermediate concepts that we have here. So, ultimately, what we would like to do is be able to show how ONC's work is helping to address these core areas. And then, ultimately, how that impacts outcomes. And I hear the points that were raised about outcomes and focusing more on that as well. And so, what we can do, we have some thoughts and have been doing some work in that area to try to narrow down some potential areas that we could prioritize in terms of outcomes. So, when we come back, we could also add that area as well as a point for discussion.

#### **Robert Wah**

Thanks. So, we're a little bit over our time for this but I think we'll go ahead and finish this discussion. We will take the questions of the people that have their hands up now ending with Abby, I think. So, next is Denise Webb.

#### **Denise Webb**

Yes, Denise Webb. Thank you. I just want to say that I strongly agree with Alexis' comments about the accuracy of the record. Particularly since digital data is so much more liquid and easily flows around much more easily than a paper record. So, I endorse that we need to be looking at that as a priority as far as outcomes. I also think that just in general, that the consumer, the patient, and their caregivers should be one of our highest priorities in measuring access to the actual use of electronic health information data. And then, I have one question on the intermediate outcome. Does the outcome related to the growth of the app econ, does that include the actual use by consumers and in that app economy growth? Because I think there could be a lot of apps out there and they could have the capability to access the data but are they actually being used by consumers? That's it.

#### **Robert Wah**

Great. Thanks. I think maybe we will take the answers to those questions at the end when they summarize. Next, we have Sheryl Turney.

#### **Sheryl Turney**



Thank you, Robert. I had a couple of questions and a couple of comments. My first question was there was a reference on a slide to real-world testing and I was a little bit curious as to what was meant by that in terms of what are the plans going forward for real-world testing? And then also was wondering what the vision was for expanding the scope. Currently, the CMS Interoperability Mandate is only focused on Medicaid, Medicare, QHP. That focus. So, is there a pathway to expanding that to commercial and ERISA as well? And then in addition to those questions, I have a few comments regarding measures for patients and caregivers. I think those would be different than for clinicians or other stakeholders. So, they might be best represented by using use case models with different measures.

Also, the burden on all stakeholders, that's been brought up by others, I do think should be considered and not just in terms of the workload but also in terms of the cost. I mean currently, the health information interoperability highway is a giant toll road with tolls at multiple gates and the impact of this burden needs to be addressed in the future vision as well. And then the third point is the ability for patients and caregivers to bi-directionally share health information needs to be built into the certification requirements. In the current framework, it appears to be more of a unidirectional for patients and caregivers. And really, I believe they need to be bidirectional. This capability is going to be very important to allow patients and caregivers to direct and manage their care journey.

#### **Robert Wah**

Thank you, Sheryl. Next, we have Aaron Miri.

#### **Aaron Miri**

Good morning. Could we go back to the previous slide please for a second? I would like to – I would like to first say this is a great list. A great starting point. I do think there are a couple of components that we could look at and consider in addition to and sort of qualify one of these, particularly around the app economy. I agree that the vibrant health economy is important but there are two components that we have found, particularly here in Austin, Texas dealing with the Covid-19 response, to be critical. One of those being equity. So, health equity. And that in our case is being multilanguage type health apps we put out for the community. We have a large LatinX community.

And so, being able to support apps in Spanish has been critical. Also, ADA compliance is another component of that. The second portion of that same bullet, I would say is around privacy and security. I do think that it is important that we look at this and we don't lose sight of that. Yes, we absolutely want a vibrant economy, but it needs to be within the mind of being secure and also maintaining privacy for the patient and the consumers. So, that could be something like using an API like ONAP 2 or something similar to that. And just having criteria that sort of qualify these components. But I think those two items, equity – health equity and privacy and security, are two items to consider. Thank you.

#### **Robert Wah**

Thanks, Aaron. Next, we have Les Lenert.

#### **Leslie Lenert**

Thank you for a really great discussion. I would like to second the call for outcomes at this point. Particularly outcomes focused on population health. That, unless we are showing that we can measure our impact on populations with these health information exchange technologies that we are talking about, we are going to have a difficult time selling this process and prioritizing it. Let's focus initially on COVID-19 because that

is where our priorities have to be. The issue should be access to test results in a timely way by both patients and providers. That is a great benchmark. Something we need to work on. But as we go forward, there are even better benchmarks, which is the successful uptake of vaccine in the population. and being able to target specific populations with vaccination programs.

That as we move toward November and December and the vaccine becomes available in stage 1, and then stage 2 distribution, we are going to need to be able to target. And the impact of successful health information and exchange on improving the precision of targeting and accelerating the pace of targeting to cover these vulnerable populations is critical. Third, I would say that there is plenty of other population and public health problems that we could use as benchmarks. Such as our ability to measure the blood pressure control in populations and to be able to drive down blood pressure control to reduce problems with – not drive down – but drive down blood pressure to control hypertension and cardiovascular disease as an issue.

So, I think that these are still intermediate outcomes. We are not really talking about cost and mortality, but that they are more measurable in that they show that health information exchange could potentially advance critical targets. To go back, there is no excuse for not – for leaving COVID-19 related intermediate outcomes, particularly related to vaccinations and the ability to plan effective vaccination strategies, off of the agenda here. This has to be our top priority and what our intermediate outcomes are focused on for the next year as we move forward. And to show the value of HIE, as a verb, in – and as a noun, in this context.

#### **Robert Wah**

Thanks, Les. Our last comment/question is from Abby Sears. Abby, are you there? I don't hear her. So, maybe the ONC team can wrap up. And if you can address some of the questions that were asked as well.

#### **Talisha Searcy**

Sure. This is Talisha again. First, I want to thank you all for the feedback that you have provided. I think that there are a number of really excellent points that were raised. And definitely things that we will work to incorporate into a revised version that we would like to bring back to you all to continue this discussion. I want to make sure that I have adequately captured a number of questions. So, there was a question about real-world testing and where does that fit? And I am not sure if that question was more directed towards my colleague's prior slides or towards the measurement's concepts that are presented on your screen right now.

I will say that from a measurement perspective, we are looking at real-world testing, not just as it relates to compliance and making sure that things are working on the ground, but also for the potential of future data access. So, we may have a better understanding of some of the requirements on real-world testing and how some of these technologies may be performing on the ground. We are so very, very early on. And so, we are not quite sure of the viability. But I do know that from a measurement perspective, it is something we are just keeping in the back of our minds as a possibility. And I will pause to see if any of my other colleagues or the person who asked the question around real-world testing Cures to elaborate on that question.

#### **Sheryl Turney**

Thank you. This is Sheryl Turney. I'm the one who asked the question. I was just generally wondering what the plans were because I, based on what was on the slide, wasn't understanding how that was going to fit

in. Whether it was really real-world testing to obtain a certification requirement or how you were going to apply it to measurements?

#### Talisha Searcy

Yeah. So, again, we are still very, very, very early on. But we do have certain ONC programs in the back of our minds, not just as it relates to identifying particular future measures, but also as it relates to potential data sources.

#### **Sheryl Turney**

Thank you.

#### **Talisha Searcy**

No problem. There was also – there was also a point raised about – I believe you also asked about CMS and whether or not there they're to be expanded into the non-Medicare/Medicaid state. So, the short answer is yes. ONC has been funding a number of projects that are designed not limited to CMS data. So, we do have a window into what is happening nationally and not just as it pertains to Medicare and Medicaid providers or Medicare and Medicaid patients. That said, there are still some gaps in terms of some of the data that we may have access to as we are talking about things like outcome measures and how we may be able to access things such as claims data that is from the private sector. That may be a little bit more challenging. But, yes. We have been thinking about measurements. While CMS provides great data for us to leverage, where it is not the only data sources that we have access to right now are that we are considering for the future. And I hope that answers your question.

#### **Avinash Shanbhag**

Hey, this is Avinash Shanbhag from ONC. Lauren, do you mind if I just add on a little bit on the real-world testing question?

#### Lauren Richie

Sure. Go ahead.

#### **Avinash Shanbhag**

Just to close the loop on what Talisha mentioned as part – as we all know with the Cures Rule of being implemented and finalized, there is a requirement in the conditions of certification for health academics to successfully test that certified health academic release in the real-world. And there is as part of it that requires to have health academics make a plan at some point in the year and then the results. So, our work in this upcoming year will be just to ensure that if there is any additional guidance that we need, to enable that activity to be completed promptly but with clarity. That's the work that will make sure that health providers can complete their requirements as efficiently and as effectively as possible. But that data that will be useful to the providers. All that answers the plans for '21 and '22.

#### **Robert Wah**

Right. Thank you. If we could just have the ONC team go ahead and wrap up, please.

#### **Talisha Searcy**

Sure. So again, I just want to thank you all for the questions. And our team will definitely go back and take a look at all of the feedback that you all have provided in the chat and also during this discussion. We also



would like to come back to you in terms of revisions based on the feedback that you have provided today. But also, to provide you all with a couple of data updates in terms of some of the most recent analyses that ONC has done with a number of its different data collection efforts that are currently underway. And we would like to talk about those results as it relates to some of the things and concepts we have talked about today.

So, again, thank you so much and we will work with Lauren and other staff to get on the agenda to continue this conversation as well as to talk about some of the preliminary data analysis and some of the results that we have done in accepting interoperability across the various stakeholder groups and to share that information with you all. So, thank you so much for your time.

#### **Robert Wah**

Great. Thank you very much. So, as people know, we are a little bit off schedule. We will just slide things around a little bit. I don't think it will be a problem. Next up we have the Report from the Annual Committee, I'm sorry, Annual Report Task Force. Carolyn and Aaron, go ahead and take it away.

#### **HITAC Annual Report Workgroup Update (00:59:39)**

#### Carolyn Petersen

Thanks, Robert. We are pleased to be able to present to the HITAC today. As Robert noted, we are running a bit behind schedule, and we want to be sure that we have a really robust and comprehensive discussion about the ICAD work that is scheduled next. So, what Aaron and I are going to do is give you an update as to where we are on the – on some of the things we have been doing with regards to the crosswalk. And then we will ask for your feedback by email to ensure that we can complete that ICAD discussion as planned.

So, the next slide, please. Keep going. This is our basic schedule for our workgroup. We have a couple more meetings before we will bring to you the final report for – the final draft report for your discussion and review. Next slide, please. And this is our meeting schedule for the HITAC. Again, we will have a more comprehensive discussion about this work in November. And then, look to – look at the draft and approve it the beginning of 2021. Next slide, please. So, our next steps for the workgroup are to continue discussing the draft crosswalk today and at the November meeting, and then to present the draft to the report in early 2021.

Next slide, please. Go ahead. So, in trying to put all of the Annual Report together, we have got this crosswalk document that brings all the gaps and opportunities together in a very clear, easy to process way. We anticipate that this will lead to some recommendations about high-tech activities for the coming years. And we will also be covering some additional topics in the landscape analysis. These topics are being presented in the target areas. The three target areas that are the priority for HITAC: interoperability, privacy and security, and patient access to information. And we are also bringing on board another target area; technologies that support public health. This is something that became apparent to us this year with regard to all the work we have done around COVID and some other challenges that we are seeing for public health.

The Cures Act does provide for us, for the HITAC to bring forward and identify other target areas as we see fit. And that is how this fits into the puzzle. Next slide, please. So, let's take a look at the key topics for the

Annual Report in terms of technologies that support public health. First, the exchange of clinical data. The gap here is that we need to collect information from clinicians and laboratories for public health reporting. And the opportunity is to improve interoperability between public health reporting systems in EHR's, accelerate the use of data standards to improve situational awareness, and to explore an expanded role for health information exchanges to support public health.

Second, privacy and security. And then here we look at a gap in issues for bio surveillance efforts, telehealth, and remote monitoring. The opportunity here would be to increase the clarity about the privacy and security concerns that are associated with biosurveillance and remote care activities. Third, vaccine tracking. We see a gap now in that we lack access to data about unimmunized populations and where patients are obtaining vaccines so that at-risk groups can be targeted for interventions. The opportunity here is to investigate how predictive analytics can be used to anticipate the needs for vaccines and target outreach. And to better target outreach education and response efforts and strategies.

Fourth, that would be the patient matching topic. Here the gap is the key information is missing when it is shared from laboratories in contact tracing records. And the opportunity would be to improve patient matching through expanded use of artificial intelligence. And finally, the fifth topic within this area is the international exchange of clinical data. We see a gap in that countries need more information about the health status of travelers. And an opportunity is to share and apply lessons learned across many countries about the use of health IT to support health information, for example, for electronic case supporting. Can we have the next slide, please? And now, I will pass the mic to Aaron to take us through the remaining topics and target areas.

#### **Aaron Miri**

Yes, and good morning. And thank you, everybody. And really quick before I start, I do want to thank ONC and all of HHS for their again continual and great partnership with all the provider organizations. It has been a really good hand-to-hand approach as we have overcome a lot of these challenges we are speaking to. A lot of the reports. I just want to just upfront say thank you for that and onward we go. Okay. Into interoperability. So, the first topic is the exchange of healthcare data across the care continuum. The gap is we need greater interoperability across the broader care continuum and the opportunity there is to encourage the collection of more complete data about a patient to help clinicians identify risk factors for procedures, offer interventions, and provide targeted care.

On the next topic there, it is the association between EHRs and patient safety. The gap is the impact of health IT on patient safety. And, again, opportunities there are to find factors that increase and decrease the safety of health IT that affect patient outcomes. I will get on the interoperability exchange of social determinants of health SDOH. The gap is a lack of standards and data availability, patient matching challenges, and variation among community service providers' IT systems entered. The opportunity is to develop and adopt standards for SDOH data collection, transfer integration, pop health, and individual needs.

Increased health equity across populations and locations in the situation is the topic. The gap there is the data is not systematically collected nor used to identify disparities in outcomes, healthcare, and risks. The opportunity is to advance requirements to collect and share data about groups experiencing health inequities, including nontraditional sources of health information. Again, around interoperability, it is sharing data with the research community. The gap is concerns about data equality, governance, and access to

ONC

data. The opportunity for us is to increase alignment between the clinical and research health information ecosystems to enable perspectives and ongoing research that happen more quickly and effectively.

I can see this has been a big bugaboo with COVID-19 vaccine research. On the topic around the use of metadata, the gap is many data management tasks are still manual that can be automated and the opportunity there for us is to determine the types of metadata and related standards necessary to facilitate machine-based, clinical data management. Again, I know I am running through this really quickly so we keep the time, but I would encourage the HITAC to please coalesce your thoughts and send them to us. Next slide. All right. On privacy and security. The topic, beyond HIPAA: rules for sharing.

So, the gap there is a lack of clear rules for data not subject to HIPAA protections. The opportunity to support increased transparency and patient education for business practices and other potential uses of patient health data when healthcare organizations share or licensed data to technology companies. Another item beyond HIPAA is called consent. The gap. Lack of clarity around parameters of data sharing and disclosure and their implications for consent. The opportunity to improve clarity around patient consent for exchange of their data and further their understanding of the accuracy and validity of clinical information offered by third-party apps. I would say that I would also support contact tracing.

A number of public health initiatives going on. Consent is a big part of that. The third item, beyond HIPAA. Internet of things. The gap. Security risks and concerns about informed consent increases IoT objects become more integrated with health IT systems. The opportunity to increase awareness of the privacy and security risks of using IoT devices to collect health-related data. And last on this page, the topic of privacy and security of synthetic data. The gap. HIPAA constraints limit the ability to conduct research and train machine learning models using large-scale datasets. The opportunity, to explore the extent to which the use of synthetic health data raises privacy and security issues in both research and healthcare settings.

Next slide. All right. Patient access to information. The topic of safety and impact of mobile health apps. The gap is safety and effectiveness concerns with consumer-facing mobile health applications. The opportunity is to provide reliable information about the quality of apps to enable clinicians to advise patients about app use and to empower patients when using apps to make decisions about their care. The next one here is the correction of incorrect data. We have been talking about this in the chat this morning. The gap. Transparency about the accuracy of patient data and the consent to share it are lacking for patients. The opportunity to increase clarity on the applicable statutes and liability that apply to the exchange of incorrect data.

Next slide. All right. So, before we complete this, I do want to say again thank you to the HITAC. I know Carolyn and I ran through this really, really quickly. But the exchange of robust debate earlier was well worth it. So, I do welcome all of you to please coalesce thoughts, look through the slide deck that should be in your email that was sent out earlier, let us know your thoughts, and next HITAC Carolyn and I will spend some time going through this with each of you to make sure that your comments and feedback is collected. Carolyn, any thoughts?

#### **Carolyn Petersen**

Yes. I do want to apologize again for the very fast overview of this work. We really do want to get your feedback, either now or as we go through the fall via email. And I promise we will have at least an hour to

look at all of this and discuss it at the November meeting. So, we will ensure that we have a robust discussion about this work as well and that it is not overlooked and then difficult to address at the beginning of 2021.

#### **Aaron Miri**

Yeah. And I do want to add really quick though and say I appreciate the ONC and their objectives and benchmarks because you can see a lot of symmetry between the report work form group, those items, and others. There are themes here emerging. So, I appreciate the HITAC 's feedback. Thank you.

#### **Robert Wah**

Thank you, Aaron and Carolyn, and your entire group for your work on this Annual Report. And thank you to the HITAC for your understanding of how we are trying to adjust the schedule today. Continue to use the chat and public comment area. Abby, I know you were not dialed in and so you are able to put your questions there. We record everything that is in the chat and public comments and put that in the meeting notes. So, your contributions in the public chat and comment area are preserved. I will also put some information there about the work on the Commons Project and CommonHealth and CommonPass.

But we do appreciate all the work of your committee and look forward to your next discussion. And please do send your feedback by email to the committee chairs as you see fit about the Annual Report. So, with that, we will proceed next – oh, also, just to say that if you are not dialed in, we can't hear you. So, even if you are on the Adobe application, you cannot speak. So, if you want to speak, please make sure you are dialed in or use the public chat area. So, with that, I will turn it over to Sheryl Turney and Alix for the Intersection of Clinical and Administrative Task Force. Sheryl and Alix.

## Intersection of Clinical and Administrative Data Task Force Draft Recommendations Update (01:12:04)

#### **Sheryl Turney**

Thank you very much, Robert. I really appreciate the opportunity to come and present this today. We want to thank everyone from HITAC for your thoughtful comments in our last update. And also, for the ONC in itself. Staff for all of their support, as well as the members of the Intersection of Critical Administrative Data Task Force. So, can we go to the next slide? Our agenda today is to just refresh your memory on the Task Force charge, the membership, review a draft of the report outline, which you have got a PDF copy with your meeting materials and hopefully had a chance to review. We will just highlight the ideal state and guiding principle updates and we will also review updates to our draft recommendations. Then, we are going to have ample time for questions and feedback. And then our next steps.

Next slide. This is the Task Force charge that was given from ONC to HITAC. And I'm not going to go through this all here for the sake of time, but this is just for your information. It is also in the report that we provided. Next slide. This is the group of task force members who we so much appreciate for their input. This was a difficult task, as we mentioned before because we did not start with an artifact. We had to actually create one and it was a lot of work to look at and create a sample clinical workflow as well as developing an ideal state, guiding principles, and then from there, recommendations. And we also engaged many stakeholders from many of the groups that we all work with, both at the federal as well as in the health information ecosystem. Next slide.



This is a draft report outline, again, which you have all received. We can go to the next slide. And then, this is a vision of the ideal state. And we covered this in our executive overview but the ICAD Task Force really heard from many stakeholders on improving the prior authorization process, as well as looking at the broader intersection of clinical administrative data. And we reimagined the ideal state with particular focus on prior authorizations that included the end-to-end integrated "sleuth process." Reduces the burden across all stakeholders, accounts for the vast majority of situations, leverages existing investments and efforts were appropriate, and also enables innovation and continuous improvement. Next slide.

So, as we were looking at the guiding principles and we presented these to you in our last meeting, we had at that time, eight guiding principles that included patient at the center all the way through designing for the future while solving the needs for today. As we broadened our scope to the greater intersection of clinical administrative data, we realized we needed to add another guiding principle. And that was reducing the burden on all stakeholders. And the focus of this was really to embrace a converged ecosystem which should enable all stakeholders across the continuum, including primary and specialty care, public health, vital records, research, payers, and policymakers to have the information they need without creating additional data capture or burdens on providers by supporting seamless exchange across the continuum of care.

This has great potential to reduce the burden by furthering the implementation of record once and reuse. Can we go to the next slide? And I will deep dive into this a little bit more. And so, the thought behind this particular guiding principle is really to support this principle. We focused on the ideal state of including the following characteristics with the hope to be a single workflow, ideally a single standard, for all transactions at the intersection of clinical and administrative data, regardless of the payer or the plan, and with capabilities available in the workflow without special effort on behalf of the provider. If portals are used, they are integrated into the workflows, again, with no special effort.

And then patients and caregivers have the ability to utilize a third-party patient credential or consent management service. To support seamless authorization and access functions to their data across the landscape if they so choose. And this could be utilized with their interaction with providers, payers, and other actors such as clearinghouses, HIEs, and public health authorities with minimal additional effort. And also, the ability for patients and caregivers to bi-directionally share data with providers and other healthcare stakeholders electronically from the app of their choice without any special effort.

And then, the final one being the CDS process which provides the right level of evidence-base and patient and caregiver centric guidance during the care process. Currently, the prior authorization process should not be the result of inadequate use of existing HI, such as clinical decision support tools, or electronically accessible practice guidelines, or patient decision aids. All of these need to be implemented appropriately and can help reduce the need for electronic inquiry and can support the need for electronic prior authorization. Next slide. And so, now I am going to turn it over to Alix. And she is going to provide an update on the recommendations. Alix?

#### Alix Goss

Thank you, Sheryl. So, Michael, today, if we can go to the next slide, is to spend some time highlighting the material updates since we last presented to you on the recommendations. So, I will be covering items 2, 7, 9, 14, and 15 to give you a framing of what changed with those or how they were added. Since we covered the other recommendations extensively in our last presentation, we are going to skip over discussing those

today to provide the maximum opportunities for us to discuss and receive your feedback on the draft report that we submitted to you last week and that is also available for the public to download from your website as well as today's meeting platform.

So, let's go ahead and start with recommendation 2 by advancing to the next slide, please. The task force has been working very hard to advance – to wordsmith and refine for increased meaning and specificity of a recommendation. We are grateful for some feedback that we received from the Office of National Coordinator that aligned with our overarching methodology for recommendation development. We wanted to really focus on the "what". Not necessarily the "how'. And we realized in recommendation 2, thanks to the feedback that we got yesterday and discussed with the task force, that we had some inappropriate language or unnecessary language within recommendation 2, which was to establish a government-wide common standards advancement process.

This recommendation is really about creating a single, consistent process for standard advancement for relative standards for healthcare interoperability, which could include transactions, code sets, terminologies, vocabulary, and privacy and security. Other — [inaudible] [01:20:26] clinical or administrative. So, this recommendation specifically has one sentence removed that got into a little bit of the how. And what we were trying to address in the inclusion of some authorities was that we do not think anything new is needed. We think we have the tools in the toolbox to allow us to work forward in creating a government-wide common state of advancements process.

So, it really does make a lot of sense that we would remove the sentence that was there previously and just stick to what we would like to see happen and so that things can move forward effectively. Next slide, please. So, the next recommendation that I want to talk about is recommendation 7.

#### Lauren Richie

Pardon, me. One second, Alix. You sound a little far away from the phone. I don't know if you can adjust your volume.

#### Alix Goss

I am so glad you interrupted me because, during that overview, my headset decided to click out. So, I have put you back on the headset. Is that better, Lauren?

#### **Lauren Richie**

Much better. Thank you, Alix.

#### Alix Goss

You're welcome. Thank you. Excuse me. So, recommendation 7 is at the heart of what we are addressing, which is really developing patient-centered workflows and standards. And really, patient at the center must be a system design philosophy and be built in from the ground up. And we do believe that when we are talking about interoperable data, we believe that administrative information is part of the designated record set. And if there is any uncertainty in that recordset, we really would encourage the Office of National Coordinator to work with the Office of Civil Rights to address any revisions that might be needed.

The second part of our recommendation is that we encourage ONC to work with other federal actors and standards development organizations to prioritize and develop administrative standards that are designed

ONC

for patients' digital access and engagement. We recognize the workforce administrative standards that enable us to have an effective provider to payer exchanges. But we also want to see that some kind of access is enabled to the API frameworks. And this would really support the converge clinical administrative ideal state that we are seeking and would be designed to support API access and patient engagement. This could also include the benefits information being readily available via those APIs in addition to claim and remittance information. That provides an overview of recommendation 7.

So, I would like to – we slightly – we worded that, but I think you got – I delivered to you the crux of what that recommendation now covers. I would like to move to recommendation 9, which is the next slide. This recommendation is near and dear to my heart, and I suspect it is to many of you as well. This is to name an attachment standard. And this recommendation was updated to be more agnostic to what gets adopted in regard to the attachment standard. We do recommend that a national approach for exchanging clinical data be established to support clinical information exchange, whether it is for care delivery or administrative processes. And we encourage the adoption of a standard, but we no longer specify a particular version of that standard.

We hope that this will provide a supportive framework for the federal efforts to advance regulations – propose regulations for review and comment. And we encourage the industry to sharpen their pencils, get ready, because we hope to, per the unified agenda, see something related to attachments. I would like to move to the next slide, please, which will be recommendation 14. This is relatively new and that – and you also got a little bit of a preview in Sheryl's remarks about burden reduction. Recommendation 14 is to establish patient authentication and authorization to support consent.

And although we realize we have a little bit of wordsmithing to do on this recommendation which emerged from our broader intersection conversation that built on top of the prior authorization deep dive, we encourage ONC to establish a standard for third-party patient authentication that allows patients to access and bidirectionally share their data access across the landscape. This will help establish a consistent authentication and authorization token, which will just make integration all that much easier. This is a new recommendation. And so, we are particularly interested in seeing if you have any feedback on this today.

Let us go to recommendation 15. The next slide, please. Recommendation 15 is also new, and it is related to establishing a test data capability to support interoperability. We believe a national approach to test data beds is critical to driving innovation and ensuring real-world functionality and interoperability. This has been a long-standing gap on the HIPAA side of the house. And we would like to make sure that as we move forward, we have converged data frameworks that we do not persist in this issue. We believe that we could undertake a series of actions to review the current administrative transactions and associated value sets and code sets to ensure that the USCDI supports the necessary concepts and elements needed for converged data frameworks.

Second, we would like to establish illustrative information models in stages, realizing incremental work to develop, that aligns clinical and administrative data for secondary use based on the highest societal priorities. I believe this really is a nice synergy with the public health-related conversations we have heard in earlier presentations today. The third bullet is going to actually be revised as a result of some discussion yesterday, but we have left it as is since it was in – it is reflective of what was in the report we submitted to you last week and is posted on your website. We seek to revise the third bullet that says establish an

unknown dataset for transactions that appears to be unnecessary because it gets a little confusing with minimum in there twice.

So, we are going to modify the language to just really more reflect establishing sufficient datasets for transactions. Because we are trying to focus on making sure that the frameworks that we advanced are aligned with our minimum necessary privacy and security objectives. And finally, we are suggesting that we advance an appropriately constrained implementation guide to really underscore the test data capabilities that would be established. This is, in summary, the final update that I need to give you for the recommendations.

And the goals of all of our recommendations to reduce burden do put the patient at the center of our design approaches. And ensuring consent, privacy, and security are established and maintained throughout all of our interoperable processes. We seek to use digital capabilities to automate manual time-consuming activities that optimize and achieve record once and reuse. And our recommendations address key barriers to effective information exchange while improving transparency and timeliness of prior authorization and decision-making processes for all stakeholders. We seek to build and extend current investments to enable maturity by providing a path to harmonize today's national healthcare policies, vocabularies, and transport standards.

Ultimately giving us an ecosystem that enables patients and caregivers to focus on their well-being, rather than problem-solving administrative process complexity. Thank you for your time today. Thank you for the leadership of ONC and HITAC and providing ICAD the opportunity to be created to undertake very important work and to present you with this draft report. We are eager for your feedback and to finalize this report. With that in hand, we will work with our task force members over the next week or so to take your feedback, incorporate it, and then ultimately submit a report to you. So with that said, I think maybe we should turn that over to Robert and Carolyn to facilitate us through questions that members may have.

#### **Carolyn Petersen**

Thanks, Sheryl and Alix. That was a great presentation. I think that has shown responsiveness to the previous feedback and also given us something to talk about today. So, with that, I will ask HITAC members to raise your hands through Adobe and we will start with the Q&A. And I know there are some HITAC members were just on the phone, and I will work you into the rotation as well. Let's start with Clem McDonald. Go ahead, Clem. He may be on mute.

#### **Clem McDonald**

How about now? Can you hear me?

#### **Carolyn Petersen**

We hear from you now. Thank you.

#### **Clem McDonald**

So, there are a couple of things. I do not remember the recommendation number.

#### **Alix Goss**

I'm sorry. Carolyn, I'm having a hard time hearing Clem. There is some background noise. And I would also like to suggest that we – yeah, we're getting some reverb. Somebody is not on mute.



Let me turn off my speaker.

#### **Alix Goss**

Can we -

#### Clem McDonald

How about now?

#### **Alix Goss**

That will be – it will be better. Yes, Clem. And I'm going to suggest in order to assist you that possibly we ask Accel to go back to slide 10 so we can see the master list of recommendations.

#### Clem McDonald

How about now? Is it okay?

#### **Alix Goss**

Yes.

#### **Clem McDonald**

One last try. Can you still – can you hear me? I have questions about item 15.

#### **Alix Goss**

Okay. Establish test data capabilities. Mm-hmm.

#### **Clem McDonald**

Yeah. I think – I think it is confused as to whether it is a test set of data or it is some system. And I think you ought to focus on the dataset for testing. I think that would work better. And then on the other one, I think it was 12 or 13, it was about attachment standard. That was very confusing to me because it was blending clinical data transmission, which is, I think, established already in prior and declared by HL. And the attachment. And the attachment that has been worked on for I think 20 years at HL7. Has that been rejected finally and forever or is that what is being considered?

#### **Alix Goss**

So, Clem, allow me to address attachment 15 first. Actually, no, let me do - yeah. And that we will take your feedback just to make sure we are being really clear around the focus on the dataset because I think we're – the testbed set is much more where we are focused as opposed to creating a platform or having the FEDs do that. So, we will take that feedback into account. Regarding the attachment standard or recommendation, let's be clear. We have not deviated from the use of clinical exchange capabilities enabled by HL7. Nor have we precluded the ability to use the HIPAA transactions.

And so, what we are trying to do is provide a more efficient ability for payloads to be clinical payloads to be exchanged, whether that is for treatment purposes, or administrative purposes. And so, if we could get a proposed Rule released, the industry can weigh in on what the right versions are for adopting that. Because historically, the attachments recommendations have been a blend of HL7 and X12 standards. I'm sorry. I'm getting a lot of feedback. So, I'm not sure if I'm coming through at all.



#### **Clem McDonald**

Oh. No, I am hearing you fine. No. Just that those standards have never been adopted. And they have worked their tail off for 20 years and I don't know what – is there something wrong with them? Or could that be a survey? Why they have been working on it? And it's a nice collaboration, it is just not being – it is not the standard - common in the standard organizations.

#### **Alix Goss**

So, Clem, I am very much empathetic with what you are saying having worked on claims attachments since the early 2000's myself. We have evolved to the point where we don't call them claims attachments anymore. We are calling them generically attachments. And NCVHS has written four letters recommending the promulgation of an attachment standard. So, I believe that we are just giving further encouragement in this recommendation to have the FEDs advance what they've already put in their unified agenda, which is that they were planning on releasing a proposed regulation regarding attachments.

So, I think we are all in the same place of waiting to get a proposed Rule so that the industry can weigh in on, "What are the right components to make up an effective attachment exchange?" Because we don't want to be duplicating data element transmission that is already handled under our base frameworks. What we want to do is increase automation and to have the data from the EHR environment for the clinical data flow all that much more effectively to support provider to provider attachment exchanges or provider to payer attachment exchanges.

#### Clem McDonald

Okay. That is very helpful. Thank you.

#### **Alix Goss**

You're welcome, Clem.

#### Carolyn Petersen

And let's go to Arien Malec.

#### **Arien Malec**

Hello, yes. So, I just wanted to clarify, and I think – I think that exchange helped, but I wanted to clarify that the issue is not so much the lack of a standard. It is that CMS has never named a standard because of the way that HIPAA is defined providers have to have a named standard in order to engage in transactions with CMS. So, what we are asking for is for CMS to actually name one of the – one of the two standards that have been out there and well-developed, one being the standard with a CDA wrapper attachment and the other being potentially a FHIR based standard.

And the only reason that the task force made the recommendation more general was that we have gone so far with – and so long without an attachment being named, that some folks thought it may just be better to skip over EDI and go straight to FHIR. And others felt like it was more important to name a standard, move on in an industry, and then start to harmonize and converge. So, that is a little bit of the gloss behind the reason that we changed the language and generalized it. But again, just to be clear, the issue that we are pointing out here is not with the lack of a standard. It is with the lack of a named standard named by HHS.



#### **Carolyn Petersen**

Thanks, Arien. Do we have questions from HITAC members who were just on the phone? Please go ahead and speak up. Okay. Do we have questions from HITAC members who are on Adobe? Could you please raise your hand and so signify? Okay. I don't see any hands raised at this moment. I will share a comment. First, I want to thank the ICAD Task Force for all the work and all of the underlying discussions and research that underlie the recommendations and the report. It is quite an achievement and I think it will help to advance all the work that ONC is doing in this area as well as things that are undertaken by industry.

I did have one comment. I would encourage you to look at adding something that further describes what is meant by putting patient at the center. I think that is one of the concepts that people feel like they know it when they see it, but it would add additional clarification and robustness to this work to have at least a bit of discussion about what that actually means to be patient-centered and how we can recognize that that is happening? How we can evaluate that? Thank you so much. I see Arien has his hand up. Go ahead, please.

#### **Arien Malec**

Thank you. I just wanted to note on the patient at the center that we have a recommendation and I forget the – offhand the number of the recommendation that makes more actionable what patient at the center means. But the intent of patient at the center is to ensure that none of the exchanges that currently exist between, for example, provider and payer are unavailable to the patient through the same means – through API-based means. So, as an example, if a provider can perform a 272, 271, or another form of eligibility check to determine benefits and benefit information programmatically with a pair, that similar capability should be available to the patient to be able to look up programmatically, and not just through a portal, their own benefits information.

Likewise, if claims information is transmitted between a payer and a provider, the patient should be able to look up and get transparency programmatically of the claim information, associated pricing, et cetera. So, we do have a recommendation where we note more precisely what patient at the center means. And I think the shorthand of what we are looking for is nothing about me without me. But then more determinatively, making sure that all of the information flows that are available between patient and provider – sorry provider and payer are also available to the patient.

And then we also note in the selection of workflows that directly involve the patient, for example, EPA, that the standard is designed to accommodate patient presentation or correction of information. So, for example, there are a number of DME requests that require information potentially where the patient is the most – the most informed participant. So, I would just encourage folks to look at the recommendations that we put around that guiding principle to see whether that covers what you intend. And then also, I think we are also quite happy if, in the guiding principle section, we need to put a little bit more meat behind that that matches the recommendations. I think that would be useful as well. So, thank you.

#### **Sheryl Turney**

Thank you, Arien. And I just wanted to add on to what you said that, essentially, the elements of the patient in the center that we do capture in the paper, really look at all of the elements that Arien just mention. Reduction a burden but also including the ability for the patient or the caregiver to have more transparency – enterprise transparency and their choices related to pricing and cost. A shared decision-making process so they have more line of sight into the processes that are part of the care journey and they are able to see the status of where things are electronically, which currently they do not have today.

And that they also have the ability to bidirectionally shared data, as we stated previously, as well as the ability to utilize a third party for credentialing to make their interaction with both providers and payers and others seamless and easier to utilize. And in the – just to correspond to that, an example of this would be with the example that Robert shared in the chat of this CommonHealth token that is being used today and tested where a patient or a member can fly from one country to another and see that they had a COVID test and get those results.

Expanding on that same type of concept that would allow the patient information to be present so that if there was a vaccine that was administered, they would be able to have that data available as well. If the vaccine is not a one and done, if it is a multiple over a course of months, they would be at the see all of that from an application. And we are embracing the fact that we would need that as we move forward. And so, that data would also be available in a public health consumption way for utilization as the patient basically travels within their life. And hopefully, that will be helpful. But if there are specific things in the description that you see, please let us know and we will add those as well.

#### **Carolyn Petersen**

Thanks, Sheryl. I am looking for additional hands. Do we have more comments or questions from a HITAC member? This is our last –

#### **Alix Goss**

Carolyn, this is Alix. If I could just add to that while you are looking for other people to raise their hands. We are very eager to receive specific feedback as Sheryl noted. We spent a lot of time trying to make sure that we have put the patients at the center and worked with some of our particularly focused advocates on our Task Force to put some substantive content in there. So, if you could help us by giving us specifics, any – whether it is yourself, Carolyn, or any of the task force members, that would be really helpful as we have a very short turnaround time to give you a final report so that we can start to move this forward. So, thank you for any specifics you could pass along.

#### **Carolyn Petersen**

Thanks, Alix. Yes, I would encourage everyone on the HITAC to really take one last hard look at the recommendations and the report and to forward that feedback to Sheryl and Alix and the ICAD. This is our last opportunity to work on this before the report is finalized. And it is really important that we all take this opportunity to do that. Again, I will ask, are there any questions from HITAC members on the phone? And any questions or comments from HITAC members who are using Adobe? Going once. Going twice.

#### Robert Wah

Carolyn, this is Robert.

#### **Carolyn Petersen**

Yes. Go ahead.

#### **Robert Wah**

There was some discussion in the public comment area about patient identification. It is a little bit tangential to some of this, but I think it is an issue about how we decrease the friction of moving information about patients and it does come at the intersection of the clinical and administrative data. And I just wanted to see if others had comments about – thoughts about where we can decrease this friction? Because, there

has been a long-running controversy about how to identify individual patients and help ID whether or not there is a need for a patient identifier, or we can identify them some other way.

But I think that is a central part of what we are trying to do here, which is to decrease the administrative burden in the movement of information in healthcare. So, while we are trying to get comments about this final draft of the report, I know that some people brought up this in the public comment area. Maybe we can have them comment for the group in addition to what was written in the public comment area. And I would also put some of the folks that are providers and represent provider organizations a little bit on the spot here to see if you have additional comments from a provider standpoint about, again, decreasing the friction and lowering the burden of clinical administrative data as we review this final draft of the report.

#### **Alix Goss**

Robert, to that point, recommendation 8 does cover creating a standardized member ID. It does not necessarily go to the point of an individual identifier. But it does recommend that we create and incorporate standards for member ID cards and following, I believe, it is international standards for that. And alternative – give an alternative if we cannot follow those for really trying to promote that standardized identification related to insurance, et cetera. But certainly, the broader issue that you brought up is something if folks feel I need to comment on, look forward to receiving those.

#### **Carolyn Petersen**

Thanks. Steven Lane. I thought I saw your hand up. Do you have a question or comment?

#### **Steven Lane**

I was - thanks, Carolyn. I was just going to say, I mean, there is a clear variability from a provider perspective in the tools available for patient identification and matching. I mean I work in a system where we interact with multiple different EHR systems in the organizations around us. You can see clearly that some vendors have figured out how to do this better than others. And I think that anything we can do to identify and name standards or best practices with regard to patient matching will help.

I mean having a member ID, having a universal identifier. Any of it will help. It seems like we have been talking around this for years and years. It has become political, unfortunately. I do not know whether some things may change after an election, but we clearly do need to lower that friction and be able to have reliable identification. I know ONC has supported a lot of work in this area and I think this task force has identified that need well.

#### **Carolyn Petersen**

Thanks, Steven. Let's go to Aaron Miri.

#### **Aaron Miri**

Yes. Thank you, Carolyn. And to – I want to echo what Dr. Lane just stated from our providers' perspective. I am going to give you the CIO hat on now and I am going to talk about it from the public health response. Given here at UT Austin we have taken on a lion's share of contact tracing in partnership with Austin Public Health. And, of course, my team was put front and center to help return the students to campus here this fall and the return of Longhorn's football, which we successfully did although they have not won the past two games. Hopefully, they do this weekend.

That all was all – that all was part and parcel part of the need to accurately identify patients, players, patients in the community, students, and whatnot. And it is amazing that when you look at – especially a lot of our students drive. They do not actually live on campus. And getting to see where they have taken COVID tests. And the Big 12, case in point, requires three tests for a player before they can step on the field. It is amazing how much duplicative work is occurring because we cannot get their priors, or we cannot with accuracy say that player Aaron had his test yesterday because Aaron is not identified in that prospective system the same way we identify him here on our EHR

So, to the degree of it, this has been a major bugaboo from a public health response and as we now begin to plan our vaccine distribution, once that is readily available here hopefully in the near future, I believe this is also going to hamper those efforts as well. So, exactly what Dr. Lane said regarding patient continuity across continuum of care. Also, so much on the public health side, the sooner we can address the strategy with something, the better it will be for everybody.

#### Carolyn Petersen

Thanks, Aaron. Let's go to Jim Jirjis.

#### Jim Jirjis

Hey. Just in response to your provider impact question. I divide up into three categories. Some of which is tangible and we have calculated. But in the ambulatory world or the hospital, the amount of costs, the people hours spent either collecting info and sending it to payers, or trying to communicate to get a response, or reworking denied claims is pretty immense. And I think, if that is where you were headed, one of the aims of 21st-Century Cures is to reduce provider burden. Some of that is highly calculable and this should make a tremendous impact to improve that.

#### **Carolyn Petersen**

Thanks, Jim. Do we have additional comments and questions from the HITAC members? Either on the phone or through the Adobe tool? Okay. Seeing none, I will hand the mic back to Alix and Sheryl, and thank you for the excellent work in the discussion today.

#### **Sheryl Turney**

Thank you very much, Carolyn. And I just want to say, again, thank you for allowing us to present today. And also, for your thoughtful input. This has been a very meaningful task for me personally. As you know, I have had a family patient care journey for over 30 years. And many of the things that we are dealing with in these recommendations would specifically aid in the exchange of data for the care of patients. So, it means a lot to me to be part of this and I want to thank you all for the opportunity to do so. Alix.

#### **Alix Goss**

Well said, Sheryl. This has been a meaningful project and, as we wrapped up our Task Force call yesterday, it was clear to us that the reason for all of this work is for the human aspect. Whether it is our direct experience, our loved one's experience, improving overall information exchange and bringing together our national frameworks in a converged manner for administrative and clinical data that really underscores the ability to automate, leaving the precious time for people to work with people as opposed to taking on administrative complexities is at the heart of what – how we all feel.

And we are eager to advance this report so we can become actionable and suspect that we have some public comments that may need to be made here today as well as being able to take that feedback from the task force and public to finalize the report in the next several weeks. As we noted earlier, our submission goal is to have a final report produced around the 5 of November so that you will have an advanced opportunity to review it before accepting it on November 10.

#### **Robert Wah**

Alix and Sheryl, thank you to you, as leaders of the group, but also to your entire team that put together this excellent report. I think the quality of it is reflected in the fact that nobody has needed to make significant changes to it. But we welcome the committee to make their comments to you. But this is important work and we really appreciate all the hard work you and your committee have done in producing it and we do think it will have a significant impact on healthcare, both on the clinical and administrative side. We are a little bit ahead of our 12:00 promised time for public comment.

And so, I thought since we had to move very quickly through some of the other presentations, maybe we can see if there are other comments about the first two presentations that we may not have had time for because we have tried to condense the schedule to make room for an adequate discussion of the ICAD Task Force Report. So, I think just briefly we can open it up again to discussions of the ONC presentation or the discussion of the Annual Report. I know some comments were made in the public chat area about both. And so, we can address those now or we can just take them in the public chat area. This is one of the challenges of trying to predict how long each presentation will take to discuss.

#### Jim Jirjis

Seems like we have time to discuss – seems like we have time to take the questions verbally from the chat as well.

#### **Robert Wah**

Yeah. Well, that is what I am trying to do. If people have questions that they put into the chat that they want to verbalize, we can do that now. Or if there are people who did not have a chance to comment on the Annual Report or the ONC presentation, I think we could do that now.

#### Lauren Richie

Robert -

#### Robert Wah

Do you have your hand up? Yeah.

#### Lauren Richie

And there is a request to see the last slide from the HITAC Annual Report Presentation. So, we will ask any contractors to do that for us. But if you guys –

#### **Robert Wah**

Yeah, can we -

#### Lauren Richie

- want to go back and forth between that, just let us know which side you would like to see.



#### **Robert Wah**

Okay. Let's see. I see Jim. Jim, you have your hand up.

#### Jim Jirjis

Yeah, hey. I just – one of the questions I put in the chat was about learnings from COVID and automating interoperability for data reporting. And some of the data, as we all know, ended up being clinical. Positive COVID tests, et cetera. But a big chunk of it with supply chain staffing, information that is largely managed outside of native EHRs. So, one question I have as to the scope of ONC and whether those other datatypes that seemed so necessary are part of the scope?

#### **Robert Wah**

I think we still have the ONC team on the phone. So, maybe they can address that as well.

#### **Talisha Searcy**

Hi. This is Talisha Searcy. I just want to make sure that - and that was in regard to the measurement work?

#### Jim Jirjis

Well, it is regarding lessons learned from COVID and interoperability. And so much of the wording is around making sure the EHR data is standard and interoperable. But my point is the USCDI was largely clinical data from EMRs for example. But when it goes beyond that and it is from other systems like supply chain systems that are not part of the HR that generate data, much of what was needed for public health went beyond the EHR. So, the question is whether the scope of ONC's work includes that are not?

#### **Talisha Searcy**

Currently, it does. So, for a number of our current data collection efforts, we are not just limiting our analyses to what electronic data folks are receiving, but also, nonelectronic methods. I just finished reviewing the draft report that we are working on where we know that many hospitals are still receiving a ton of data – sending and receiving data using non-electronic methods. So, we are still keeping those points in mind. And also, still trying to measure the extent to which that is happening. In my view, I kind of see it as contrary to electronic.

If you see that folks are moving away from non-electronic means, that might mean that some of the electronic methods are valuable and folks are transitioning over. So, we do measure both. One of the things that would be helpful to hear from you all, and this is something we can incorporate as we come back to you, is whether or not we are fully capturing some of those non-electronic methods that folks in the field are currently using. Especially as it relates to the public health space. That would be helpful to hear. And then that way as we are trying to work on finalizing measures as it pertains to the specific use case around specific stakeholder groups, we can keep some of those nuances in mind. Does that answer your question?

#### **Avinash Shanbhag**

Sure. Sure. This is Avinash from ONC again just to kind of piggyback, as typical, off Talisha. I think, in short, the answer is yes. The USCDI is supposed to be probably electronic health information. So, again, it is really broadly defined. So, I think we have had in our current situation, where we have – we are looking for submissions for the next work. We have got submissions around facilities and organizations and locations. So, again, it is broadly like outside of very specific clinical. But again, with the connection to others, I should say, non-activities or information that provides information that can be used for connecting the dots.

So, again, in short, the answer is yes, very broadly. We are looking for public input. So, again, if you all have ideas, USCDI is open all -24/7. So, again, even though the cut-off for version 2 ends in the next few days, the input from the public for all the various data to be considered in the context of electronic health information is very broad. Hope that answers the question.

#### **Robert Wah**

Thanks. Alexis? You had your hand up?

#### **Alexis Snyder**

Yes. Thanks. This line that is up now is the one that I had a comment on. So, in the topic area of correction of incorrect data, which I know I brought up today and brought up at some previous meetings, I think that the gap could be a little bit better addressed as well as the opportunities. Where I don't think that the gap is really - is a lack of transparency about the accuracy of patient data, it is more just about the inaccuracies that exist and not having avenues for folks, patients, caregivers, et cetera, to have a hand in easily and quickly fixing those so that it does not affect their care and outcomes and safety. And so, I think just maybe some rewording of that.

Transparency, of course, is a huge piece, to begin with, but it is not about transparency or accuracy. It is about transparency to the records first, and then the accuracy of the data. And as far as the opportunity side, I am not sure that just increasing the clarity on what the statutes are and what the liabilities or any repercussions thereof would be to the exchange of incorrect data. That is certainly a piece of it, I imagine. But I think the opportunities far expand and needing ways to improve again the way that patients and caregivers can be fully engaged in correcting that information quickly and easily so that there are no poor outcomes because of it.

And the last thing I will just have to offer is that the consent piece in the gap is something that I definitely agree with. I think some loopholes exist that patients are not aware of when you become a shared patient between hospitals. And automatically those two systems can share information without any consent. So, I think those are some other – some other gaps that would then have an opportunity for improvement.

#### Carolyn Petersen

Thanks, Alexis. That – those are some really important points and some great feedback. And we will ensure that that is reflected in the version we bring to the HITAC in November.

#### **Aaron Miri**

Yeah. This is Aaron. I also want to say thank you really quick on that. I think it is great clarity. Give me some context on the incorrect date and I can also call on Dr. Brett Oliver who is part of our group to speak towards one of the issues that we are all looking through as we prepare for the information blocking enforcement rules. It is working with our providers. And a misnomer that seems to occur with people concerned about liability, if something in the EHR is not 100% understood or accurate and the variability between states and statutes. That's how this sort of was coined from some of those – that dialogue. But I think your points are well taken. I think they are both together. But I also do think that we need to work on clarification so everybody understands, not only the importance of this, to your point Alexis, but also to try to put to rest some of those misnomers or clarify them so that people all understand what the playing field is.

#### Carolyn Petersen

Thank you.

#### **Robert Wah**

Thanks. Jim, you have your hand up still. Did you have a second comment?

#### Jim Jirjis

No. No, I didn't.

#### **Robert Wah**

Okay. I just wanted to make sure I did not miss if you had a – if you had a follow-up question or comment. So, we continue to – we are a little bit ahead now of our promised time to the public when they can make their comments. So, we have a little bit of time to continue the discussion about the ONC Presentation and the Annual Report. Again, we were not able to take a lot of comments on the Annual Report Workgroup. So, I want to make sure if we have this time, that we should do this. So, and I will just thank Sheryl for noting my comment in the chat about the Commons Project.

You know I have been trying to update the HITAC on that. The CommonHealth, which is the Android equivalent of MedicalHealth, is well on its way now. We hope to have some 300 academic medical centers connected through their Epic instances to CommonHealth by the end of the year. And then the big news this week has been CommonPass, which is a project that we started with the world economic forum to smooth air travel and border crossings. And last Thursday, we had a pilot project through Cathay Pacific going from Hong Kong to Singapore, which was very successful. And as I noted in the chat, there is a flight from London to New York that lands at noon in New York City today where passengers are going to be using CommonPass as their way of identifying their COVID status when they land in the US.

And they did that already when they landed in London yesterday. So, I refer to the chat about some links about media coverage. CNN had a nice piece on it today. And Reuters did as well. So, I think we are going to put up the public comment slide. Yes, it is up. So, those of you who were planning to make public comments, please begin to dial in and join the queue. We are a little bit earlier than our promised time, but we will start taking public comments. We were told that there were several folks that had public comments about the ICAD Task Force Report. So, we want to make sure we have adequate time to take those public comments.

#### **Public Comment (02:08:05)**

#### Lauren Richie

Thank – thanks, Robert. At this time, we will ask the operator to open the public line.

#### **Operator**

Thank you. If you would like to make a public comment, please press \*1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press \*2 to remove your comment from the queue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the \* keys. Our first comment is from Lauren Riplinger with AHIMA. Please proceed.

#### Lauren Riplinger



Thank you. And thank you for the opportunity to comment this morning. I just want to offer a few comments regarding the draft report of the ICAD Task Force. First off, I want to say that I think the task force has produced a thoughtful analysis of how integrating clinical and administrative data can improve efficiency and reduce the burden for both providers and payers. And, they should be applauded for consistently considering the patient's point of view and for introducing ideas that would allow individuals to be more fully informed.

I would also note that we appreciate the emphasis in the draft report on adhering to existing requirements on sharing only the minimum necessary personal information. Although it is also important to consider how clinical data shared for one administrative transaction might be used for other purposes, I do want to note there are some of the recommendations made by the Task Force that are ambitious. And they would have a wide-ranging impact. But they lack some specificity about how to achieve them. And I take the point during the discussion today about the intention of the task force to focus on the what and not necessarily the how.

But if we look specifically at recommendation 2, establish a government-wide common standard then advancement process, it establishes a really important objective but does not necessarily map out how to get from our existing five faceted approach of setting clinical and administrative standards to this desired state. Furthermore, I would also note that this recommendation makes no mention of involving stakeholders outside of the federal government in developing this new standards process. Although presumably, all stakeholders would need to use these standards that are adopted. Similarly, I think a number of the recommendations reference incentives across a range of federal healthcare programs without necessarily describing the form that they might take or the rationale for having them.

And it is currently unclear what the Task Force has in mind with respect to these incentives and what these incentives would necessarily achieve. I think ultimately from our perspective to be successful our collective efforts to integrate clinical and administrative data needs to engage all stakeholders. But also, carefully consider operational and workforce impacts. And, of course, prioritize privacy and security. And so, we look forward to providing more detailed written feedback to the Task Force's recommendation as the HITAC continues to consider the full written report. And just thank you again for the opportunity to comment this morning.

#### Lauren Richie

Great. Thank you so much, Lauren. Operator, do we have any additional comments in the queue?

#### **Operator**

As a reminder, it is \*1 if you have a comment. We will pause for a brief moment to poll for additional comments. There are no comments at this time.

#### Lauren Richie

Okay. Before we begin to wrap up here, Carolyn and Robert, anything else from your perspective?

Final Remarks and Adjourn (02:12:22)

#### Carolyn Petersen

I want to thank everyone for the excellent comments and discussion in the discussion sections following our presentations today. I think we have brought out some really important topics and some additional considerations for all the Task Forces. I also want to thank the ONC Workgroup Team who assisted us with developing the material for these meetings as well as the Annual Report. They do a great deal of work to help us make this happen. And we really could not get the work done without them.

Also, I want to thank the ICAD Task Force, all the members, and the leadership, Alix and Sheryl, for all the work you have done. I know you have had weekly meetings for several months now as well as a lot of work that happens off-line. And it really shows in the very comprehensive recommendations and reports that you brought forward for us. Thank you for that.

#### **Robert Wah**

This is Robert. Let me just echo Carolyn's remarks. And again, thank you all for your patience today as we try to adjust the schedule. As I said, it is an ongoing challenge to try to predict exactly how long each segment is necessary to have an adequate discussion. And so, we appreciate your indulgence as we try to be flexible with the schedule and move things around. But it has been a good day of feedback, and some great reports from ONC, the Annual Report Task Force, as well as the ICAD Task Forces as we have already mentioned.

There is still an opportunity for comments from the committee to go via email. So, do not hesitate to do that as well. And so, if you have other comments for Carolyn and me about the meetings, as always, we welcome your comments and suggestions to make these meetings better and smoother. And so, we look forward to our next meeting in November. And I appreciate everyone's comments today and I will turn it back over to Lauren.

#### Lauren Richie

Thanks, Robert. And I will just check to see if any of our ONC Leadership Team have any additional closing remarks. I believe Dr. Rucker had to drop, but Elise or Avinash or anyone else from the ONC Team?

#### **Avinash Shanbhag**

This is Avinash. I was – definitely. Elise, go ahead. Please.

#### **Elise Sweeney Anthony**

Yeah. Okay. Yes. I just wanted to thank everyone for joining today. I think it was a very helpful meeting for ONC to hear the feedback as it relates particularly to the presentation on measurement and benchmarks and outcomes as well. But also generally, I thank everyone for the time. I know it is definitely not an easy time. There is so much going on in terms of COVID response and so many folks are working on the ground or working to address and support COVID response. But generally, a lot is going on, and I appreciate everyone taking their time to join the call. Avinash?

#### **Avinash Shanbhag**

Likewise. Appreciate it and just the one additional public service announcement, that I like to make that Dr. Rucker kicked off with, is the USCDI deadline for submission is October 23. So, please, if – I know some of the folks have been interacting with our team. So, please do get those submissions in time. And folks who are interested in commenting, the comment periods are open. And, again, submissions are available

ONC

24/7. So, please, we look forward to seeing a very robust set of data to consider for future expansion of the USCDI. So, thank you again. Appreciate it.

#### **Lauren Richie**

Great. Thanks so much, Avinash and Elise. So, with that, just a quick reminder for members of the public. The next full committee meeting will be on November 10. The ICAD Task Force, obviously, will be racking up their activities as well with their next meeting next week on the 27. And again, if you are interested in downloading the draft report that can be found on healthit.gov on the HITAC calendar page. Just click on today's meeting and you will find the materials and the report there. So, with that, I believe we can adjourn now. I want to thank everyone again for your time and we shall meet again here next month.

#### **Carolyn Petersen**

Thank you, everyone. Have a good rest of your day.

#### **Elise Sweeney Anthony**

Thanks, everyone.

#### **Robert Wah**

Thanks, everyone.

#### Clem McDonald

Thanks. Bye.