



Health Information Technology Advisory Committee

Transcript

January 15, 2020, 9:30 a.m. – 3:00 p.m. ET

IN PERSON

SPEAKERS

HITAC Members		
Name	Organization	Role
Carolyn Petersen	Individual	Chair
Robert Wah	Individual	Chair
Michael Adcock	Adcock Advisory Group	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 Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Federal Representatives		
Name	Organization	Role
Terry Adirim	Department of Defense	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Kate Goodrich	Centers for Medicare and Medicaid Services (CMS)	Member
Jonathan Nebeker	Department of Veterans Affairs	Member
Ram Sriram	National Institute of Standards and Technology	Member
ONC Speakers		
Name	Organization	Role
Lauren Richie	ONC	Designated Federal Officer
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Cassandra Hadley	ONC	HITAC Support
Steve Posnack	ONC	Deputy National Coordinator
Seth Pazinski	ONC	Director, Strategic Planning & Coordination Division
Avinash Shanbhag	ONC	Director, Office of Technology
Donald Rucker	ONC	National Coordinator
Seth Pazinski	ONC	Division Director, Strategic Planning and Coordination
Thomas Mason	ONC	Chief Medical Officer
Kathryn Marchesini	ONC	Chief Privacy Officer
Al Taylor	ONC	Office of Technology
Peter Karras	ONC	Lead, Federal Health IT Strategic Plan

Call to Order/Roll Call (0:00:12)

Operator

All lines are now bridged.

Lauren Richie

Operator, is the line open?

Operator

Yes. All lines are now bridged.

Lauren Richie

Thank you. Good morning everyone. Again, Good morning and welcome. Welcome to our new members, our existing members. Welcome to you members of the public that have joined us today. We appreciate your time in joining us for the first official meeting of the HITAC for the calendar year. We will officially start the meeting starting with roll call. Carolyn Petersen.

Carolyn Petersen

Good morning.

Lauren Richie

Robert Wah.

Robert Wah

Good morning.

Lauren Richie

Michael Adcock.

Michael Adcock

Present.

Lauren Richie

Christina Caraballo.

Christina Caraballo

Present.

Lauren Richie

Tina Esposito. I apologize, she is absent. Cynthia Fisher. Valerie Grey. Anil Jain.

Anil Jain

Present.

Lauren Richie

Great. Jim Jirjis.

Jim Jirjis

Present.

Lauren Richie

John Kansky.

John Kansky

Present.

Lauren Richie

Ken Kawamoto.

Ken Kawamoto

Present.

Lauren Richie

Steven Lane.

Steven Lane

Present.

Lauren Richie

Les Lenert. He has stepped away. Arien Malec.

Arien Malec

Good morning.

Lauren Richie

Clem McDonald.

Clem McDonald

Here.

Lauren Richie

Aaron Miri.

Aaron Miri

Good morning.

Lauren Richie

Brett Oliver.

Brett Oliver

Present.

Lauren Richie

Terry O'Malley.

Terry O'Malley

Present.

Lauren Richie

James Pantelas.

James Pantelas

Present.

Lauren Richie

Raj Ratwani.

Raj Ratwani

Good morning.

Lauren Richie

Abby Sears.

Abby Sears

Present.

Lauren Richie

Alexis Snyder.

Alexis Snyder

Present.

Lauren Richie

Steve Ready.

Steve Ready

Present.

Lauren Richie

Sasha TerMaat.

Sasha TerMaat

Good morning.

Lauren Richie

Andrew Truscott. Are you here?

Andrew Truscott

Present, sorry.

Lauren Richie

Sorry about that. Sheryl Turney.

Sheryl Turney

Present.

Lauren Richie

And Denise Webb?

Denise Webb

Present.

Lauren Richie

And has Kate joined us? Goodrich?

Kate Goodrich

Yeah.

Lauren Richie

Yes, okay. Adi Gundlapalli?

Adi V. Gundlapalli

Present.

Lauren Richie

Great. Jonathan Nebeker?

Jonathan Nebeker

Hey.

Lauren Richie

And do we have Ram Sriram on the phone?

Ram Sriram

Yes, I'm here on the phone. Thank you.

Lauren Richie

Hey, Ram.

Ram Sriram

Yeah, can you hear me?

Lauren Richie

Yes, we can hear you fine. Thank you.

Ram Sriram

Thank you.

Lauren Richie

Terry Adirim is also absent today. And from ONC, we have Dr. Don Rucker, our National Coordinator, Steve Posnack, our Deputy National Coordinator, Elise Sweeney Anthony, Executive Director of Policy, Seth Pazinski, and I believe we have Avinash Shanbhag, our Director of Office of Technology at ONC on the phone. And with that, I will turn it over to our National Coordinator for opening remarks.

Welcome Remarks (0:02:37)

Donald Rucker

Thank you, Lauren. First of all, I'd like to welcome everybody, in particular our new members, and wish everybody a Happy New Year, and frankly, thank folks for the extraordinary amount of hard work that happened last year. I know there were a lot of times when we and the exigencies of the workload really just jammed into your schedules. Frankly, I felt guilty a number of times over the course of the year with how much we asked folks to do, and in what a compressed timeframe. So, I want to thank folks for that. Hopefully we will have a more balanced schedule this year. But who knows? That will be our goal certainly. So, the overall mass of what we do in the country with Health IT is obviously moving forward in a lot of different ways. It is moving forward in the private sector and products. It's moving rapidly forward in the underlying new computing technologies, both hardware and especially software, that allow us to absolutely reimagine what a world might look like. Just a glance at your smart phone sort of tells you that.

From the federal government's point of view of course, we want to try to be as smart as the federal government can be smart about things and think about things and make sure we are synced up. Syncing up within the federal government is a challenge of its own, as with any large organizations. One of the things we have been doing – I believe it's actually required under HITAC, but I'm not sure – is a Federal IT Strategic Plan, and we just released this morning the 2020-2025 Federal Strategic Plan. This is really an effort of the various federal agencies to get together to think about what the priorities are, to think about what the approaches are, and just really to be common-sense smart about what we are doing here. I think it also serves as a document, as agencies within their boundaries come up with planning, just so that we can sort of have an understanding of the broader efforts. That is obviously both important and good.

We will be discussing that here. I believe you have copies of that, or we'll get copies of that to talk about and look forward to that discussion, as well as the public comments here on our draft. As we get to some of the more specific things, I would like to thank Carolyn and Robert for signing on. It took a little arm-twisting, but they've done a great job, and so we are highly appreciative of that. As folks know, these are three-year terms that are staggered, and so a number of members have been up, and we would like to welcome for reappointment Les Lenert, John Kansky, Raj Ratwani, Denise Webb, and Brett Oliver. In terms of prior members, Denni McColm has stepped down, so we'd like to thank her for her work. We have new members, Alexis Snyder, James Pantelas, and Abby Sears, and also Dr. Jim Jirjis is here for his first in-person meeting. He was actually appointed, as I think the public knows.

But the membership is comprised of an interesting mix largely appointed by the GAO, but we have other membership tracks that are appointed by the Senate and House members. We have folks who are here ex officio from our major agency colleagues. And then, there's a couple of very specific callouts for the secretary to a point. So, it is a very ecumenical group by design of Congress and the Cures Act.

In terms of things coming up, obviously the big thing is the Cures final rule. As folks know, we have received 2,000 public comments. We are allowed to meet with folks who have submitted public comments to clarify their comments. We've had some of those clarifications meetings. There is a vast process within the federal government to make sure that all federal rules, but certainly some things like the Cures Interoperability Rules, that these really meet the standards of what the American public needs. And the needs of the American public are really fairly broad in many ways. We know clearly there is a need for more transparency in healthcare. We know clearly there is a need for patients to have some agency, some level of control over their healthcare, which through our payment system has largely disappeared over the many decades. That is a huge public outcry. I'm sure there will be more in the political campaigns as we have that national discussion.

Obviously, we also want to be mindful in these kinds of rules to a series of technical considerations, like can this even be done, what is the expense of doing it? Does this have a competitive market? What are the expenses that might be borne by providers and the provider software systems? So, there are a lot of things that sort of come into this. I think when you see the rule, you will see it is a very balanced representation of the country's interest of the various folks that have talked to us about specific issues. I know there has been a lot of discussion, absent of being able to provide the final text, on what might or might be on there. But I think people will find it to be an extremely reasonable approach that is very much pro-public and done in a way to minimize the cost to the system, both to the people involved in doing this, and to maximize the opportunities for the country. But that will be coming out soon, we hope.

We're going to review, I think, some of our activities for the year. And as was pointed out, as has been pointed out a number of times, this federal advisory committee – I don't know how much folks here have been on other federal advisory committees; I've been on a couple. They each have their own sort of view of the world. Because of the complexity of Health IT, we are charged with a couple of specific things here, that Lauren has nicely laid out. So, that's what we are going to do. Let me ask Steve and Elise, who are really running the show. For folks that don't know, we were asked by Congress and the

White House when the term came in OMB to arrange ONC to have largely two large operational areas. One is in policy, and the other is technology. So, can you think of one as sort of the rule-writing, and the other is all the standards support work.

And Elise Anthony has been running our rule-writing, our policy operation, which now, we're doing a number of things internationally. These standards really are increasingly international standards. This is becoming a global economy. There are large international vendors. We have representatives from folks like IBM. I know Epic has a lot of international products out there. And of course, there are companies that originated outside of the U.S.; Phillips, Siemens – where I by way of disclaimer worked many years – that also have big stakes in these computing standards. So, there's international work going on. Steve has been running our standards operation, our Office of Technology, and is now also replacing Jon White, who has joined the Veterans' Administration in Salt Lake City. Jon White, I guess the air is good out there, or something appealing. I know the skiing is good.

Jon White

We're just waiting for you. Got a little spot saved. We have a very nice office reserved for you.

Donald Rucker

Oh, okay. Well, I am prohibited by law from considering future employment, so I appreciate trapping me in a felony, but I'll have to demure on that. But thanks. So, anyway, we want to thank Jon White, too. You did a great job here. And so, maybe we will start with Steve. Any thoughts on both the technology and your broader role?

Steve Posnack

Sure. Thanks so much, Don. I appreciate the opportunity to be with you all today. Exciting work ahead as we get into the 2020 agenda. Also, the beginning of a new decade. Many of you I'm sure are part of the HITECH Act's push stimulus, all of the activities associated with that. And it really feels, again, a renewed sense of purpose for the work we are doing this time around in 2020.

Donald Rucker

Elise?

Elise Anthony

Good morning, everyone. So, I want to start by echoing all of the appreciation for the work that you have done in 2019. It was a huge undertaking, and in the spirit of HITAC, of course 2020 is going to be another great year. We will discuss today the 2020 plan, and I want to just provide a little background that in thinking about the 2020 plan, we worked of course through ONC leadership, and we also worked with the cochairs. We looked at the annual report that HITAC released last year. We looked at what ONC is seeking to achieve in the years to come, and of course quite timely, as we released the strategic plan, the 2020 plan for the HITAC considers all those activities. We think it's going to be a great opportunity for the HITAC to contribute not only from a standards perspective, but also from the policy perspective of advancing Health IT.

On the strategic plan, I just want to give huge thanks to all of the work across the federal organizations in support of the plan. More than 25 federal organizations contributed to the plan. It's really provided a great opportunity not just from ONC's perspective, but from the federal government overall in terms of the Health IT vision and the opportunity it presents, whether it's buying power, the policy and regulatory work that exists, all supportive of the API app economy that puts information in the hands of patients. So, I think it's going to be a great year on many of the fronts in terms of what we will be engaging in. And just in advance, thank you for all you have done so far that will contribute to the work to come, and for the work to come this year. So, thanks.

Review of Agenda and Approval of October 16, 2019 Meeting Minutes (0:15:35)

Carolyn Petersen

Thanks. Good morning, everyone. I will just reprise my comments from the closed administrative meeting this morning in welcoming you all and expressing my appreciation for your work so far. And our excitement at the year ahead. I'll pass the mic to Robert now.

Robert Wah

Thank you Caroline. Again, I'm having to come in remote for this in-person meeting, but I appreciate the opportunity to do so. I also want to thank the committee for its hard work last year. As we begin 2020, I think it's worthwhile reviewing the work we accomplish last year, and we will do that in the annual report. But I think it's also worthwhile noting that Carolyn and I signed off on behalf of the committee, some 250 pages of comments to a 750-page proposed rule that was put out by the ONC. And so, that really represents a tremendous amount of work by all of you and the public people, folks that joined our subcommittees and task forces, as we crafted our response to the proposed rule. We hope that that was able to improve the final rule that will be coming out soon.

But I just want to express my thanks to the committee for all of its hard work, and also acknowledge all of the great support we have had from the Office of National Coordinator, from Dr. Rucker on down to the rest of the team. This is a large undertaking. It is important that we have an opportunity to provide our input into the national discussion about how we best use technology to approve the health of our citizens in this country. So again, it's been my privilege to serve as your cochair along with Carolyn, and I look forward to another great year in 2020.

Carolyn Petersen

Thank you Robert. We have in front of us on the slide the agenda for today. We will begin with a review of the HITAC 2020 Work Plan from Lauren Richie, followed by a review of the Annual Report Draft. We'll have a break and then a presentation on the Intersection of Clinical and Administrative Data Standards Discussion and Next Steps. After lunch, we have the 2020 to 2025 Federal Health IT Strategic Plan Overview, followed by an update from ONC's Chief Privacy Officer. We will then have a short discussion on Integrating and Using Received Data Discussion and Next Steps as well. And there's two public comment areas. The first is before lunch at 11:30 a.m., and the second is just before adjournment at 2:45 p.m. Before we start into the Work Plan Review, we need to approve the minutes from the October 16 meeting. Could I have a motion, please?

Male Member

Motion moved.

Carolyn Petersen

And is there a second?

Female Member

Okay.

Carolyn Petersen

Thank you. Would all those in favor of approving the minutes of the October 16, 2019 meeting please signify by saying "Aye?"

Members

Aye.

Carolyn Petersen

Would all those opposed to approving the meeting minutes please signify by saying, "Nay?" And are there any abstentions? All right. It appears we have approved the meeting minutes, thank you for that. And I will now pass the microphone to Lauren Richie to take us through the proposed 2020 Work Plan.

Lauren Richie

Thanks, Carolyn. Just actually one other quick housekeeping matter. As per our new procedure that we just discussed, if there are any members of a committee at this time that would like to disclose any additional outside activity with ONC, please let us know now. Starting with Christina.

Christina Caraballo.

Christina Caraballo. I will be working over the next couple of months on a small white paper for ONC on social determinants of health.

Lauren Richie

Okay.

Steven Lane

I work with the EHR reporting program contractor as a consultant. I also work with the ASPE/ONC group working on the technical expert panel on provider data integration, and through my roles with care quality and the Sequoia Project, I hear a bit about the TEFCA work.

Lauren Richie

Thank you, anyone else? Ken?

Ken Kawamoto

Ken Kawamoto. So, I have honoraria, consulting, sponsored research, or sponsored travel related to HIT in the past three years with McKesson, Hitachi, Kaiser, Premier, Klesis, RTI, Vanderbilt, University of Washington, UC-San Francisco, Mayo, the Association of American Medical Colleges, and ONC via ESAC, JPS, A-Plus, **[Inaudible] [00:20:45]** and Secure Risk Solutions. And I'm also an unpaid board member of HL-7. And I'm also helping develop a number of Health IT tools which may be commercialized.

Lauren Richie

John?

John Kansky

Just echoing Steve, I serve on the board of the Sequoia Project.

Lauren Richie

Thank you. Raj?

Raj Ratwani

The MedStar Human Factors Center is a recipient of the ONC LEAP award, so we have that contract work going on.

Lauren Richie

Thank you.

Clem McDonald

You all kinda jumped, so I'm not sure this really works, because I did an outside activity and I was a reviewer for a grant project at Boston Children's for two days.

Lauren Richie

Thank you. And seeing no other – sorry, Jonathan?

Jonathan Nebeker

I don't know as feds we need to disclose, but we coordinate frequently with ONC. So, a lot of us do.

HITAC 2020 Work Plan Review (0:21:57)

Lauren Richie

In the spirit of coordination. Okay, I think that's it. So, let's transition to talking about the work ahead of us for the year. Next slide. Okay. So, as Elise mentioned, a lot of work went into planning out the activities for the committee for this year. We have had a number of conversations with you to get your thoughts and input on where we should go. We also have the parameters of Cures and TEFCA to address and consider as well. And so, I just wanted to provide that context so that you know a lot of work went into this, and there's also timing and other considerations that we want to be aware of. But we are still within the boundaries of our three priority target areas of interoperability, privacy and security, and patient access. Next slide.

So, we have had a number of conversations, and a number of topics have come up over the past, actually more than a year now. I think we started some of these conversations in late 2018. And so, these are topics that may or may not have been specifically spelled out in Cures. They have organically come up through conversations around the annual report, other industry related activities, just your own personal work experience that you want to bring to the committee for awareness. So, not an entirely exhaustive list, but we wanted for you to see everything that we've heard so that you can see where we land and how these conversation helped to inform where we land for this year. So, next slide.

So, this is essentially a short list – or the long list depending on how you look at it. And so, we'll go into a little bit of detail, but there will be some new task force activity that we are starting this year, even today as a matter of fact. So, that's starting with the EHR Reporting Program. That will be a task force that we will stand up a little bit later in the year. The CMS has an interoperability rule that we anticipate this year. As Don mentioned, we have our strategic plan hot off of the presses just this morning. Our Annual Report Workgroup, that is an ongoing group that will continue to work and close out the '19 report and begin the '20 report. Integrating and Using Received Data, we're going to have a little bit of a discussion today with the committee, but we hope to flesh out specific activity and tasks later in the year. The Intersection Of Clinical And Administrative Data Standards, again, we will have a discussion and a presentation later today, so this will also be a new task force activity and we will get a little bit into the timing and specifics of that a little bit later.

Obviously, our final rule, when that is published and released as Elise mentioned, we'll do a deep dive and determine what if any steps are required there. The same with Patient Access. It's just something that cuts across all of these topics, but we did want to highlight it as something that we want to make sure is always front and center on our radar. But if there are specific patient access activities that we would like for the committee to consider, we will have an opportunity later to chat a little bit about that. And then lastly, the TEFCA. And so, like Elise mentioned as well, we'll see what comes with that and what the HITAC will do as a result. Next slide.

So, there were a number of other topics that kind of rose to the surface that we just want to take a little bit of additional time and explore with the committee. Again, we want to get your input on what are some specific tasks, what are some activities, what are some initiatives that you are aware of or that you are working on, that you would like to bring to the committee. We didn't quite have a specific charge or a specific timeline, but we did see these as additional priorities for the committee to address, in 2020 as well as beyond. So, as our Work Plan continues to flesh out, and as you are having ideas, please don't be shy about sharing that here in this venue. Next slide.

So, this is just a visual of everything that I just laid out, with the green being kind of a more confirmed timeline. As I mentioned, that EHR Reporting Program, we are anticipating final draft criteria proposed for that program somewhere in the March or April timeframe. The Intersection Of Clinical And Administrative Data, that's a task force that we are kicking off, but still a little bit unclear in terms of how long that task force will last. It just kinda depends on the charge and the constitution of the task force. And then, obviously the elephant there being that we don't quite have a timing yet for the

TEFCA , and the final rule from ONC and CMS. So, it's a little white but once the rules are dropped and once the activities of the task force get going, we'll be quite busy. Next slide.

So, just to focus on the immediate horizon, looking at just quarter one of 2020. We will be wrapping up the fiscal year '19 report. You all have the first final draft of that you got last week. The EHR Reporting Program task force, again around March or April. The Strat plan we will start today and continue next month, as well as the Clinical and Administrative Data Standards. I think we'll have to come up with a nice acronym for that task force, but we'll be starting that again today. Next slide. So, with that, I am going to pause to see if there are any questions, either timing or topic-wise to raise before the committee now. Ken, do you have your ten card?

Ken Kawamoto

Thanks, Lauren. So, it was in the potential other things to consider, but I would recommend that the privacy/security issues that were reflected in the Annual Report, and that I added a few additional comments on, get some attention. I do think on the ground from a health system perspective, this is probably the biggest issue that we are seeing as concerns from healthcare providers. Things like if we want to give a patient hemoglobin A1C test result, we now need to give a third-party vendor access to the patient's HIV and gonorrhea test results. That just seems unacceptable, and we need to fix it. Thanks.

Lauren Richie

Other comments, questions or thoughts? Terry, and then Steven.

Terrence O'Malley

Hi, it's Terry O'Malley. Just one minor point and that's about metadata. It's going to underlie a lot of the activities we want to do like Provenance, and de-duplication, and versioning. All critical points for interoperable exchange, and it is not mentioned anywhere, and I am not aware of standards that exist for metadata, but we might want to look into that entire area, because it will be a critical component going forward.

Lauren Richie

Thanks, Terry. Steven.

Steven Lane

Stephen Lane. I want to second Dr. Kawamoto's comments. I think the area of patient privacy, of data as it leaves the protection of HIPAA, is really important and could be a real opportunity for HITAC to weigh in. I know a lot of people in the industry are putting energy into this. There are a lot of folks are trying to address it; it's become very political. We're going to get a presentation I think from Katherine later today on this topic, but I think it's an area of real interest.

Lauren Richie

Thank you. Clem, then Christina.

Clem McDonald

Yeah, I just wanted to respond to Terry's comments. I think that maybe it's important what he said, for sure, and it might not be available in all the standards we are using. But FHIR is really rich with all of that stuff, but it's a heavy lift to get into it. But I don't think you have a problem with FHIR with those things.

Lauren Richie

Christina?

Christina Caraballo

On the patient access, it was one of the cross **[Audio cuts out]** that was identified, and I think that we still need to look at patient access a little more. Right now, I don't think there is a scalable approach. You've got a lot of one-off in a lot of places that we can log in and get access to our information. I do think that one of the things we need to start thinking about now is laying a foundation that is a place where patients can come in and access all of their health information from all of their healthcare providers. One of the things that I would like to evaluate more is potentially having a patient focused QHIN. I know that there are a lot challenges to that, but I think that if we don't start thinking about it today, then we are not going to get to where we need to be in the future. So, maybe this HITAC group can look at identifying what would be needed in order to make that successful. Thank you.

Lauren Richie

Thank you. Now, Carolyn.

Carolyn Petersen

Thanks. I just wanted to reiterate support for Ken and Steve's comments with regard to the importance of doing some further work around privacy. Certainly, as the M-health and the app ecosystem expands and reaches into ever greater aspects of our personal lives, the privacy and security measures around patient and person-generated health data is extremely important. We haven't really touched upon that at all in the work of this committee to date but given the prevalence and the growing interest and pressure on patients to use these tools, I think merits a deeper look. Thank you.

Lauren Richie

Jonathan, and then Cynthia.

Jonathan Nebeker

Okay. So again, I'd like to double down on the privacy issue, but also raise another topic that hasn't been covered yet, which is exploring some of the certification approaches of ONC to EHRs. I think that there is a lot of evidence that there is a good start, but big gaps need to be addressed. And I think there's a lot of people on this committee with skills and interest that could really help maybe first explore the issues and then second, make some recommendations, looking at the timeline. But a big interest to VAs, we're moving more into commercial area of getting safe and effective systems.

Lauren Richie

Thank you.

Cynthia Fisher

I would like to expand a little more beyond what Christina mentioned regarding patient access to their health information. We have been conducting market research across country and understanding what the key issues are from patients. And a big part of the issue that they had in the feedback has been their increasing distrust of the medical system in essentially keeping them from getting access to their health information in a usable way and transparency in the exam room and transparency before and after. So, if I may, I think there's a call for us to look at the future and how patients utilize, as Dr. Roberts said earlier, their smart phones in every other functional competitive marketplace. But the excessive need to be able to get their entire records, so including their x-rays and their MRIs and their laboratory results. So often, they get referred to specialists for care and have very difficult time getting access and delays to their data, as do their follow-up physicians.

The other thing that they have shared with us is extensively the need, while they are in exam room where the back is turned and the entry by their physician is spent in front of the computer screen, that there's a distrust about what is being coded and said about them. So, we've heard over and over again how it would be lovely to have that entire screen put on the wall so they can see what is entered, because when they get their bill, even though they say, for example, may get a free annual checkup, because they asked three questions, they may be up-charged \$850.00 or so because it was coded into their electronic health record. And so, there's a distrust for what is done clinically and entered into the system and then what they find in the results months later in billing. So, just to give feedback on patient access, I think if we can look towards the future as we look at these standards of marrying one, the price information in a broad way, which is across the system, cash and negotiated rates, with what the patients want from their clinical experience.

So, having access to their clinical data across the spectrum. And then, finally, getting to the financial payment. So, another feedback is why can't we get a single, comprehensive bill that reflects the price and reflects what I experienced in the clinical setting? So, if we can move towards a standard to bring about the connection between the price, the clinical experience, and finally a very simple, comprehensive bill that oh, by the way, would have a digital – not paper, snail mail, many months fragmented pieces, but a digital provenance so that patients can have recourse when they feel they've been up-charged, overcharged, price gouged, or financially sent to collections in the delay between insurance reimbursement. So, I just wanted to relay that we have this opportunity to essentially make a functional, digital experience across the spectrum for patients, and ultimately also their employers. Thank you.

Lauren Richie

Thank you, Cynthia. Raj, and then Sheryl.

Raj Ratwani

Thank you. This is Raj Ratwani with MedStar Health. So, Dr. Nebeker had mentioned looking at certification and mentioned safety as well. So, I want to reiterate that, and I think really focusing on the broader framework for patient safety that would include certification, but also consider different methods for proactive safety surveillance. I know the ONC's expressed interest in the use of audit log

data. So, I think there's an opportunity to look at this more comprehensively and built out a framework for that. So, I think that would be a good area of focus for us.

Lauren Richie

Sheryl?

Sheryl Turney

Thank you. Sheryl Turney. I wanted to make two comments which relate to patient access that really, I think are in need of standards for interoperability. One would be price in terms of what makes up the price, because there are definitely issues. I can tell you I have seen them firsthand from a payor perspective, where innovators don't understand, and so they put out information on a price, yet they are creating a price that looks like one thing for one service and a different thing for another service. We don't know what is included in it. So, there needs to be some standards related to what it is in the bucket. But also, I'm gonna bring up the topic of all payor claims database, because there's a huge issue there as well where there's no standard that exist in any of the states. People have a right to know what other data is contributing to these organizations who are then selling the data to someone else.

And also, there's no standards for how the data is collected, how the data **[Audio cuts out]**. And there's no standards making an organization who has any oversight into any of this as well. So, it all becomes very expensive, and it's included in basically the prices that we all pay. And right now, there is about 20 organizations collecting data, all different ways. And so, you take that information times the group of national payors which is a large number. It's millions of dollars per state, times 20.

Lauren Richie

Thank you Sheryl. I'm not seeing any other tent cards. This has all been helpful.

Robert Wah

Lauren.

Lauren Richie

Sorry, a bit of an echo, but I'm going to go to Andy, and I think I heard Robert on the phone.

Andrew Truscott

Thanks. I know it's quite late to get my sign up. Essentially, many of the issues which have been raised by my colleagues around the table today are issues we've actually been discussing for the last 18 months anyway, and we have all got thinkings around this. It would be a shame to say it's the beginning of a new year, and we've erased our minds from the last 18 months. So, I know Cynthia raised these issues that we have been discussing. So, again – and Steve and Ken – so, why don't we kind of meet again and in the groups we already have – because we do – and actually come to some kind of census as a committee as to what we would recommend and suggest for ONC to consider. That seems like the logical, sensible thing to do, rather than hit 'erase' and start again on the tape.

Lauren Richie

Thank you. And Robert, did you have a comment?

Robert Wah

Yeah, thank you Lauren. This has been a great discussion and I appreciate the committee's engagement with this. As has been said a number of times, our federal advisory committee had a very detailed prescription given to us by the 21st Century Cures Act on the agenda that we would follow, and we have been trying to make sure that we afford the committee an opportunity to expand upon that list of prescribed activities for the committee. And I hope that the committee recognizes that in this summary that was just given by Lauren. Certainly, we want to continue to have an ongoing discussion of the committee about the things that we believe from our various perspectives, and stakeholder positions, that are important to be advising the Office of the National Coordinator and Health and Human Services about the use of technology for improving healthcare.

One of the things that I think I have heard in this discussion this morning is the importance of patient access to digital information. Both access and ease of access I think are two main things I have heard along with all the others. But we want to continue to encourage the committee to think about what we as a committee would like to take on, in addition to the charges that have been given to us by the 21st Century Cures Act. On the issue of patient access, I did want to say there's a new activity that I have become aware of. The Rockefeller Center funded a nonprofit organization called the Commons Project, which is seeking to be a nonprofit organization that sits between the public sector and the private sector, to accomplish things that both the public sector and the private sector may not be able to do on their own.

And while that is a large and high level description of it, a very concrete project that the Commons Project will be taking on is to put out an Android version of the current iOS health version, where in iOS, as many of you know, iOS users can now pull their data from their electronic records by giving the iOS system their passwords, and it just acts as a proxy to pull all their information and puts it on their mobile device. But that is only available to people that are on the iOS system, so the Commons Project will release in the first quarter of 2020 an Android version of that same capability. Again, I think this will accelerate the ability to patients to access the data. It is not as complete as many would like it to be, but it has the opportunity to start that process of giving patients access to their information. The folks from the Commons Project have met with I think Dr. Rucker and his team at the National Coordinator's Office, and there may be an opportunity to hear more detail from them at the HITAC level as well.

And finally, as full disclosure, I was invited to be a board member on the Commons Project as well. I think this is an example of the kinds of things that we can start discussing as a committee and start looking into in more detail. So again, I hope people have seen their comments reflected in this presentation, because we have been trying very hard to make sure we had an opportunity to hear from the committee about issues that go outside and beyond the prescribed areas that were put in the 21st Century Cures Act. And so, if you have additional comments, as always, your cochairs would welcome them, both in the public forum that we are discussing here, but also to send them to us as your chairs, as well.

Lauren Richie

Thank you, Robert, and I think we will take one final comment on this topic, just so that we can get not too far behind on the agenda. I think it's Abby Sears.

Abby Sears

Thank you. One thing I think we might want to think about as a committee and for the ONC, is how we want to embed the social service record locators into our process. Right now, they lack – they are not part of the certification process; the standards around the data that we are being asked to move and/or store and/or use is not entirely clear, and they are gaining more and more momentum. I think that's going to take more and more of our capacity and time as we think about the social determinants of health in that data that is nontraditional medical data.

Lauren Richie

Thank you. So, I think with that, this is a great segue into the Annual Report discussion, because some of the topics that we have heard now will bubble up with report. So, I will turn it over to Carolyn and Aaron for this.

HITAC Annual Report Draft Review (0:46:21)

Carolyn Petersen

Thanks, Lauren. I would just ask the members of the HITAC to please make a point to speak up and speak close to your microphone. We understand some individuals who are listening to the webcast are having some difficulty hearing. We can help them by being sure we are speaking up loudly. Thank you.

Good morning again, everyone. Aaron and I are pleased to present the work of the Annual Report Work Group this morning. As you have seen in the previous batches of information from ONC, we have sent out a draft for your review, and we do hope that we will receive any written comments you would like to submit by January 21st. Today, we are going to go very briefly through a set of slides that hit on some of the high points and tried to get to the discussion as quickly as possible, so we can cover anything we need to here as a group. With that I will get started. Again, here is our membership: myself and Aaron Miri, Christina Caraballo, and Brett Oliver. In conjunction with several staff from ONC as well, to support the production of the report. Next slide, please. Our scope is to inform, contribute to, and review draft and final versions of the Annual Report, which goes to the National Coordinator, who then sends it on to Congress. Next slide, please.

In more detail, our scope involves analysis of the HITAC progress, which we were able to do with this version because we now have a history. Assessment of the Health IT infrastructure and advancements, analysis of existing gaps in policies and resources, and then identification of some potential activities in areas of interest and concern to members on the HITAC. Next slide, please. Next slide. So, what we need to do as a working group is to get your input today and through the next week on the draft of the report. We hope to finalize that and get your approval at the meeting next month, and we will then transmit that final report to the National Coordinator, who will share it with Congress **[Audio cuts out]** Cures Act. Next slide, please.

As you can see we have gone through quite a few meetings this year. We still have one coming up next week where we will discuss your feedback, and then we will be wrapping up the activities on this report in February and March and taking a break before we begin on the FY20 version in June. Next slide. So, our work today is to review the draft to hopefully go to approval in February, and then to relax until the fall when we start again on the next one. Next slide. So, today we're just going to go through some of the high points of the draft that you've seen very quickly, and then we'll keep going. Here is our outline. This is essentially the same format that we used as with the previous year's version. We simply now have a HITAC progress report as well to present. Next slide. Our target areas: interoperability, patient access, and privacy and security. We also have the opportunity to **[Audio cuts out]** any other target areas that we think are important. Next slide.

Our progress this year. Here you can see a roundup of the statistics, the meetings of subgroups, recommendations. This is a really great summary of the many, many things we have done, and hopefully a foundation for moving forward in coming years. Next slide. And again, another way of looking at the accomplishments of the subcommittees. Next slide, please. So, looking at the infrastructure landscape analysis, we're looking here at our key topics within those three areas and other things that are going on in the federal environment and emerging issues of concern, such as some of the things we talked about this morning in the conversation we just concluded. Next slide. The gap analysis: here we're looking for opportunities and things we need to be doing going forward. Next slide, please.

We also had some recommendations for HITAC activities. These are based on comments individuals have made during the past year in various conversations at meetings. Our discussion in the September 2019 meeting, when we talked briefly about some essential activities, your written feedback and also verbal feedback from the October and November meetings of the HITAC. Next slide, please. We have kind of taken a tiered approach looking at our opportunities. Some things for the immediate future we envision in the next year or perhaps two years, and then things that are longer-term opportunities that could start this year and next year and then move forward as things change and as we know more about the info blocking rule and the other things the federal groups are working on now. Next slide. And with that, I will hand off the mic to Aaron to work on the opportunities, then we'll discuss.

Aaron Miri

Good morning, and thank you all for being here, and Happy New Year. Up front before we go into this I want to take a moment to also call your attention to Page 51, which has the listing of all the ONC staff who helped us write this report. They are heroes in this work, and they do a tremendous amount of behind-the-scenes for all of us, so I just upfront want to say thank you to Michelle and that entire team for the great work, working with the ONC leadership team. All right. Let's go into it, next slide. Thank you.

So, the recommended HITAC activities you can see here that we have down are 1.) review and make recommendations on best practices for Health IT developers and providers, 2.) Offer ideas for the role of Health IT in improving price transparency for health care services, 3.) Convene a hearing to understand trends related to UDI data integration and understand the effect on various workflows,

and then 4.) Review and make recommendations about the ONC's role in setting guidelines for the use of health data to be made available electronically within research. Next slide.

Some of the other recommended activities: convene a HITAC workgroup to review and provide recommendations about federal agencies such as the OCR, FDA, FTC and others, addressing third-party access to health data, identify educational approaches, technology mitigators and potential regulatory solutions that offer improved transparency and privacy protections outside the purview of HIPAA, develop recommendations for additional steps for HHS and industry to enhance education about requirements and applicability of HIPAA, Title 42 of the Code of Regulations, FERPA, and others, and to help ONC identify and define policy needs, the functional requirements for data segmentation for patients, providers, and other stakeholders. Next slide.

Identify and suggest how consent should be captured in TEFCA, review the consent policies and data use agreements of early adopters of social determinants of health HIEs and others develop best practices for healthcare entities looking to exchange SDOH, review actions already underway regarding the management of and processes for protecting the privacy and security of patient-generated health data, and identify educational approaches that offer increased transparency for international regulations such as GDPR and others that affect the U.S. health care system. I can tell you that last bullet, this is a big one that's affecting a lot of us particularly in the academic medicine space. Next slide.

Regarding patient information, assess patient portals' and patient-facing mobile apps' operational effectiveness, patient engagement, and/or patient understanding to use of data to establish measures in the future. We are really recommending to hold listening sessions of experts and representatives of stakeholder groups, assess deployment of 2015 Certified EHR Technology in the field to identify any early gaps in existing API trust frameworks and OCR guidelines and develop recommendations on how to fill those gaps. And of course, suggest ideas for guidance by HHS on API use. Next slide. All right, so that was a lot for that one section, but I'm gonna go kinda quickly because I think everybody here ate their Wheaties this morning and want us to keep going into the next section.

All right. Around interoperability, we are recommending to encourage the adoption of standards to support data segmentation by identifying policy needs and functional requirements to address patient privacy and provider needs, identify opportunities to use TEFCA to enable the exchange of data necessary to support the response to the opioid crisis, hold hearings to explore how new and emerging technology, such as machine learning and referential matching, are improving patient matching, and develop recommendations to inform ONC's patient matching strategy in light of the findings. Continue to refine, to review, and recommend SDOH data elements for inclusion in the U.S. Core Data for Interoperability (USCDI) framework and promote the continued SDOH standards development, and to review opportunities for HHS to require the use of standardized physiological, social and behavioral data across agency programs.

Also, develop recommendations on ways ONC can include EHR-related patient safety events in the EHR Reporting Program and review and recommend steps for ONC to improve the ability of behavioral health and long-term care providers to electronically exchange data.

Okay. Now my favorite section, privacy and security. All right. We are recommending to review and make recommendations about the federal role in setting guidelines across states for the exchange of data. Also, collaborate with the National Committee on Vital and Health Statistics on its proposed revisions to HIPAA and consider strategies for aligning policies across the states. This is a big one, considering for a lot of organizations that share a lot of data. No. 3, identify additional steps HHS should take to raise awareness about how de-identified data is used today and about the ability of new technological capabilities to re-identify de-identified data, convene a listening session to assess the development of technologies that prevent identification, review existing ONC cybersecurity educational resources to identify any necessary updates, revisions, or new materials that should be developed.

I should give a lot of credit to the ONC. They've put some tremendous material out on the market that I've used for many, many years now, so continuing to refine that would be helpful. And then, hold a hearing to identify additional opportunities for the HITAC to improve cybersecurity preparedness. Lastly, to explore patient and provider experiences with sharing and using PGHD to continue to identify best practices and gaps related to patient access information. All right, Carolyn?

Carolyn Petersen

So, that was kind of the really fast tour of slides which you all are familiar with and hopefully expect from Carolyn and Aaron. We now really want to get your feedback on the report. We have a bit of time to refine that and hopefully get it to a stage where this group is comfortable approving it. So, we will start with Denise and go from there.

Denise Webb

Thank you, Denise Webb. Excellent report, very well written. It is amazing how much was packed into the report. I would like to make some suggestions to our committee to adjust some of the alignment around the timeframes of what we are going to focus on, immediate versus longer-term. So, if I understand it, the immediate is more in the current year, next couple of years and the longer-term is three to five years. I believe recently in the budget bill, there was some language passed to provide a directive to ONC to look at the effectiveness of the current methods related to patient matching and making recommendations, and we do have this particular activity as a longer-term activity. So, I'd like to recommend that we consider moving that up to a more immediate activity.

The same with related to EHR-related adverse events. We have that in a longer-term activity, but since ONC is working on the EHR reporting program this year and will be looking potentially for feedback from us as a committee, I'd consider moving that one also up to immediate opportunities. And then, my last comment is related to social determinants of health. We have one activity that is focused on near-term, immediate, as far as collecting more SDOH. Yet the standards and developing the standards around the SDOH is a future activity. I think those two timeframes should be aligned in the report. Thank you.

Carolyn Petersen

Thanks, Denise.

Denise Webb

I'll submit these in writing as well.

Carolyn Petersen

Perfect. All right. Thank you. Let's go to Steven and then Ken.

Steven Lane

Steven Lane. When you're discussing patient-generated health data, are you thinking both of manually entered data such as questionnaires and surveys, as well as automatically generated device data and data from other sources?

Carolyn Petersen

Yes, we are including patient-reported outcomes in that large bowl of the PGHD. Should that be called out separately as well, do you think?

Steven Lane

It just wasn't clear to me as I was reading the document whether we were thinking of both of those categories. I think it's worth clarifying.

Carolyn Petersen

Right. Thank you .

Steve Posnack

And that's a good point, Steven. Also, the gap with standards, particularly as it looks like PROs and others, and how that plays out. I think that's critical. It's a good point.

Carolyn Petersen

Let's go to Ken.

Ken Kawamoto

Thank you. Great report. A few comments. So, 1.) there's a number of recommendations on the task force etc. that aren't reflected in what's **[audio cuts out]** 2020. So, I think to the extent that the annual report is recommending that certain things be reviewed, etc., I think we should really consider that they be followed up on and not just be recommendations for next year's annual report. With regard to the privacy and security, I think that focus is really important. I think we believe in the interoperability and all that can be done but I think all we need is a few flagrant examples of where this doesn't go well, and all of this will sort of be put on hold for like 5-10 years, or maybe forever. I don't know. I think it's something we can't take lightly. Along those lines, I think there was some information on how often people just ignore the kind of, "Hey, this is what's going to be shared information," and I think that just really needs a lot of emphasis and view.

It's one thing to say, "Hey, you're going to show demographic data." It's another thing to say, "Hey, by the way, we're going to give this person the last four digits of your Social Security number," which may

happen, for example. And I put in writing, and I'm just going to verbally briefly go over it for consideration, what I recommended for additions to this. So, one was around privacy and security, I had a section recommending for the gap analysis. We talked about the limited support for restricting the scope of data shared with third parties via FHIR, which is really coming to age now. So, part of the FHIR capabilities specified by ONC regulations only provide limited support for restriction of scope of data shared with parties.

So, for example, consider the case where ONC-certified Health IT product is used by a healthcare system or patient to provide access to a patient's cholesterol level. The third-party vendor product, which is a patient's smart phone app, under today's conditions it's currently not possible for the health system or a patient to only provide access to that. They must provide access to all the patient's lab data, including potentially highly sensitive data such as the patient's HIV, syphilis, gonorrhea, and chlamydia test results. Similarly, for the healthcare system, for a patient using these products to provide access to the patient's age and gender, it's currently not possible for that health system or patient to only provide access to that. You must provide access to all of the demographic data, including potentially things like the name, race, medical record number, other general identifiers, marital status, home and cell phone number, personal work email, home address, etc.

I think it is something that if you were a patient you would be pretty surprised that this is what we are doing as the federal government. So, my recommendation simply here is to address this. It has been brought up many times in groups like HL-7 Argonaut, and it has been kicked down the road, saying, "Oh, that's going to be challenging." But I think at the very least we should be in a position as recommending to ONC that this type of filtering, for example to say, "Hey, it's okay for you not to send the patient's HIV test results to a vendor that has no need to access it." And there are vendors out there who are saying, "Well, ONC certified these Health IT systems, you're breaking certification if you don't give us everything." And there are certain vendors, for example, who are just trying to take **[audio cuts out]** medical record, even when they only need 10 elements. So, I think this is something we have to address. And there are very feasible technical ways to approach this, and I think it would be remiss if we don't. Thanks.

Steve Posnack

Ken, if I could quickly ask a quick follow-up question for you. We do talk about patient education, and really going into detail there. You're saying break that into specificity of really understanding what consent means, what are you agreeing to, what is being shared, why that's being shared. Is that what you're asking for?

Ken Kawamoto

I think consent is, and also there's several elements. So, I think patients really need to know that is happening, and also there should be technical controls. So, it would be kind of like saying at this point when we share data with third parties, what we typically would do in those cases is say, "Okay, what do you actually need, and we will give you that data set." FHIR currently is basically saying, "Well, I know you only need the patient's weight, but we're going to give you access to every single lab test the patient ever has had, and please don't **[audio cuts out]**," which to me is crazy. Thanks.

Steve Posnack

Carolyn, may I just make one clarification to Ken?

Carolyn Petersen

Yes.

Steve Posnack

Just to clarify the scope here, because it's a complicated landscape. The third parties in the context in which you are referring are providers, partnerships with third-party apps they are using, for the purposes of patient care. Because when it comes to the patient getting their own data via third-party apps, we know that their concerns are related to that secondary use of that data by those apps, but the patient elected to get data on that app, and they know what data they're getting. So, it's more about B2B, so to speak, interactions of apps or other services that are FHIR-based that providers would use and narrowing the scope of that data and those interactions.

Ken Kawamoto

Yeah, so I think the B2B interaction is really important, especially as healthcare providers. We feel like we are stewards of this data, and it just doesn't make sense for us to provide access that's not needed. I think from a patient perspective, though, if you have third parties who need access to your cholesterol results, would you prefer an approach that only allows them access to cholesterol results, rather than in order to get that information out, you have to send them your HIV test results. I think they would probably say yes.

Steve Posnack

Sure. No, I agree. And the fundamental point about having more specified scopes in terms of how that data is shared and authorized by the patient, I think there's just some contextual layers and differences that would need to get unpacked. Sorry. That was Steve Posnack, sorry.

Carolyn Petersen

Thanks Steve and Ken. Let's go to Les and then Clem.

Les Lenert

I want to congratulate you all on producing a very impressive report with excellent recommendations. But one of the things that I think would improve the rigor of this report is linking back to the approved recommendation documents from each subcommittee that **[audio cuts out]** where the specific recommendations in the report come from, because I can't really trace back to the work of the committee. Otherwise, we're going to have to start again and rehash every statement in this report. Which would take a very long period of time. But if you were able to reference each statement back to an approved report from a subcommittee, I think we would be able to go through this and to accept and endorse every element of the report. In my reading of the report, it's an excellent report, and I agree with everything there. I just wanted to see it mapped back to what actually came out of this committee's work.

Aaron Miri

Les, is that just from HITAC, or do you also consider linking back to recommendations for the previous policy committee and standards committee?

Les Lenert

I think that since it's this year's scope, we are trying to focus on what we approved as a committee here, during the year, which would include all these reports from subcommittees which we struggled over so many times to get the recommendations from those exactly right. And so, if there was a reference to saying this subcommittee letter is where this particular item came from. That would make all of this very transparent, as opposed to having this gap that we currently have.

Carolyn Petersen

Okay, thank you. I'm not sure I can promise to reference every single statement, but we certainly will do what we can do and look to capturing information this way for future reports. Can we go to Clem?

Clem McDonald

Yeah, I just wanted to ask questions and maybe comment about the externally produced data. I haven't digested it carefully enough to know, it may not be an issue, but I do worry that if that data just flows in without any consent or interaction with the receiver, it could create lots of problems. Firstly, the volume could be unmanageable. And secondly, there is a responsibility for a piece of data that came in there with potential malpractice things if it wasn't reviewed and reacted to. So, I think there has to be a consent on both sides, or an understanding on both sides of what is coming in and how it's going to be dealt with. I don't know if that has been dealt with, and if it isn't, it should be.

Carolyn Petersen

Was there a particular recommendation for something in the report that you suggest revision or changes to?

Clem McDonald

Like specific changes?

Carolyn Petersen

Just in reference to your comment just now, how would we capture that in the annual report?

Clem McDonald

Okay. Don't ask questions. I'll do that.

Carolyn Petersen

All right, thank you. Andy and then Adi.

Andrew Truscott

Thank you. Great report. Enjoyed reading it, enjoyed commenting on it. Thank you very much indeed. Just a couple of things. I agree with everything what my colleagues have said here so far, but on picking up on Les's point on traceability. So, coming out of the information blocking task force, we actually

deferred to a later point in time around price transparency deliberately, because we didn't want to make any recommendations which could potentially slow down the lawmaking process and taking on board. Cynthia eloquently discussed this earlier today. I noticed on the slides for stuff to delve into, the patient access one was remarkably full of white space. I suggest that maybe we actually say, "Look, we have got traceability. It came out of a previous report that was done during 2019 around approaches to price transparency, what we mean by it, etc." Needs to go on the agenda. That's a suggestion.

Also, another issue that came out of the information blocking task force was this fear for members around what we call the "twin track" approach. So, the idea you could actually have – for want of a better word – app vendors who are not seeking to be Certified Health IT, who could not have conform with Certified Health IT boundaries, and therefore could actually mistreat or mishandle patient information. I think that's a topic which should be addressed – and this is my personal view – in the next few weeks and months, because it's a real risk to everything we're seeking to achieve by enabling information to flow more liquidly. So, I think that should be addressed, and not in a manner to prevent but in a manner to assist, make clear, and enhance and augment. Thank you.

Carolyn Petersen

Thank you. Adi.

Adi Gundlapalli

Thank you. This is Adi Gundlapalli from the CDC. One special case of sender and receiver is the public health reporting situation, where there is a mandate by statute locally to report cases that are reportable at the state and local jurisdiction. So, I think we resonate with Dr. Kamamoto where he said the type of data that is exchanged has to be very much in tune with what the jurisdiction is supposed to receive. So, either access or not. So, we see opportunities and challenges. And so, I think there are some opportunities here to make sure that not everything is sent, or not everything is received. And that's a special case of sender and receiver. Thank you.

Carolyn Petersen

Okay. Thank you. Let's go to Alexis and then Cynthia.

Alexis Snyder

Hi. Alexis Snyder. I wanted to echo a lot of what Ken was saying about the privacy and security and the sharing of data, and particularly in the privacy and security area of the report under lack of control over sharing and variability of info sharing. I think Ken had mentioned something about patients often ignoring what is being shared and/or not understanding what is being shared. I think actually going back to the consent process, there is a great number of patients who aren't even aware they are agreeing or consenting to sharing, and there needs to be a lot more stringency around the sign-off process. Many times, patients are given a little electronic tablet, and sign it, keep signing, keep signing, and they don't know until later on that they signed off on things that they normally would not have consented to, and I think that's super important.

The one other piece I wanted to point out, on interoperability and the easier integration of sharing data, I think an important piece of this – and this may go back to newer topics for new business in the

next annual report – but in particular into patient involvement into correct data. It's very difficult for patients, whose data may have been entered incorrectly, particularly in physician notes, to get those matters corrected before they are shared with another party as well. And that just goes to the larger piece in the report about patient safety and the transparency of the errors that happen when the incorrect information is shared.

Carolyn Petersen

Okay. Thanks, Alexis.

Steve Posnack

So, real quick, I want to add to that. I would also say Alexis, do you also see a need to talk about consent for research and also for clinical operations? Because there's a distinct difference between the two in the way they are governed, and then particularly, it's consent around any kind of mental health status and those sorts of things. So, I think you're right about them, I just want to make sure I break it down further, is that you're talking about that granularity, correct?

Alexis Snyder

Both, and/or all. There's just not a clear consent process. Many times, you're just asked to just keep signing, and you have no idea which piece.

Carolyn Petersen

Okay. Thank you. Cynthia, and then Terry.

Cynthia Fisher

Thank you for that excellent point about the consent process. I would reiterate as well and add on that often times, the electronic health record on urgent care or the outpatient and even inpatient care, it is simply a signature line. Nothing is even given to the patient to read. They don't know what they are consenting to. And then on the financial side, Andrew and I spoke about this last year. It is almost appalling that a student can have a health insurance plan at a university which they have to have, and then the family health plan, and then on top of it just to get care, I know hospital systems in Boston require both parents' name, address, Social Security number, and private financial information, as well as credit card, on top of two insurance plans before they can receive urgent care. And they will be denied care if that field is not completed in the EHR system.

So, I find it kind of crazy that if we don't want a unique identifier for the patient, and yet we go get very confidential information required from both biological parents and legal guardians. But that said, I would like to also focus on Andrew's comment regarding traceability and choice and control. So, patients actually – and I think the administration, Secretary Azar, and Dr. Rucker at ONC – because I think there's been a real emphasis and you all have moved mountains to actually put the patient first. I applaud the efforts of the administration and the ONC to do that. And here, I think as we move forward in this report, I think we can go much further to put the patients not only first but in control. They actually want to be in control.

So, Ken, to your point about the confidential information of the patient, for instance if they have HIV tests, I think that we are hearing very clearly from patients that they are really frustrated about being paternalistically treated by the healthcare system and they instead want the ability to have access to the information, to get the information, and then be in the driver seat of control, that they themselves be able to determine what they want kept confidential and what they want shared. And what they want in other innovative applications, not just within the portal or within the EHR vendors' API. They want to be able to be in the driver seat and in control, and they want to be able to share their data with caregivers, and they want to be able to use apps that will be able to let them share with other parents that will be taking care of their children on a go away weekend and then be able to time out that access to information. But they absolutely need it in their hands.

And they also share with us that without this control and without this choice, they are spending an inordinate amount of time that isn't even counted here financially in our nearly 20% GDP healthcare budget, which is by the way, one working day a week, each of us, American citizens who are working spend just to pay for healthcare. So, on top of that, getting access to the records and trying to navigate the system or even access to care, they are not in the driver's seat today and they want to be in the driver's seat. And that confidentiality and determinate, they are asking they get to choose. And also, to your point, which is very important, want to opt into research and know what that research is, and know the provenance also of all the marketing and remarketing of their data, whether it's de-identified or re-identified. They want to be able to be in control to shut that off or be able to opt in. So, I think as we move forward we need to think about empowering the patient to have choices and be in control and actually be informed. Thanks.

Carolyn Petersen

Thanks, Cynthia. Terry?

Terrence O'Malley

Yes, to continue the consent theme, I suspect you're going to need a consent task force to handle this, because it is so complicated. Cynthia raised some really good points, and it gets even more complicated when you think that there is a group of people who want to have control over all of their data, there is a group of people who don't know what their data are and don't know what control means, and you're going to have to deal with a spectrum of interest and engagement in that. That is one challenge. It's a heterogeneous group who's looking for data. And other pieces are the challenge of integrating research consent with this now gets thrown in the mix, because of re-identifying de-identified data. So, that just adds another area of complexity, and it makes me begin to think whether there needs to be a basic consent form that everyone agrees to that says – how you get to that consensus of a basic consent form is, I don't know. But it's a process we should look at I think.

And at least have a baseline to start. And then you can change your consent anyway you want, but these protect people who are not going to read consents. I think that's one of our challenges. Big challenge, but it's one that's worth doing. Particularly because most folks don't know what consent means. And if they don't understand it, there's certainly no way of enforcing it. And then, once you get the consent form down for sharing information, we've got another level of consent that has to be put

in, and that's consent for treatment. And that is just another layer of complexity that rests on the original consent, I think. So, good luck.

Carolyn Petersen

Thank you.

Terrence O'Malley

And it is a great standing report.

Lauren Richie

Carolyn, if I may just quickly. So, we were scheduled for a break, but this is an important discussion. So, if you need to step away, feel free to do so. But we need to honor and acknowledge the public comment period that we have scheduled for 11:30 a.m.

Carolyn Petersen

We will do that. I see that we have some individuals who have not yet spoken, and also some who have previously. So, I am going to work my way through the individuals who have not yet spoken and go to the HITAC members on the phone. And if we have time, we will circle back for a second round of comments by those who already have. So, let's go to Arien and then Jim.

Arien Malec

Thank you. I just wanted to double down on the importance of the need to segment data, but also underscore Steve Posnack's comments that with respect to patient access, patients are the ones who are in control and not the health system or provider organizations to the extent that we explore standards for scoping of data. It's an important policy perspective that the patient, with respect to patient access, be the one to control the scope and not the provider health system.

Carolyn Petersen

Okay, thanks, Arien. Jim.

Jim Jirjis

Yeah, I wanted to lend support again for the sub-segmentation of information. And it kinda gets to what Clem, you said, and others, is that some of the issues we are challenged with are the issue of liability. When all somebody needs is the cholesterol and we send everything, there's liability. The receiving end also has liability in what they do with it, not to mention the burden of the receiver in understanding how to integrate and get through that tsunami of information. From a privacy perspective for patients, they'll get the right size CCD we used to call it. Now, I think it's sub-segmentation. If on the sending side, on the patient management side, and on the receiving side, we had a framework for how we allow public reporting, the right individuals in the right place in the workflow to select what the appropriate subsegment is, I think that would address a number of challenges around provider burden, patient privacy risk, liability, and internalizing external data. So, I wanted to lend support that we really go deep in that area.

Carolyn Petersen

Thank you. Denise?

Denise Webb

Thank you. I just wanted to add two Les's comments about the traceability in our report and suggest an easy way to deal with that might be to add a traceability matrix in the appendix where you can actually list our committees with URLs, as far as our recommendations, and then trace it to the individual areas within the report. And I think it would make our report much easier to use and to track going forward if we numbered the items in the report. At least the recommendations on pages 39 through 44. These areas in the recommendations. There's no numbering right now, so it's hard to have any traceability.

Carolyn Petersen

Okay. We can do that when we have the final text. Then we'll know how to number that. Thank you. Christina, I saw that your card was up earlier, did you have a comment?

Christina Caraballo

I was just going to follow up on Andy's comment on the third-party apps. I think this is another great opportunity for that patient facing QHIN. It'll be a governance model for third-party apps and enable us to create an app marketplace where patients can actually come in and choose an app of their choice. Thank you.

Carolyn Petersen

Great, thank you. Do we have any comments from HITAC members on the phone?

Ram Sriram

Hello?

Carolyn Petersen

Yes.

Ram Sriram

This is Ram here. The only issue that I have is the patient demographics. Sometimes depending on where they are from, like for example in underprivileged neighborhoods, they don't know what to do with the patient record, how to access it, and there's a fundamental problem in that. A lot of people who actually use iPhones and things have it but have no clue what to do with it in terms of accessing records and things. They don't even understand that. So, we have a whole segment of the population of underprivileged people who are not very computer savvy. So, I don't know how to deal with them. Are there any provisions for them? And in fact, even the doctors who treating these patients, they have a problem, too, because they think that the criteria for them is that the patient has to access the portal, but the patient doesn't access the portal at all. Because the patient has no means to access the portal.

Carolyn Petersen

All right, thank you. Are there other comments on the phone from HITAC members? Well, I want to thank everyone again for your interest. I'm sorry, given the time situation I think we're going to go without a second round of comments from HITAC members. We are now at 11:00 a.m., and we have a presentation from Dr. Thomas Mason and Alix Goss on Intersection of Clinical and Administrative Data

Standards Discussion and Next Steps at 11:05 a.m., so I want to thank you again for your efforts in reading the report. I encourage you to send us any follow-up comments in writing by the 21st, and we will take a five-minute break. Thank you.

[Event Break] (01:27:50 - 01:29:30)

Lauren Richie

Okay, everyone. We will get started here in another 30 seconds. Okay, everyone, if we could start to take our seats please. Thank you, everyone. We are going to go ahead and get started. If we could start to take our seats please, thank you. This isn't working. Everyone, if we could take our seats please, and start to wrap up our conversations, thank you. We are going to try to get back on track on our agenda. Thank you. I appreciate the flexibility with just a quick break. We are trying to get back on track here. All right.

Carolyn Petersen

And with that, we will move into the next item on today's agenda, with the presentation on the Intersection of Clinical and Administrative Data Standards. We have with us today Dr. Thomas Mason from ONC and Alix Goss, the cochair of the Standards Subcommittee with the National Committee on Vital and Health Statistics. The floor is yours.

Intersection of Clinical and Administrative Data Standards Discussion and Next Steps (0:01:30)

Thomas Mason

Thank you. I wanted to start by thanking you for allowing us to talk about the work that we are doing, focused on the intersection of clinical and administrative data standards. I'm Dr. Thomas Mason, an internist at ONC, and have been working closely with Dr. Andy Gettinger, our Chief Clinical Officer, on work required by the 21st Century Cures Act. The Cures Act directed HHS to explore how to reduce regulatory and administrative burdens related to the use of electronic health records. To inform this work, ONC partnered with CMS and other key stakeholders and went through a series of listening sessions to gather feedback. From our outreach, we heard from the clinician community that excessive documentation within the electronic health record, prior authorization, lack of interoperability, and issues related to usability were the top burdens that we heard from the clinician community.

Data from a 2018 AMA survey of 1,000 physicians showed that practices are spending an average of two days or 15 hours, each week to complete prior authorizations. And we have heard loud and clear that this is an area that we should be thinking about, what are the technical barriers, what are the policy and regulatory barriers that we need to be thinking about. And as we started to explore these challenges, we were really thinking about fully automating prior authorization within the electronic health record workflow, and we found that prior authorizations and the issues there really are the symptoms of a much larger problem. One key data point to illustrate this is as of 2018 only 12% of the healthcare industry was using the national adapted electronic prior authorization standard, while other administrative transactions were in 80% to 90% adoption rate.

To give some historic context, in the late 1990s the administrative simplification provisions of HIPAA were really an initial starting point to focus on standardizing transactions electronically in order to improve the efficiency and effectiveness of healthcare, while at that point clinical data was largely still paper-based. Over the past decade we have seen tremendous successes in the adoption of electronic health records, and the advancement of clinical data standards for capturing and transmitting health information, but currently we are going through a change for how healthcare is paid for and what we expect of the healthcare system. And as we transition from fee-for-service to value-based care, we have administrative standards dating back to the early 2000s, and we have EHR capabilities, and what we are running into now is a lack of harmonization of the clinical and administrative data standards to which is creating burden.

Clinical data and financial data exist in separate information workflows and have entirely different electronic standards for transmission, processing, and storage. This is one of the underlying root causes of burden related to the prior authorizations, as well as having price transparency at the point of care. Listed here are a few of the key ecosystem burdens we have heard as far as inefficient workflows, how that impacts patient outcomes, the time-consuming process of discovering payor-specific requirements, technical barriers related to vendor support. And I think it's critical to tie all of this back to the impact patients and the impact on patient safety. The same AMA survey that I referenced showed that 91% of physicians reported that care delays are associated with prior authorizations. The 28 reported that prior authorizations had led to serious adverse events for patients in their care. And the evolving landscape of policy really encourages the integration of data and exchange of data to reduce burden.

It is also of note that the 21st Century Cures Act calls out the importance of the collaboration of ONC, the HITAC, with NCVHS to consider areas where we can collaborate to help further development of standard policy. Back in March, as many of you remember, we had a hearing to look at the prior authorization landscape. What are the issues, challenges, aired solutions that were promising, and ONC and NCVHS collaborated in that hearing? Since that point, we have continued our partnership and collaboration with ONC staff and NCVHS, to explore what should we be thinking about in terms of helping to solve the issues and challenges related to the distinct separation between clinical and financial data.

As a result, today we will be announcing a new task force focusing on a vision to support the convergence of clinical and administrative data to improve data interoperability to support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency furthering the implementation of "record once and reuse." The overarching charge, and this is an initial charge, is to produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision. And at this point, I will pass it over to Alix to talk about NCVHS, what NCVHS does, and how it is important for us to really collaborate on this topic to take advantage of the advances we are seeing in the technology used to deliver healthcare.

Alix Goss

Thank you, Tom. This is a tremendous opportunity and I think it's an important point in time, where federal advisory committees are really starting to identify a concrete activity that can help us advance the clinical and administrative data convergence. It is something we have been looking at within the National Committee on Vital Health Statistics or NCVHS for a couple of years. So, first, by way of sort of background, let me just make sure that folks are familiar with what NCVHS is and what role we play in the healthcare ecosystem. As a federal advisory committee with over 70 years of advisement to the Secretary of HHS, we focus on health information policy data and standards. We do have also some obligations related to HIPAA in that we need to report on HIPAA to Congress on a regular basis. We have a subcommittee that is very focused on the administrative simplification provisions of HIPAA, but also beyond that, we have responsibilities under the Affordable Care Act and MMA.

More specifically to the discussion about the HIPAA standards and the convergence aspect, we as NCVHS are the critical gating step for private sector standards advancements and recommendations for national standards in that we provide the forum for evaluating those standards and then making the recommendations to the Secretary of HHS to adopt or upgrade standards, operating rules, vocabularies, terminologies, and identifiers. This role is very important in that we provide input from the industry and standards development activities into the regulatory authorities. Let me segue now to talk a little bit about how we get those regulations, because it is not centralized in its current form, and the rulemaking authorities are segregated often by program areas. The next two slides are going to give you a thumbnail sketch view into the landscape of promulgating regulations.

In 1996, the HIPAA law was passed. And to the regulatory framework necessary to fulfill the law, the Department of Health and Human Services delegated the responsibility to what was known as the Office of HIPAA Standards. That is currently known within CMS's world as the Division of National Standards or DNS. In contrast, the EHR standards and certification-related standards are within the authority of ONC, as you all know too well. Sometimes, multiple programs are involved in advancing regulations to establish policy and standards. For instance, related to HL7's adoption of FHIR, both CMS and ONC proposed regulations in 2019.

MMA, or the Medicare Prescription Drug Improvement and Modernization Act of 2003, created the Optional Prescription Drug Benefit Program – Part D as we know it – which went into effect in 2006. Regulatory authorities for that sits with CMS, the payor. And just keep in mind that CMS the payor and CMS the Division of National Standards, do have a long-standing firewall between them. Aside from the insurance aspects for drugs, the Drug Enforcement Agency holds the regulatory role for e-prescribing of controlled substances. And they sit within the department of justice. For HIPAA-covered entities, DEA have provided the rules of the road for other pharmacy standards by the regulations promulgated by DNS.

So, in summary, most but not all of the responsibility for proposing and adopting and administering clinical standards lies within the program areas of the Department of Health and Human Services. It is critical to understand that our work is infused with the guidance that comes out of our respective federal advisory committees and is critical infusion point or funneling point. The two federal advisory committees have the ability to shape the trajectory of the convergence of administrative and clinical standards, with prior authorization as a focal point.

To that end, let's take a bit of a deeper dive into what is prior authorization to make sure we have some level across setting standards. It's an administrative process which requires a healthcare provider to request approval from a health plan to provide a medical service, prescription medication, or supply to a patient. The authorization must be obtained in advance of the service or prescription being delivered, and the health plans' purpose for authorizations is to ensure the use of evidence-based guidelines, prevent potential misuse or overuse of services, control costs, and monitor care coordination.

With that in mind, prior authorization from an administrative standard perspective adopted under HIPAA is written into regulations and has specific boundaries in that it is a request for a healthcare provider to a health plan for the review of healthcare to obtain authorization for that care and to request from a healthcare provider to a health plan to obtain authorization for referring an individual to another care provider. It also includes the response from a health plan to a healthcare provider as described above. To provide a little bit more context, standards for prior authorization under HIPAA for medical services currently obligate us to use what is called the 278 when we do electronic exchanges. For pharmacy it's the D.0 Telecommunication standard. Under part D, we have the Script Standard.

There are different methods currently for exchanging electronic prior authorization. I noted the 278, for electronic data interchange as a mandated standard. However, HIPAA also permits the functionality of portals which we used to call direct data entry. Promoting interoperability **[loud feedback]** **[01:49:58]** we often refer to as FHIR. We really need to be mindful that most of the exchanges for prior authorization are done via portals, phone, fax, and mail. We also know that the pharmacy industry is using the SCRIPT standard on a voluntary basis for exchanging information. That context, I'd like to turn it back to Tom to talk about the big questions on the table.

Thomas Mason

Sure. So, thank you, Alix. I just wanted to talk a little bit about the discussions that we had and the questions that we would like to bring forward to the newly formed task force. After the hearing last year, we went down the path of looking into what are the most common high-volume medical service prior authorizations. We found there wasn't a lot of good data out there to target and narrow which medical service prior authorizations we could be thinking about in terms of what is the clinical data that is needed to support the prior authorizations? And is that clinical data accessible or available through the US data for interoperability? These are some of the questions that we posed to the industry. We worked with AHIP and WEDI, CAH, HL7, X12, and a number of surveys went out the end of last year to try to gain industry insight into some of these questions.

So, there is a lot of work that this newly formed task force can build upon. We really hope that there can be consideration of these questions that we have on the slide or other input from the HITAC members or other subject matter experts that can be brought into the task force to help answer some of these questions. This slide just reiterates the vision and overarching charge. We also have specific charges that we have outlined here that I won't read, but we hope that this taskforce will be a collaboration between both NCVHS as well as HITAC and looking forward towards any additional industry subject matter input to fill in the gaps where that may be necessary. We are hoping to have a

public summary of the findings completed no later than September. The findings we also hope to be used by NCVHS, any deliverables, advanced work that NCVHS is also considering. And I will let you talk a little bit, Alix, about that and the work that may be going on in parallel.

Alix Goss

Yeah, thank you, Tom. So NCVHS has its methodologies for advancing our body of work, and we are currently creating a specific project to pick up on some of our earlier work related to prior authorization and the work of convergence that's come out of our predictability roadmap efforts. So, if we're talking about convergence we also need to be thoughtful about how we engage the industry and ask them to give us input, take on pilot projects, and support our broad-based thinking and the details that would actually improve the overall system and reduce burden. So, the NCVHS project related to convergence and prior authorization will look to learn from the task force result and use that as an infusion point into what we might do which could be things like to make recommendations to change the HIPAA standards.

Thomas Mason

So, the last slide, we really wanted to talk about immediate next steps and engage HITAC membership interest, and at this point I will pass it to Lauren Richie to talk more about the process of forming the task force, and next steps from there.

Lauren Richie

Thank you, Tom. So, we certainly have been here before, with standing up a new task force. I know everyone is super excited. So, we have a little bit of time if you have additional clarifying questions or comments for Tom and Alix today. But otherwise, if you're interested in this task force, please let me know. Just send me an email, or you can grab me at some point today during the meeting. And then, we hope to kick off the task force with their first meeting next month sometime. As need be if we need to refine the scope or the charge, define a timeline for the task force. I know some of that information will help you decide. But if you have an immediate interest let me know and we will certainly get back to the full committee with a defined and final timeline for the task force. I see a comment or question from Arien, and then Cynthia?

Arien Malec

Thank you. This is incredibly exciting, and I'm very pleased that ONC and CMS and NCVHS are jointly spinning up this task force. One question I have about the charge is that when we heard from the CMS department or division – I forget the formal name – we heard a perspective that CMS does not have the authority to name different standards for the same transaction sets. So, that seems like some of those policy considerations seem like they should be in the span of the task force. And then, equally, thank you, Alix, for the overview of where standards get done, the rather urgent need for coordination of where standards get done from a policy perspective. So, I just request that some of these policy considerations be part of the formal charge for the task force. We're very excited and thank you.

Thomas Mason

Thanks for that comment, and I'll take that specific question. We work very closely and coordinate very closely with the Division of National Standards, so we will definitely take that back and address that as well.

Cynthia Fisher

Thank you Dr. Mason and Alix. It is very exciting to see this task force come about. Les had a great idea last year about how this could easily be automated in the pre-authorization world, and really put substantial efficiencies into the marketplace. So, I commend ONC for this task force. More often than not, we hear so much about physicians spending unproductive time on the phone trying to get prior auth, and then we also hear substantial complaints about these processes are oftentimes iterative and keep them away from the patient to physician transaction, and they have to hire substantial staff to also administer this as well. And so, to be able to timely provide the digital answer to this is very exciting.

The other substantial problem we hear from patients is also about the harmful delays and gaps to their care in waiting for prior auth. So, even if a drug is way too expensive when they're at the counter, especially the new prescription for types of insulin, when they want to go back to the old drugs, just even getting authorization for new or different drugs or more affordable drugs may leave a two-week gap in what is a critical drug for their care, and a debilitating and unproductive time and lost time at work. So, the costs are beyond what we see from the healthcare system, but they actually domino in many other aspects in that patient's life. So, I commend it.

I would ask one more thing, and that is just a question to you both, is we're getting prior auth, and we're getting it digital, and that's going to the health plan. Isn't there also ability as you approach the standard setting to have the electronic explanation of benefits, the EOB, done at the same time, before we get care within the plan? So, if they're authorized with prior auth, one would think that we could potentially [audio cuts out] organization, or I don't know if it's under your jurisdiction or a separate entity, but that would look at the delivery of that Explanation of Benefit after the prior authorization to the patient so they would know ultimately the price of their care before they get care, and their options with that prior auth. So, I would ask while we're doing this work, why not add that Explanation of Benefit in front of the patient care, rather than the patient getting it weeks later, since it's digital and it's agreed upon anyway through the process.

Carolyn Petersen

Thanks, Cynthia. We appreciate the comment. WE are now a couple of minutes across the order for our public comment period, so we are going to stop the discussion for a moment and go to public comment, and we will come back to your questions after we've done that.

Lauren Richie

Thanks Carolyn. At this point, we open it up to members of the public that would like to provide comment on matters we've discussed to this point. So, I will first ask if Dr. Mason and Alix may vacate the presenter table. If we have any members of the public that are in the room, we would like to start here first. Please feel free to come to the presenter table and state your name. Okay. Seeing none in the room, operator, can we please open the public line for comment?

Public Comment (01:55:00)

Operator

Yes. If you would like to make a public comment, please press "*1" on the telephone keypad. A confirmation tone will indicate your line is in the queue. You may press "*2" if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment while we poll for questions. There are no comments at this time.

Carolyn Petersen

Okay. Lets go back to questions for Dr. Mason and Alix Goss, if you'd like to sit back at the speakers' table, please. Thank you. I'll hand it back to Lauren for facilitating the discussion.

Thomas Mason

Just wanted to make a comment on the last question. I couldn't agree more about using this as an opportunity to improve price transparency at the point of care so that we can get that information from the payor to the clinician to be able to have a discussion with the patient in front of them in terms of not only is prior authorization required for this particular medication or medical service, but also to have discussion around price information that's available at the specific member level through the plan. Dr. Rucker and I, we have been working very closely with Dr. Rucker on this, and it's really one of the underlying issues, this separation of clinical and administrative, that leads to issues around cost and price transparency, prior authorization, quality measurement. All of these things can be improved with this convergence and recommendations on how to best leverage modern standards to bring together the administrative, financial, and clinical data at the point of care, or through smart phones or other devices.

Lauren Richie

Thanks. Clem was next, and then Alexis.

Clem McDonald

This is a very complex space, and I don't think we can assume that the computer magic can solve all of it and think about some of the issues. So, specifically, one overwhelmed with dumb forms coming up on your computer. And in fact, a lot of times the data that it wants you don't have, so there's still a delay that you're probably going to get. Secondly is there's a lot of these things, at least I perceived, were just nuisances to reduce this thing to save money on the part of someone, they weren't related to patient safety or any other kind of dimensions. I think we should just try to find a way to just rip those off, get rid of them. And the third, I have a specific example. Some of the devices – the wheelchair.

I had an example of the electric wheelchair. Two. Where the \$6,000.00 wheelchairs, the patients got it completely free. In both cases, the physical therapy said it wasn't necessary, our consultant which was required. Both cases, they found some physical therapy group that signed off on it, and both cases, they never used it. They sat in a room and said, "Oh, it's too wobbly, I'd rather **[audio cuts out]**." In one case, the son was on social security benefits because he was there to push the father around. So, I

think there's a well-known case of some extreme things. We could take cases, those should be either skin in the game or some darn thing to make it, "Oh, yeah, free electric wheelchair. That'll be fun." But that was a \$6 billion a year or \$8 billion expense. I don't know if it's still cooking.

They're wonderful for people who need them, no question about it. Anyway, so I think we've gotta deal with many kinds of cases, try to just get rid of a lot of this stuff, which is just a pain in the butt. The other issue, it may tie also to knowledge about pricing. So, we did a study of Medicare data, and these new diabetes drugs that look really, really good are hardly used by physicians, and our suspicion is because their reported price is \$10,000.00 a year. Medicare, they're paying \$500.00 a year in actual out of pocket costs. So, this is another argument for getting the pricing and the right cost information back to everybody pretty fast.

Lauren Richie

Thank you, Clem. Alexis?

Alexis Snyder

I wanted to point out some cases and the importance of not losing sight of where the burden is, not only for the physicians, but for the patients in the prior authorization process. So, often, even through an electronic process, once it's coming back it's either not seamlessly entered across systems and patients don't have access to the actual numbers, so they show up at the pharmacy and the pharmacist says, "You need a prior." This is just one example. "Prior approval." It's, "Oh, I got a prior approval, my physician's office told me it was all set and ready to go." "Well, we don't have the number." So, there's this access issue again with patients having the access to those prior authorizations numbers. Especially when there's a denial, or even when there's an approval, of the patient being stuck between the provider's office and the insurer in that process.

And you really can't get information on either end, and you're this person who's stuck in the middle, provider is often saying, "Well, this is what came back. Now, you deal with it." And then, the patient is trying to deal with it, and then the insurance company is saying, "Well, your provider needs to call us." So, there needs to be a more seamless process there as well, and I would echo what Cynthia was saying as far as patient safety concerns, because people are going sometimes months and years without things that they need, and on top of that I would point out because of the physician and staff burden process in getting prior approvals that often, providers are not prescribing things that they would, and using other drugs, other procedures, other prescriptions, because they know that this is going to take a lot of times and a lot of burden, and it'll be easier if we try this first, because getting the approval is going to be very near impossible.

And then, the other piece that I just had a question more for you was I would love to hear more about the "record once and reuse" process that you were recommending.

Thomas Mason

Sure. That process really was a working theme, and the feedback we received back from the clinician community about the burden related to EHR use, and that there would be multiple instances of recording the same information over and over, looking for information within the chart, and having to duplicate that information. But really, it's the concept of recording once and allowing that information

to be used for a variety of purposes where we can think through the workflow and the unnecessary standards and policies to enable that system where we can have that full automation and best use of the technology if certain data elements for a particular prior authorization are contained within the electronic health record. The description that you gave perfection illustrates how can we seamlessly transmit that information to the payor and have seamlessly prior authorization number decline or approval without special effort on the part of either the clinician or their staff.

I think it's also important to note that there has been a lot of work in this area, and a lot of coordination between HL7, X12, the Da Vinci Project is doing a lot of work in this area and has a number of use cases that are looking to automate within the EHR workflow specific types of prior authorizations that they've started to develop implementation guides around. But I don't know, Alix, if you wanted to add to that?

Alix Goss

Yeah, I'll round out the information taking off my NCVHS hat and putting on the fact that I'm a consultant and I'm supporting the Da Vinci Project. I think there's a really fascinating opportunity in front of us to create a much more effective clinical dialogue between the EHR, the provider, and the payor systems and their methodologies with the patient sitting there with the ability to say, "Do I have a coverage requirement? What do I need to give you to fill out that request for prior authorization and be able to do that in a much more real-time effective integration with the EHRs, with data we know does exist as far as data elements' functionality within the EHRs, and with the data captured by the clinician? Ultimately, creating a better framework using APIs, we can help that real-time experience of the patient be improved, but we do have a long journey to figure out the workflow and how we're going to pivot our policy and our national standards, putting back my NCVHS hat on, to really get to that seamless process that we're looking for.

Lauren Richie

I think we'll try to wrap up with these last few comments, starting with Les and then Denise.

Les Lenert

I just wanted to echo Cynthia's comments about getting patients in the middle of this process and helping them to own it as part of the standard. That it's a travesty that this is only a communication between the doctor and the payor. The alternatives may not have been made available to the patient at some point, that the insurance company would pay for, that physicians or other healthcare providers are often biased in what they present based on the types of procedures that they offer, and that there's not really an explicit way to include the patient in this discussion, and the standards need to be rewritten.

The second comment I'd like to make is that the basis of this whole process of prior authorization is extraordinarily weak, and that this represent from a systems view one entity optimizing the process for their financial gain, but not looking at the overall cost from the system. So, there's almost no evidence that shows that when you go through the cost of the provider to the patient I, and to the employer for the impact of prior authorization on the health of the person at a cost to the system, that everybody is benefiting and that unless we can develop an evidence basis for whether prior authorization actually

works across the entire spectrum of parties that are here. So, it might save money for the insurance company, but it took a day for the provider to do it.

Do we improve the efficiency of the overall system, or do we just balance where the burdens are? If it takes two days or two months out of a patient's life and out of an employer's, and that we misburden the system so that there's not enough evidence, and that enclosing these kinds of rules should only happen when there's an adequate evidence basis for the rule.

Denise Webb

Denise Webb. I would suggest on the overarching charge possibly broadening the focus beyond prior authorization, particularly on that idea of "record once and reuse," or at least not preclude your ability to address other use cases. So, I understand the focus and the priority and probably the most complexity is around prior authorization. There's certainly benefits when it comes to care management, care coordination. I mean, particularly in the health networks where they have the provider network and the health plan. And so, I think there's certainly a lot of benefit that goes way beyond prior authorization that might have even greater impact in some respects.

Lauren Richie

Thank you. I think I see Jim, and then Cynthia and then Ken.

Jim Jirjis

I just wanted to comment that we have some of these health claims that are coming to us saying, "Hey, let's do this mediation thing." And what they talked about is 30% of the number that one large organization said could be adjudicated immediately with the information at hand. And so, the phased approach is 1.) let's show in the prescribing tool what the cost out of pocket to patient is, 2.) things that can be automatically adjudicated, let's go ahead and do that, because you've just removed 30%. And then, for the things that are more complicated, well, that's the deeper discussion. And one comment would be are there things we can do that doesn't make a perfect enemy of getting rid of that. If you look at what's happening, it's to save on premiums. We're looking at operational inefficiency for the doctor, the patient, and don't forget the pharmacy. Right?

There's enormous cost to this, and if there's a subset that's just, "Hey, give us the right data and we'll approve it," that's fine. But back to Arien's question about when there's an ulterior vested business interest to actually have delay so the doctor may not actually use the expensive medicine because it's too burdensome? We're not gonna naturally solve that one. Case in point, sometimes getting prior authorization for medical services doesn't always mean the payment occurs later. Right? So, the admonition here is to say it seems like for win-win-win-win, patient, pharmacy, doctor, plan administrator costs, there's a subset of things that we can define in those three realms, through medical equipment, medical services, and meds, maybe starting meds, that you can just tackle and knock off, and then figure out the more complex ones.

For example, if more dialogue and data has to happen, some hospital services have social workers or case managers that actually are working that. Some don't. Right? That's complex workflow. In the clinic, my nurses when I was a primary care doc, the bane of their existence was the 60 prior

authorization forms they had to fax back and forth, right? Most of them about meds. So, I say all that to say that there's complexity to things that are more than just is the data available. We should separate that and perhaps consider phasing things that we can do so that we can deliver value to a variety of stakeholders while sidestepping some of the vested business issues.

Cynthia Fisher

Dr. Mason and Alix, I think it may be worthy to follow-up on Les's point of really looking at are there any existing studies that really show the cost of this whole prior authorization system, and where it's worthy to say, "Where can we eliminate it and allow for efficiencies, and allow for more patient-physician time?" And some of the examples I can give you, I had two pediatric neurologists approach patient rights advocates recently that shared in the adjudication in the authorization at their level for surgery from a peer to peer review, and one case was brought forward to us where the individual reviewing for the plan, the highest level of education was a G.E.D. And yet, they're on the peer to peer review. And the other pediatric neurologist brought forth when it was pushed up the ladder in the chain on another situation on another case, it was **[audio cuts out]** actually determining their neurosurgery plan.

So, when you have a specialty that's so narrow such as pediatric neurology – I think what, there's 200 in the country or something at the children's hospitals? So, when you have that type of specialty and the delays in the care and the ability, one has to question when does the doctor know best with the authorization to what is really a medical necessity? So, I add that to the equation with other issues that I think go back to Les's point of where does this really play out where we stop to use common sense?

And we have another case of another individual reporting – and we've seen this over and over again – where the new modality of a proton beam or radiation treatment is actually less expensive than the care that's authorized, and the patient can't get coverage for this new modality even though it's less expensive. And so, the providers are asking these cancer patients who are covered, who are working, who have plans, to become beggars. And because they want to have the best of care and the best chance of survival, they start their GoFundMe pages. And hospitals have entire staff to help them figure out how to beg their family and friends for their survival. That is where we are in this process, that insurers and plans are not covering, even when they can save tens of thousands of dollars, even hundreds of thousands of dollars, to the employer and to the patient.

And so, I think we really need to look at this process, at what can we eliminate, what can we make efficient, and where can we rely on common sense?

Lauren Richie

Thank you, Cynthia. I think Ken was next.

Ken Kawamoto

I'll be brief. So, the idea that there's a common infrastructure that crosses a lot of use cases really resonates with me. I think this will be also one of these cases where the hardest part is are the data specified in a consistent way across systems? And if you take some examples for something like home oxygen, well there may be a profile for determining how you say, "This is the patient's pulse ox on this

many liters of oxygen," while what may happen in a real system is that the number of years of oxygen may just be in the comments, for example. Right? So, these are the kinds of things, or even if it's labs, that we know for a fact there's a fair amount of labs that are not properly coded, which means it's just not going to be correct in the initial adjudication.

My suggestion is we don't wanna boil the ocean, so focusing first with things that are easy to pull, like medications are pretty consistently encoded, conditions are, etc. But as we get into these areas where there is need to say, "Hey, we need to make sure the lab are properly mapped, or our observations are otherwise properly mapped," to really take that as an opportunity to say, "Punch this through, for example, USCDI, and say pulse ox and the number of liters somebody's on. We're going to figure out how that's actually consistently encoded across systems and map." And start with some of those baby steps. But I think what's typically happened here and which keeps happening is we say, "Well, we can't possibly do that for every single thing in the universe, so we're never gonna even start." I think we should just take a few of these that are high priority and just figure out how to actually do that. Thanks.

Lauren Richie

Thanks. Alexis and then Jonathan.

Alexis Snyder

Before my initial comment, just with a reaction to what Ken had just said, the only caution I would have with that is that there's a lot of grey areas, especially in rare disease and rare drugs. And so, I think trying to find a seamless way to go across the easiest first, there's a lot of grey area rather than just the traditional evidence base, certainly in rare disease case and rare drugs. The comment that I wanted to make before in reference to asking more about the "record once and reuse," I would just caution you that perhaps a red flag area for the administrative staff that are reusing the forms and trying to pull what they can from the EHR, and making sure that the information is actually correct and didn't need to get updated, particularly in the use of getting a PA for drug changes. And so, often, I think the information is just pulled again, and you may be getting more denials and running into more burden.

And then, I think another piece of the burden, I per se don't have experience with the physicians actually filling out the PAs, it's the administrative and front-line staff that are doing that, and a lot of them are not trained well to fill them out or realize the emphasis and the importance, and I think a lot of people don't know how to go about doing it, and haven't been trained correctly. And going to that patient safety issue of waiting for what you need, because the right person doesn't have the right training to get that PA pushed through, or deal with the electronic systems. And then, lastly, something that I wanted to mention before as far as using the electronic health record to lessen some of the burden, reminders for when the PAs are expired and need to be renewed and getting that out to the provider and the patient caregivers.

Right now, you basically have to tick your calendar and hope you mark it right and remember and remember to make sure that you call the provider three months ahead of time, so they have that

three-month window to try to get something approved. And so, I think the EHRs can be really helpful in that process.

Jonathan Nebeker

Okay. So, I appreciate the comments and response. The title of this workgroup is powerful. The specific immediate use case is powerful and needed and focus is required. However, some of the other people here took the title to be an opportunity to more broaden this very important issue. Resolution of these conflicts has an opportunity to decrease perversity in better aligning **[audio cuts out]** of care.

Currently, we have two sets of books, one for the payors and then the other's for the clinicians, and the books are optimized for each of those different purposes. And you can imagine all the diversities that arise from that. Even within the VA benefit system, we have separate codes for service-connected disability that don't match the VA codes, as James and others are aware. This is not in a unique area, and very powerful.

Second, CMS with its two types of initiatives generated some discussion on this issue. They are now making APIs available to their administrative data, but with the intention for clinical use. And there's multiple sets of APIs that CMS is now providing on Medicare data. I think it's gonna be dynamite. I congratulate the administration. But there was discussion around this at the announcement at the White House, that there's an opportunity again for convergence of administrative and clinical data, especially around the billing data. However, there may also be unintended consequences. And so, I think some of those unintended consequences need to be considered.

Finally, I'd like to rephrase, make a friendly amendment to Ken Kawamoto's suggestion about other topics. The focus is important, but I think there's an opportunity here for a prioritized bag of issues to address that various stakeholders may be able to move the needle on, and so I hope that that can be part of this task force's scope of work.

Lauren Richie

Thank you. And we will give the last word to Les before we break for lunch.

Les Lenert

We can focus on the data transmission or the extraction from the EHR in the transmission, but there also needs to be a standard for the analysis of the data, or at least a transparency of the analysis of the data at the insurer level. Why is that payors can essentially be a black box that sets whatever rules that they want without exposing that in some way? If they used a standardized approach for describing their rules, then all of this would be transparent. So, the idea is that every step of this process needs to be transparent in that we really need to think about how we put the computation of the provider's side at the back end into the process, and to make that as transparent as possible. Providers wouldn't just publish all the rules that they use each year, having written them in some guideline language, and make that available to people based on the processes.

No, it's the fact that those are not transparent, and we haven't developed that standard for how providers can use data to make an adjudication decision. Or if the standard is really people, which I think is probably what it should be, then how do we replicate people making that decision?

Lauren Richie

Thank you. And with that, we will break for lunch. Again, thanks for the flexibility in shortening that, but we do wanna give you at least a full hour. We will return promptly at 1:00 p.m. for the Federal Health IT Education Strategic Plan Overview. Thank you, everyone.

Break for Lunch

2020-2025 Federal Health IT Strategic Plan Overview (02:25:47)

Lauren Richie

Okay. Thanks everyone for coming back on time. We are going to get started.

Carolyn Petersen

All right, friends. Let's regain our seats and get ready for our afternoons presentation. Let us reconvene for the afternoon portion of the meeting. The first item this afternoon we have on our agenda is an overview of the 2020-2025 Federal Health IT Strategic Plan. We have Seth Pazinski, Director of the Division of Strategic Planning and Coordination at ONC, and Peter Karras, the Lead in the Federal Health IT Strategic Plan, also from ONC. The floor is yours.

Seth Pazinski

All right. Thank you, everyone, for the chance to present and provide an overview of the draft 2020-2025 Federal Health IT Strategic Plan which HHS released for a 60-day public comment period this morning. The public comment period ends on March 18th, and the draft outlines Federal Health IT goals and objectives, to ensure that individuals have access to their health information so that they can manage their health and shop for care. I'm Seth Pazinski, the Strategic Planning and Coordination Division Director at ONC. My role is to quietly sit over at the ONC table over there, so I'm happy to get a chance to present today. Also here is my colleague Peter Karras. So, we're going to give you an overview of the plan. So, we started today with HITAC focused on the year ahead, and we'll continue the theme of future-looking agenda items with a look at the plan.

For purposes of HITAC engagement, we want to make sure that we get your feedback on the draft plan. So, today is just really intended to be an overview, so we'll provide some context on why we're updating the plan, who is involved in helping to develop it, as well as what you can expect when you take a look at it. So, we recognize the plan came out this morning, so we're not asking for any immediate feedback today. Certainly, we'll take any if you have any initial thoughts, but we'll be on the agenda again for the February 19th meeting, so we have just two asks of you between now and the February 19th meeting: 1.) if you could take a look at the plan and come prepared to share your thoughts, comments, and questions about it at our next HITAC meeting, and also we please encourage you to share with your professional networks and colleagues so that we can get their feedback as well through HealthIT.gov, again with that March 18th deadline for public comments.

And the plan is only 20 pages of content, so I'm gonna say confidently it's probably the shortest thing ONC will ask you to take a look at this year. So, let's start with the why. So, why are we updating the plan? 1.) We're statutorily required to maintain the Federal Health IT Strategy. The current plan runs

through 2020, so as we celebrate the new year, it is time to update our plan. Also, our Health IT environments continue to evolve, and there is also the 21st Century Cures Act, which if there's any group who understands the impact of the Cures Act on the Federal Health IT Strategy, it's this group that provided ONC with 170+ recommendations related to HITAC over the past year. And lastly, federal agencies, just like the rest of the healthcare industry, are increasingly relying on electronic access, exchange, and use of data to fulfill their mission.

So, in addition to the Cures Act, there are a few key sources that are helping us develop the plan. So, one is we're collaborating with our federal partners, so we convene a series of working sessions with federal agencies over the summer and into the early fall, as well as iterating on draft documents. Second, we looked at the feedback that HITAC has provided, and in particular, the HITAC Annual Report for FY'18. So, I just wanna pause and really emphasize, that is a really great resource for us as a federal agency, both in looking at the federal strategy and also looking at ONC's federal coordination activities. So, we certainly will look at the FY'19 plan as that gets finalized, which will be actually perfect timing as we look to wrap up public comment and consider the public comments over this coming summer. So, we'll look to build off of that feedback.

I really do wanna also thank specifically the Annual Report Work Group for the draft FY'19 report that we talked about this morning. Really helpful to have the timeframes laid out there. It's really great input for us as we look at updating our Federal Health IT Strategy. So, again, we'll have the opportunity to come back in February 19th to get your public comments, and we'll also be taking any public comments that come to us between now and March 18th. So, these are some of the federal agencies that participated over the summer and fall to help inform the development of the strategic plan. There's about 25 federal organizations in all, including the various subcomponents of some of these different departments. Federal agencies play a wide role with regards to healthcare and Health IT, so purchasers, users, developers of Health IT.

And I do want to emphasize that this is a federal strategy, so not just for ONC but really federal-wide, so it's very broad in its perspective, and these are organizations that both help inform the plan, but that we will be working with and coordinating with to implement key aspects of the plan as we move into implementation. Next slide. So, as far as what are some of the cross-cutting aims of the plan, one was to as I mentioned at the top, ensure that individuals have access to their electronic health information, so that enable them to manage their health and shop for care. Also, create new business models leveraging APIs that benefit individuals and providers. Establishing data sharing practices for the industry, and the last item is from a federal perspective useful for federal agencies as a tool to both prioritize resources and provide us a way to collaborate and focus our collaborations.

So, with all that background and context, these are the four goals that are laid out in the Federal Health IT Strategy. The first, promote health and wellness. The second, enhance the delivery and experience of care. The third, build a secure, data-driven ecosystem to accelerate research and innovation. And the fourth, which is kind of a cross-cutting goal that supports the other three, connect healthcare and health data through an interoperable Health IT infrastructure. So, we really wanted to have an outcomes-driven framework for the plan, and the intent here is really for that fourth goal

about connected healthcare and data supported by IT to support the other three goals, which speak to the different stakeholders that we hope will benefit from a connected health system.

These are some of the key **[audio cuts out]** that we hope will be benefited by a connected health system. This is not meant to be comprehensive, but just going through the goals of the plan. So, for the first goal, it's about individuals and caregivers. Second goal, about providers and payors, and that third goal, about researchers, developers, and innovators and ensuring they have the data they need. And the last piece before I turn it over to Peter Karras to take us through the nuts and bolts of the plan, public comment is the stage that we are in now. Again, that ends on March 18th. Once we get the public comment in, we'll consider that and also re-engage our federal colleagues to develop a final version of the strategic plan which we'll aim to publish over the summer. That final plan will serve as a roadmap for our federal coordination to help agencies prioritize resources and align and coordinate efforts, as well as track progress over time.

And one thing I just wanted to highlight as far as measuring and tracking progress is another statutory requirement that ONC has is to provide an annual update in what's the state of affairs with Health IT and data access, exchange, and use. Our most recent one was published early in 2019, and we're going to use that Annual Report as a key vehicle for measuring progress against this Federal Health IT Strategy moving forward. With that, I'm going to turn it over to Peter Karras to get a sense of the plan components.

Peter Karras

All right. Thanks, Seth. And thank you all for the opportunity to speak on the Federal Health IT Strategic Plan and give a little bit of an overview. So, I'm going to spend some time on the overall structure and content of the plan itself, but before I get into that, I just wanted to kick us off with a couple of key imperatives that ONC had at the onset of developing the Federal Health IT Strategic Plan with our federal partners. And that was first and foremost, we wanted to use plain language. And I know that sounds simple and not necessarily overly complicated, but because of our goal of the strategic plan essentially being a communication tool for how we communicate to the general public how we as the federal government intend to use information and technology to ultimately improve health, we wanted it to be a plan that was easily understood by providers, not just researchers and scientists, not just developers, not just public health professionals, but really mainly the patient.

That's really the center. That's the bullseye. And having a plan that was understood by the patient who does not play in the Health IT space at all other than the fact that they are a recipient of healthcare services in this country was something that was really important to us. And then, the second imperative was to not be text intensive. So, as Seth alluded, if you include the appendices and the references, it's about 28 pages. So, I think it's pretty short for a government document. Hopefully easy to read, easy to see, easy to understand.

All right. So, with that, the way the plan is broken out, it has various sections that we'll go through on this slide and then unpack a little bit as we move forward to the presentation. But it kicks us off with a Letter from the National Coordinator. And that starts off with the fundamental premise and belief that a better health system hinges on access to health information, particularly by the patient. That for the

patient, access to health information is something that benefits patients, and it improves the healthcare system overall. So, patients and individuals, that's the focal point. And that's where it starts. And then, the plan gets into our Federal Health IT Vision and our mission statement. The vision is essentially where we want to go, where we want to be, and the mission statement describes why we exist as an organization, what's our fundamental purpose.

And then, we get into our Health IT principle section, which lists out and outlines our principles, our core values, our beliefs, and really the lens by which we look at implementing this strategy. The introduction section is a narrative that discusses what Health IT is, how it's used, the federal government's role in Health IT, and we didn't want to take anything for granted. This is the plan that we want the general public to understand. We didn't want to assume that everybody knows what Health IT is, and what the federal government's role in Health IT is. So, we wanted to make that clear. And then, we outlined some key bucket challenges, which are challenges and issues we hope that our strategy as we implement can help mitigate and move the needle on. And then, the opportunities of what a future Health IT-enabled digital health system would look like in the future as we implement this plan, and what we can expect.

And then, we get into the strategic framework, which delineates the goals, the objectives, and the strategies by which we move the needle on implementation. Another general point I wanted to offer in the scope of the plan is it's a strategic plan, so by design, **[inaudible]** which kind of identifies when departments develop strategic plans, things to include and how to specify things. With a strategic plan, it's a tool to document what we want, why we want it, and who benefits. It's not going to explain the specifics on the how we are going to get there. That is strategic implementation, and that is going to be this plan serving as an operational tool by which we use to ascertain that progress and the feedback and align it to the plan. So, just as an example, when you see, as Seth alluded to in Goal 4, "Connect Healthcare and Health Data through an Interoperable Health IT Infrastructure," and then an objective is establish transparent expectations for data sharing.

I'm sure Elise would love to see, "Implement TEFCA," right? Like a very ONC-esque program. It's not going to speak to specifically implementing a program that one federal agency or organization is working on doing. It will talk to the construct and the overall function of what TEFCA, as an example, is used to accomplish, to obviously promote and establish a common agreement for sharing information. Same with various other aspects of the plan. So, you won't see implementation of specific programs, rather the function, and then with strategic implementation, we'll use the programs, the activities, that leverage that federal government has to align to the plan.

And then, the next slide is our vision and mission, which we'll unpack. So, our federal Health IT vision, really what we want ultimately is empowered individuals, engaged individuals. Individuals that have access to their health information. We want to couple that with lower costs, deliver high-quality care, and improve individual and population health. That's what we ultimately want, where we want to be in an ideal situation. Our mission goes unchanged. It's why we exist. We improve the health and well-being of individuals and communities, and we want to leverage technology and health information and have that information be accessible where and when it matters most.

The next section is our Federal Health IT Principles. So, not to be overly dramatic, but these are principles, right? They're core values, they're beliefs. And this really helps in the strategic plan with visual linkage controls. It serves, really this list, as a litmus test by which federal organizations will resource and put forth activities. And the idea behind these principles is if it doesn't meet one or more of them, then we're not going to do it. If it doesn't focus on value, if it doesn't put individuals first, if it's an effort that's not building a culture of secure access to health information, if it's not helping to put research into action or encourage innovation and competition, or using funds and resources across government judiciously and being a responsible steward-ambassador, then it's not going to happen and we shouldn't be satisfied with moving things along that don't tie back to our principles and really our core values and beliefs for the strategic plan.

So, it's a good way to kind of assess and use these principles as just a delineation for decision making. So, I was to ask ONC leadership if we can get some ice cream stand or something, it's not going to line up to these principles, so it wouldn't happen.

Challenges in Healthcare. So, these were the big challenges that as we went through our workgroup meetings that we kind of coupled as things that really kind of impact the achievement of the plan's goals and things that we really want to work through to help mitigate. Increase in healthcare spending is one of those challenges. The average rate of inflation is about 2%. Healthcare spending is almost three times that. Expenditures are going up, and you'll have poor health outcomes, and you see the expenditures rising and the cost rising, and it's not necessarily translating to better outcomes. The increasing rates of mental illness and substance disorders. We're seeing that there's an increase in opioid and drug-related deaths, which is something that the administration is taking very seriously, and something that we definitely want to leverage Health IT to help mitigate.

Then there's the access to care. We talked about the spending, and I think we can probably all agree that we have physical access to care, that there is the potential to be priced out of it, and that you may not necessarily be able to afford. So, although there are providers and there are specialists and there are physicians in your network, you might not be able to afford the care, and then what good is access? And then, coupled with that, we want to be able to use information in a very innovative **[audio cuts out]** in order to use information, we want to leverage technology. So, access to technology is also a big issue. About 25% of Americans do not even have access to broadband, which really does limit the progress.

Opportunities in the digital health system. So, this articulate really what from a Congressional perspective, as well as a societal perspective, what we ultimately want from a modern, 21st-Century healthcare system. This is what a digital health system should look like, and these are the things that we should be taking advantage of. We want patient empowerment, and with that comes patient access. A reduction of regulatory and administrative burden. That focuses on providers and gives them the satisfaction they need to really deliver care. Movement to value and increasing the margin between what you're paying for and what you're getting. Achieving interoperability. Privacy of health information, security of health information, and leveraging the new technologies and these new business models that are supported by data and technology to really improve competition and just innovation.

And you'll see this tie back to the Cures Act, as well as what you all see in your priority target areas with HITAC, with the patient access and/or patient empowerment, achieving interoperability, and then the privacy and security target areas.

So, our Goal 1 is promote health and wellness. Now, under the health and wellness, we have a couple of objectives that we want to pursue in order to get to these outcome-based goals. The first objective is improve individual access to health information, and that's improving access to information via mobile apps and other tools and being able to use your smart phone to access your information. And not only that, but we want to promote affordability of that data. So, you're not necessarily as an individual locked into a specific tool or an application, that you're not in that ecosystem. That you can have data liquidity and move that information along.

Advance healthy and safe practices through Health IT at the individual level, where patients can manage their disease. They can use wearable technology to track their exercise and their diet. They can share and compare themselves with others who have similar conditions. And then, at the community level, where we can leverage data to predict the next epidemic. All that factors into advancing healthy and safe practices through Health IT.

The other big thing we heard was the integration of health and human services information. When we did our federal engagement, especially within the department, we have our health arm and then our human services, and at the federal and state level, oftentimes there are an administration of services across health and human services programs, and they're siloed, and the information's not flowing and connecting and integrated. So, that's a big piece that we heard, and the idea is to be able to capture social needs data and social determinants of health data, NCHRs, and create some bidirectional exchange between these two services and functions to really support the whole person.

Goal 2 is enhance the delivery and experience of care, and this focuses on the patient, but it also focuses on the provider. We want the best possible experience for the patient during the point of care and at care, but we want providers to have a renewed sense. We want providers to be able to deliver care with a satisfaction and a sense of fulfilment which was an initiation to why they began practicing in the first place, which is to really help patients and really bring about that healing. And with that, we have four objectives. The first one is ensuring safe and high-quality care, and this is about systematic, targeted care leveraged through things like precision medicine, advanced clinical decision support, using Health IT to better enable safer prescribing practices, having tools and workflow that are intuitive and usable that really benefit providers, as well as looking at quality and being able to not only report against it, but have that circle back and really improve the clinical practice and outcomes. So, it's a two-way street of communication.

And then, another big thing we heard in Objective 2b was fostering competition, transparency, and affordability in healthcare. We want to bring the bargaining power back to the consumer, so they are price-sensitive, there's competition, there's more elasticity, and you're able to use information to shop for care, to manage your health, to understand quality services that are offered up at the front, so you're not surprised later. And then, we heard a little bit about reducing the regulatory and

administrative burden on providers in our Objective 2c. That's streamlining documentation, reducing the time and effort required to record in the EHRs, reducing the time and effort required to report to complete activities such as prior authorizations, reporting to various registries, and then get that renewed satisfaction for providers to give them more time to provide patient care.

And then, the last objective in this goal enable efficient management of resources and a workforce confidently using Health IT. That is something that enables a workforce to leverage intuitive tools to be trained on Health IT, and not have it be a hindrance, but something that can help promote care and align the workflows, and really establish a culture around a fully-equipped team across the care continuum to leverage and use technology and tools that work for them.

Goal 3 is our research goal. This is to advance individual and population, like bulk transfer level of data so that having that data, you can more look at a holistic view of supporting research and analysis across various functions, whether that's claims data and financial data, clinical data, all these things we would like to integrate to help support research and translate that back into practice.

And then, Goal 4 is really the underlying infrastructure by which Goals 1-3 are realized. It's the policy and the technical aspects and components will really help move and progress the other three goals. These are not supposed to be linear; they are all in tandem, and if you'll notice the objectives, Objective 4a: Advance the development and use of Health IT capabilities; Objective 4b: Establish transparent expectations for data sharing; I'm going to jump to 4d, the promoting security of health information that protects patient privacy. Those three things tie in nicely to the priority target areas of interoperability, patient access, and then privacy and security with the respective benchmarks in the initiative that we will use to help as we progress.

Last, I know I'm low on time here. So, questions for consideration when reviewing the plan. Just a couple of things to look at. Obviously, you didn't read the plan, but when you do, just look at challenges and factors that could impact the achievement of the Plan's goals, other opportunities that we can leverage Health IT for consideration in the Plan's strategy, and then look at gaps specifically in that Goal 4 that can limit progress in Goals 1-3. And with that, I will turn it over back to the chairs. Thank you.

Carolyn Petersen

Thank you for that very informative and helpful presentation. I see that to HITAC members, an email has gone out with a link to the actual document which is now posted on the web, and we now have a few minutes for questions. We'll hold it to five minutes, because we're running slightly behind. Certainly, this is an opportunity to get a couple of first-level questions in. Aaron?

Aaron Miri

Yeah, thank you. Seth, great job, and to your entire team that worked on this. Just one quick question. Maybe I missed it, is there a section on public health or anything like that at all in here that needs to be expanded upon? Or did I miss that in one of the texts here that you meant to speak towards?

Seth Pazinski

Yeah, so we definitely referenced public health in the document. It starts off at the beginning. I know there's a graph that you probably saw that had various stakeholders. Public health is not necessarily in that graphic, but we definitely refer to public health as a stakeholder, especially in our goals one.

Aaron Miri

Yeah, no, I saw it. The graphic's what I'm referring to. Yeah, exactly. All right.

Seth Pazinski

Yeah, so it's there. It's not an exhaustive list by any means, but the stakeholders and the public health professionals you're referring to are incorporated.

Carolyn Petersen

Abby?

Abby Sears

Just a couple of questions, because we haven't read it, so it's probably in there and I'm just checking. Did you give any consideration or have thoughts on medical grid networks and access issues that we might be able to impact from a – you have an overall federal IT strategy, so part of it is making sure there's access in rural areas and that they have the same access to medical grid networks. That's my first one. And my second one is how would Health IT be used in a transformative way to redesign the care delivery system, which is a little different than what I kinda saw in your goals. But thinking about virtual and tele-health and those capabilities, there's a lot more we can be doing.

Peter Karras

Yes, just to jump in on a few points there. So, a number of the federal agencies that we collaborate and work with on the plan that represent that point of view, in particular HRSA, support rural communities, so it's definitely represented in there. I'd say in particular as emphasis related to Goals 1 and 2, as far as the infrastructure to support safety and things like that. And then, the other aspect to telemedicine and virtual care is reflected in the strategies.

Abby Sears

The last point would be, when you're looking at the research and the research standards, [audio cuts out] from NIH on this committee but thinking about they're building their own approaches to things. I've been hearing some of that and I am wondering how we can help connect those dots related to that as well. More than what is explicitly said.

Peter Karras

Sure. So, Clem McDonald in the HITAC provides the perspective of those NIH and the research community. There is also a number of NIH representatives. In addition to the NIH, too, the NSF and ARC – I know I'm using a lot of alphabet soup, sorry about that – but those are the other federal agencies in particular who are kind of leading in the research space and really helped inform Goal 3 of the plan.

Elise Sweeney Anthony

This is Elise Anthony. We also have [inaudible] [04:02:15]. She works at ONC, but works very closely with the NIH community, so her engagement throughout the process has also been contributing to that conversation.

Abby Sears

I'm sorry, new person.

Elise Sweeney Anthony

No worries, absolutely.

Carolyn Petersen

Anil.

Anil Jain

Thank you. Anil Jain. So, a couple of things on the federal Health IT principles – and if it is there already, I apologize – but I don't see where we are aligning our workforce training our medical education to where we need to go from a Federal Health IT Strategic Plan around digital health. That is one. The second, as we start to think about this, we're going to have information overload, and we're already starting to see clinician burnout, partly due to the technology. So, are we referring to how we're going to address in our strategic plan not just the administrative and regulatory burden but the actual clinical care burden that technology may be placing on providers? And the third point would be around the aspects of access to technology. I think you laid it out, or it was made out as a challenge. But I would argue that it's not just the access to technology, it's the access and usability of the technology for those who need it. So, when it is available, it may not be usable in the way that it is needed. Thank you.

Carolyn Petersen

Thank you, and we will take one more question from Raj.

Raj Ratwani

Great, thank you. It's Raj Ratwani from MedStar Health. I have a comment and a question. First comment, just on preliminary glance, is I really appreciate the focus on safety from two levels. The first is the safe use of Health IT, and then utilizing Health IT to improve safety. So, I hope that stays as a core focus. The other question I have is can you help us think about how you prioritize execution of these over the course of the next five years? And I recognize that may be difficult to answer, and you may not be able to answer it, but I'm just wondering how we think about this getting done over five years. Are these running in parallel? Things like that.

Seth Pazinski

Two perspectives on that are one, each agency in the pursuit of their mission is advancing different aspects of this plan, as we talked about it representing the full spectrum of Health IT activities. So, with the individual agencies, this is a way for us to try to stay connected and find areas where issues are cross cutting that support multiple use cases or kind of the first three goals and the different types of users. So, at least in the initial phase, a lot of things from ONC's perspective in coordinating with our federal partners is there are a lot of things that we have been talking about at HITAC over the past

year. So, the implementation of the Cures rule and the impact of that, and modern implementation of that going forward.

The other aspects are the Trust Exchange Framework and Common Agreement and then a variety of standards work particularly around FHIR coordination and USCDI expansion which we talked a lot about at the end of last year. But also, making sure we have the federal perspective on those issues as well is a factor. So those are some of the initial areas in the next 12 to 24 months that would be particular areas from an ONC perspective of working with our federal partners to coordinate on.

Carolyn Petersen

Thank you. I appreciate your response to our brief questions. I would encourage everyone to take a look at the draft report which is now online and to bring back your feedback to the February meeting. I am going to conclude the presentation now because we are 10 minutes behind, and we are running up to the point where we cannot go further beyond the end of the meeting. So, thank you again, Seth and Peter, for coming to the meeting and giving us this presentation. We will now hear a presentation update on Privacy from ONC's Chief Privacy Officer, Kathryn Marchesini. The floor is yours.

Chief Privacy Officer Update (03:00:45)

Kathryn Marchesini

Good afternoon members of the HITAC committee. Thank you for giving me the opportunity to speak with you today. I am Kathryn Marchesini, the Chief Privacy Officer at ONC, where I help address privacy matters, particularly at the intersection of Health IT development as well as implementation and coordinating with federal partners to tackle some of the challenges in the electronic health information privacy space. I also contribute to privacy and data stewardship activities that are happening at the international level. In my role, I spend a lot of time thinking about how we as a federal government, industry, individuals can best work together to balance the public interest in getting and using data, carrying on business interests, and data stewardship and protection for individuals. Particularly as **[Audio cuts out]** moving towards variability and using advanced technology in care.

So, as you have probably been aware, it's a busy time in the world of privacy and security, particularly with discussions around secondary and reused health data. As you probably know, there are several new stories and different privacy bills and related discussions happening on the hill, and there is national discussion happening around data privacy in technology. In general, these concerns are not unique to healthcare, health information, and the health industry. With that being said, we thought it would be a good idea and time to discuss some of the landscape as it relates to health data. I will provide some general context on the regulatory landscape as it pertains to health information and the laws that shape and support patient sharing of health information. This will include discussions around nontraditional health actors. This by no means is going to be a deep dive and a full legal analysis, but I hope it will serve as a primer to set the stage for the rest of my presentation. I will then share a little bit about what ONC has done in this area as well as some industry activities before turning it to the committee for comments and a discussion.

In the U.S. legal system, we have a sectoral approach to information privacy. This often is referred to as a patchwork. So, each industry generally has different laws and requirements on how actors in the

industry have to protect data. This usually includes identifying purposes for which the data can be used or disclosed. In many cases, the requirements or the protections that are put in place have to be triggered because of the type of actor that they are within a given industry, and it doesn't necessarily transfer when information crosses sectors. As you are probably more than aware in the healthcare industry, we have what is called the HIPAA privacy rule. This provides federal requirements or protections for health information when they are held by certain actors.

Just to note, I will not be talking in full detail about state law and the intersection but in general, HIPAA sets a regulatory floor, not a ceiling. So basically, HIPAA does not create laws that create stricter or more privacy protective requirements for protective health information, so other laws can augment HIPAA's requirements as mentioned. For example, state laws or there may be some other federal laws for sensitive information. So, for the purpose of our conversation today, I wanted to just share for information privacy in the health arena, we basically have three stories. The first is HIPAA-covered entities, which generally are most healthcare providers, health plans, and clearinghouses. Some see this group as traditional healthcare actors.

The second group you'll see on the slide is HIPAA business associates. So, these are persons or entities that are performing certain functions or activities on behalf of a healthcare provider, a health plan, and this also includes subcontractors of the business associates. So, for these first two groups of actors, they are subject to HIPAA. There are specific federal requirements and responsibilities that the actors have to follow, or they have to meet when using, disclosing, or handling information. If they don't follow the requirements, the covered actors could be subject to enforcement actions.

You will see, as far as the third category that I'll speak to, and we'll spend a lot of our conversation around today, deals with non-HIPAA covered entities. So, these are organizations, entities, persons that might have access to, use, or handle health information. For example, consumer-directed applications. These sometimes are referred to as non-traditional actors in the healthcare space. For these actors, generally, there are no federal privacy specific requirements that dictate how these actors can use or disclose health information. Just to mention, because I would be remiss in not doing so, there is a Section 5 of the FTC Act that focuses on consumer protection in which it prohibits unfair or deceptive trade practices and/or affecting commerce, and it extends both to HIPAA and non-HIPAA covered entities. So, while it does look to unfair and deceptive trade practices, it does not prescribe the specific privacy requirements per se.

So that's a little bit on the who. Now, I want to speak a little bit about the why and the what. So, in addition to establishing requirements for covered actors, the HIPAA privacy rule also establishes rights for patients, including the right to access their health information. An individual's HIPAA right of access has existed since the 2000s, and the HITECH Act actually strengthens this right of access with respect to covered entities that use or maintain an electronic health record to manage information about an individual. In particular, HITECH notes, "For a given healthcare provider that uses or maintains an EHR, individuals have a right to get a copy of their health information in an electronic format, and the individual may direct the covered entity to transmit a copy directly to an individual's designee, who for example, may not be covered by HIPAA.

So, through HITAC activities, ONC working to establish Health IT certification criteria, including the 2015 edition, ONC has worked to help operationalize the HIPAA right of access and continues to do so as a result of the 21st Century Cures Act, which calls on HHS to improve patient access to their electronic health information, as well as adopt conditions of certification to include APIs. So, against this statutory backdrop, there is a heightened sense of awareness around privacy, particularly as it relates to patients gaining access to their information. Some have expressed concerns about the privacy of electronic health information once it leaves the healthcare providers or the EHR stewardship if a patient chooses to share the information with a third-party application, particularly those that may not be subject to the HIPAA privacy rule.

Privacy in this context is not usually speaking about secrecy or confidentiality, it is really about control. Control over who has access to health information and when and where it can be used. Also, traditionally when talking about secondary use or reuse of data, it is about using data for a purpose it was not originally collected for or how an individual might reasonably anticipate or expect their data to be used. It is not about security, is not about what happens if there is a breach. Generally, it is about who has what data, how it is being used and shared, the business practices of the entities receiving the patient-directed data, as well as the requirements that those organizations have to follow once they receive the data.

So, Congress is currently looking into this area and whether federal legislation is needed. There is concern as mentioned earlier around secondary use broader than just in healthcare, and we at ONC have been monitoring and involved in this issue for quite a while. While ONC does not regulate the privacy and security practices conducted by non-HIPAA covered entities – and this includes consumer-directed apps and technology – historically, actually for the past decade, ONC has been involved in and contributing to addressing this area and has made resources available. This slide, you will see it highlights some of ONC's activities including two reports to Congress and educational material for individuals on how to use and get access to their health information from their provider, including consumers, what they are able to do with the information once they receive it, questions they should consider when evaluating an app.

We've also provided what is referred to as the Model Privacy Notice, which is MPN for short. This is a voluntary, openly available resource and template that's designed to help developers clearly convey information about their privacy and security practices to their users in a standardized manner. I will go into this in more detail in the following slide. So, similar to the FDA nutrition facts label, the MPN provides a snapshot of a company's existing practices. So, this is our effort historically and currently to encourage transparency in helping consumers make informed choices when selecting products. It is intended for the developers to complete and to be transparent about how their digital health information is handled. The current version of the MPN actually is an update from a 2011 version as well as a 2016 version of the MPN, and it was an effort to address the large variety of products that now currently collect health information in the emerging market.

You'll see here on this slide that these are some of the questions from the Model Privacy Notice that a developer would answer or provide responses to in order to convey the information to the patient. Here, some of these include letting individuals know whether a developer uses or shares individual

information, whether or not data is sold, how technology might access other information, for example, on the individual's phone, as well as what individuals can do with the data that is collected about them. You will see here just a few snapshots of areas that are the templates that show the layout of the information that a developer can choose to respond to. Developers are able to communicate and share and be transparent. As mentioned, this is just a snapshot that was developed as part of a stakeholder feedback as well as input from the HHS Office for Civil Rights, as well as the Federal Trade Commission. Just to share, the Model Privacy Notice does not mandate specific policies or intend it to substitute for more comprehensive or detailed policies.

ONC works to advance the development of the use of Health IT, which you're all very familiar with. We know that everyone plays an important role, an equal role, in maintaining the public's confidence and trust. In addition to the ONC efforts that I've shared, industry groups are encouraging health companies as well as developers to self-regulate in this area. This basically is to voluntarily adhere to a code of conduct, guidelines, principles regarding collecting, using, and exchanging health information, and this is particularly in the area where HIPAA does not apply to the entity that receives the data. So, groups like the CARIN Alliance, the Consumer Technological Association, and Xcertia have developed codes guidelines with their members to support the efforts to codify best practices for specific activities to standardize behavior across the health industry.

So, similar to the Model Privacy Notice, many of these guidelines, these codes of conduct, are intended to help address the concerns that folks have that are associated with sharing personal information with, for example, consumer-facing apps. You will see here on the slide the matrix that generally shows how some industry group efforts explicitly address some key privacy concepts regarding information practices which you will find that are many in common with the Model Privacy Notice. We are very supportive of initiatives that get consensus on tough problems to which some in the industry, some are stepping up trying to do just that. If you are interested in learning more, feel free to dive into some of the areas. As I mentioned, there are some links here. We continue to monitor and do what we can in this area given our authority. I will now turn it over to the chairs and Lauren to open it up for HITAC members for discussion and sharing any thoughts on this topic.

Carolyn Petersen

Great. Thank you, Kathryn, for that very informative presentation. Let's start with Ken.

Ken Kawamoto

Thank you. I have a question, and the question is under HIPAA's requirements that healthcare providers only share the minimum necessary data to the business associate, use reasonable care for them to be so. Does ONC or any other agency provide any guidance on whether the current approaches to basically providing open access to data to FHIR endpoints is in fact HIPAA compliant?

Kathryn Marchesini

I think you may be speaking to the minimum necessary requirement under HIPAA. As far as guidance on how to apply the minimum necessary, that would be guidance that would be issued by the HHS Office for Civil Rights. As you know, the minimum necessary requirement does not apply to treatment, it doesn't apply to an individual's right of access. To the extent you're looking for guidance on the topic,

the HITECH Act actually requires the HHS Office for Civil Rights to issue guidance on the minimum necessary standard. That activity, to my knowledge, there is nothing that is publicly available.

Ken Kawamoto

So, maybe just to follow up on that, I think that would be a great place to get explicit guidance and to facilitate that. Thanks.

Carolyn Petersen

Thank you, let's go to Aaron Miri.

Aaron Miri

Thank you, great presentation, I appreciate it, Kathryn. So, two questions, please. No. 1, with one of the task forces that we used to have on the policy committee was related to API task force, there was a security and privacy section focused on developers around HIPAA, and it was a great work product that was done by ONC at the time, this was in 2015 or so timeframe. It tried to lay out for developers where HIPAA came into play and where it didn't, what some of those great thoughts you're speaking towards are. Is there any activity to update that document and maybe provide a refresh document out to the public on that that you are aware of, or could we work on that together and develop that?

Kathryn Marchesini

Thanks for the question. So, if I am understanding your comment, I am aware of the prior output of the task force that looked at APIs. We at ONC actually use that resource as part of our work supporting NIH Sync for Science Project, which is really looking at exercising the right of access to encourage individuals to share information from their healthcare provider directly to a researcher. We do have a resource that is available, I think it is a key privacy and security considerations for APIs and healthcare, so that would be a more recent educational material that is out there for developers as well as healthcare providers that are trying to figure out or trying to operationalize the HIPAA right of access -- HIPAA right of access using, for example, a third-party app or a consumer-directed app. There are some considerations in there to look at which build on the recommendations of that group.

Aaron Miri

Excellent, thank you. And one more quick question, and Carolyn, this is maybe more for you, is it possible for us to consider or make a motion to consider a new task force focused on privacy and security particularly on third-party access and that sort of thing?

Carolyn Petersen

I sense I have ONC friends here who would respond.

Aaron Miri

Oh, okay.

Carolyn Petersen

From my perspective as a co-chair, absolutely. The Cures Act laid out a number of items and work for this task force with HITAC to do, and we've covered that, and I think the field is now open for us to look at other things we see as related to that work as well.

Donald Rucker

Aaron, to address your question, first of all, certainly in terms of task groups that can be jointly discussed to the privacy and security and the massive considerations in our Cures rulemaking. I think a lot of the time it has taken to do the Cures rule is directly related to maximizing protections on privacy and security and do that in a way that still protects right of access. Because when you have this discussion, I think often in the last year it has been clear to me, the discussion is focused purely on "limiting patient choice on various privacy considerations." But I think if you looked at the public's interest, which ultimately is as federal employees we have to represent, I think you would find the right of access and the ability to manage their lives and their healthcare in the global non-transparency and the delivery system today, I think there's half a million people here going bankrupt from healthcare related things in the U.S. as we speak, roughly. I don't know the exact number, but I've certainly seen some evidence around that.

So, we have to – and I think HITAC has to – balance the right of access and these extraordinary considerations with the public that is not well served by the way healthcare has evolved over the last 50 years. So, I think the balance is what we're doing, that a lot of work is going into maximizing that. The interesting thing about technology is technology now gives extraordinary audit trails on what goes on. So, a lot of these things that might have been black boxes or private things or loosely de-identified, a lot of this stuff is now extraordinarily available for tracking, which is profound consumer protection.

Steve Posnack

Yeah, this is Steve Posnack. I just wanted to sing backup to Kathryn on one other thing to address Aaron's point. We don't often do as great of a job as we could with some of the coordinated resources that we have developed over time. So, there is one for mobile health app developers that we jointly put together with our colleagues at OCR, FDA, and FTC that lays out the federal laws that could be applicable to the apps, depending on certain questions that they answer. And so, that is a resource that's available today. Certainly, based on feedback we could refresh that as well.

Aaron Miri

Thank you.

Carolyn Petersen

All right, thank you. Let's go to Steven Lane, or did you withdraw your question? Okay. Arien?

Arien Malec

Thank you. Kathryn, I think first of all, great presentation. I think it might be useful for you to maybe refresh the committee on two points that are often misunderstood. One is pretty basic, which is how is a covered entity defined under HIPAA, which I don't think maps to what people think a covered entity is defined as. And then, maybe more importantly, if you could cover the guidance that OCR and others have provided on the role of patient access, and in particular the role of patient access with regard to readily available forms and formats and their applicability to APIs. Because again, I think there is a perspective that HIPAA provides for a role for provider organizations to serve as well-meaning gatekeepers for patients to protect patients and limit data availability, data access. I think it might be

worthwhile just grounding the committee in both the right to access and also the interpretive guidance on readily available forms and formats and APIs. Thanks.

Kathryn Marchesini

Okay. Do we have time to go into full?

Carolyn Petersen

How full is full? Thirty to sixty seconds is all.

Kathryn Marchesini

Okay, yeah, yeah, yeah, yeah. So, thanks for the questions. The first being that in 2016, the HHS Office for Civil Rights actually issued guidance specifically about the HIPAA HEPA right of access. If you have not checked that out, definitely do so. There are several FAQs, questions that answer specific challenges. The one that's spoken to is about, to give you an example, I am an individual and I request information. I have the right to receive information in the form and format that I request it to the extent it is readily producible. Questions about whether something is readily producible or not, that is up for interpretation. A lot of it has to do, too, with whether or not the information you're trying to send to a third-party, if it creates an acceptable security risk to the disclosing party.

With that being said, if a provider, for example, does not provide the information in the form and format that's requested or it is not readily producible, the individual is entitled to receive the information in an agreed-upon alternative form and format. But basically, the guidance does say to the extent you maintain information electronically, you have to provide it electronically.

The second question which I think had to do with what is a healthcare provider, how are you covered by HIPAA, basically it has a lot to do with if you're exchanging information or you participate in electronic transactions, and this has to do with I think there was a presentation earlier today about the HIPAA administrative simplifications as well as the transactions that are identified for purposes by the HHS Secretary. So, for example, if you participate in electronic billing, you exchange information with healthcare providers for purpose of payment, pretty much every healthcare provider absent concierge medicine or if you're not necessarily taking insurance, you're covered by HIPAA.

Carolyn Petersen

Thank you. Let's go to John Kansky.

John Kansky

Thank you. I may be about to demonstrate my keen sense of the obvious, but I wanted to give you a chance just to comment. So, I think ONC and CMS are on record as trying to create an ecosystem of third-party apps that patients can access to do stuff with health information. Dr. McDonald, who is on this committee, helped to invent the electronic health record in 1972. EHRs were not in use until probably sometime in the mid-80s. Then it was another decade before we had HIPAA, where the government decided they needed to regulate the access of information because of the interests in the provider/payor/etc. community. It seems to me that we are about to create an ecosystem of health data outside the HIPAA bubble, but we are lagging in terms of the regulatory thinking about that.

That was a long-winded way of saying, if we needed HIPAA 10 or 20 years after we invented the EHR, can we not anticipate what regulation we might need on consumer for-profit companies that are going to have access to the same information?

Kathryn Marchesini

That is a good question, and that is a conversation that is happening on the hill as well as the broader national level. I think some of the challenges that I think through is some of these gaps actually already existed when HIPAA was passed in 2000. So, I was thinking through what the original intent of HIPAA was. I don't think anyone is arguing or in disagreement that there are folks that are covered by HIPAA. I think the challenge is that we as ONC, part of our role – the right of access to information already exists today and what our role is in the broader ecosystem is to encourage the development and use of technology to allow patients to get access to their information. So, it's trying to find that balance, we as ONC, to try to move our priorities as well as for statutory mandates forward but realizing the reality that we are operating in and how best can we contribute to the conversation.

Carolyn Petersen

Okay, thank you. Let's go to James.

James Pantelas

I am going to piggyback on John's comment, because there seems to be, especially within the cancer community and probably elsewhere, a growing number of providers that are creating disease-specific data repositories. And essentially, what they are asking for is patients to provide their usernames and passwords to their EHRs in trade for being able to see EHRs of other patients of like diagnoses. They are claiming typically, if you look at their websites, they'll claim a responsibility to HIPAA, but I don't know how they can. Are we doing anything to at least identify what their correct status might be? It is patient-provided access, so I think it is probably legal, I'm just not sure it is identified accurately.

Kathryn Marchesini

Your comment as well taken, and I know that there are a lot of actors out there that say that they comply with HIPAA or they're HIPAA-compliant, even though HIPAA may not apply to them, which is a valid effort. I think to your point, though, part of the challenge is as an individual, if an app may be saying that they are holding themselves accountable to something does not necessarily make it so. So, part of the challenge – and this is where some of the Federal Trade Commission jurisdiction comes in – is they are looking at consumer protection as a whole. So, to the extent that organization is making an unfair or deceptive business practice or communication that is not true, that is kind of where their jurisdiction triggers.

Your question about is there a way to know if something is covered by HIPAA or not, absent the clear lines between healthcare provider and health plan, you mentioned that some of these technologies may be offered on behalf of or they might be providers. So, it could be a situation where maybe the application or technology was offered on behalf of the providers, so it would be considered a business associate, but the business concerns around organizations touting themselves as HIPAA compliant or

compliant with HIPAA, no one can determine if you are HIPAA-compliant other than the HHS Office for Civil Rights, and they do not issue advisory opinions about this topic or other topics.

Carolyn Petersen

Okay, thank you. Let's go to Andy.

Andy Truscott

Thank you. Thank you for the presentation, it was good to listen to, and good to hear those comments in full. A couple of comments, just to stay on top of what other people have been saying. I personally think that going to a dying fight about the rights and wrongs of HIPAA isn't really something we should be doing here but recognizing that there are conversations going on elsewhere right now about the applicability of HIPAA. I think we recognize the legislation was created in a different time, when there were different capabilities available in Health IT systems, and different levels of enforcement. I hope that the focus upon actor might actually shift to being the focus upon the nature of the information being protected, controlled, and otherwise managed. I think that would be advancement, but that probably isn't for us to have discourse on.

I think what is for us in this committee is to look at how the standards can well support the enforcement of those policies and decisions that get made. So, as legislation matures and goes forward, how actually the standards can ensure that the decisions are made by a patient around how the information should be controlled, are taken and enforced inside Health IT, whether it's certified or not. I think this is where when we touched upon earlier, with the potential for twin facts going on where we have technologies which are part of the certified Health IT programs and technologies which are not, and how actually we can ensure the patient wishes are appropriately checked across them both. Does that make sense?

Carolyn Petersen

It does.

Kathryn Marchesini

I appreciate the comment.

Carolyn Petersen

Okay, thank you.

Donald Rucker

Yeah, to Andrew's point, I think one of the broader societal challenges is that much of what we historically think of as part of an electronic medical record is now inferable without any reference to anything that anybody in this room typically does. From consumer databases, from Google searches, from mapping functions, from the GPS on your cell phone. So, it is a very challenging thing because most of the things, I know the example about HIV testing – I guess Ken's not here at the moment – but that was pointed out, you can infer somebody's HIV status more ways from Sunday now with modern technology on where they have been, what their searches are, any number of other things. And so, I think as we look at these things, we have to have that broader context.

There was something that Deven McGraw had in one of her blogs where she cited that health information outside of the medical records is 2700 times as large a volume as that within the medical record. Again, that is obviously an unknowable number. I think she ascribed it to one of your competitor consulting firms. But it does bring up that in this world, the privacy issues that are probably at the forefront in terms of healthcare really have nothing to do with any of the sources we classically consider as healthcare. I mean, that's just an observational fact of the way these algorithms work and tools work.

Carolyn Petersen

Thank you. It looks like we are slightly behind, but we can have one brief comment. Cynthia?

Cynthia Fisher

I would like to support what Dr. Rocker said and also what he mentioned earlier. There has been a lot of brouhaha from the entrenched provider electronic health record vendors and even insurers on the paternalistic protectionism concern of releasing to patients their much-needed health information, and even researchers, over the discussion of privacy. And Kathryn, I thank you for your input, and I would just say that if we invert this concern on its head to say HIPAA in 1996, we didn't have the electronic health information in the records. It was really giving patients the right to be fully informed of their mental/physical care plan, their healthcare plan, and their past/present/future payment information, because at that time, what was only electronic was mostly financial information transacted.

So, here we are today where the patients are struggling, and I can only say that I would hope that we don't use the shroud of privacy to yet further delay and deny patients and their caregivers and the people they choose to share their information with and the applications they choose to share their information with as the barrier yet to prevent what has so much work been done to deliver the patient. And then, I would further support to say that I think it really is upon us to make sure that in all of our hard work that we change the game for the legacy of the future. Because as Dr. Rucker said, we can't do one focus group without tears being shed because of the financial ruin and devastation that hard-working people who are covered and are insured are facing because of unaware billings and surprises. There is so much fear and fragmented distrust of the system and we all have it in our hands to deliver it.

And then finally, to Dr. Rucker's point, let's be real. Another portion of my own family's business is a consumer brand. Now, if you go into a pharmacy or a store that sells products, Bluetooth is connected to your phone. As a consumer brand company, we can cheaply buy access to the planogram and the placing of products on those shelves that gives us, very economically, software companies following your tracking of your store purchasing. So, there are Bluetooth eyeballs when we go grocery, pharmacy, and that data is aggregated along with your purchasing data. And so, we can compare whether you stand in front of that generic brand versus prescribed big brand, and the timing of your decision-making. And now, there's software that is even looking at your eyeballs. Okay, so you can even buy very inexpensively as a consumer brand, you can buy where you stand that aisle and where your eyeballs are shifting.

So, to Dr. Rucker's point, there is no privacy, and that is being aggregated. And if you are looking at social determinants and all these wonderful new buzzwords, this is happening on a much broader scale than Deven's report went about. So, the real issue here is health records, we have it, patients need it, and what is happening on the outside world of aggregation of artificial intelligence and big data is happening across the marketplace. And I just think that we need to be realistic and know we also know health systems and others that have our data are selling it and remarketing it. So, if we inverted it on our head, wouldn't it be nice if the consumer were empowered with cookies and we would actually see all of the cookies of all of the places that our data was sold. Whether it's de-identified or identified. I think it would be absolutely remarkable.

Going to the New York Times article a couple of weeks ago that showed your GPS locators and all the traceability of people all around the maps of the U.S., this is a world in which we live. So, I would just encourage us to not pretend that the rest isn't happening around the world, but to actually give patients access to their data and not use privacy as the barrier to kill by delay. Thank you.

Carolyn Petersen

Thank you for your presentation, Kathryn. It was very helpful. We will now move to our final item of the day, our presentation and discussion on Integrating and Using Received Data. It will be given by Dr. Al Taylor of the Division of Standards at ONC. The floor is yours, sir.

Integrating and Using Received Data Discussion and Next Steps (03:40:45)

Al Taylor

Thank you very much, my name is Al Taylor. I'm a clinical informaticist in the Standards Division of the Office of Technology at ONC, and I am here today to discuss or at least begin the discussion regarding a priority item that the HITAC decided on for the 2020 year, and that is integrating and using received data. It is an awfully big topic. It's basically another way of saying interoperability. And so, we would like to begin the discussion to start refining the topic and refining the problems, so that we can see the best way forward in the coming year. So, the goal is today, we will go into a little more detail, but the goals today are getting a better idea and definition of what is meant by these issues with addressing and using received data and identification of specific use cases. There are some examples, that the HITAC had already identified. And trying to figure out problems and what sort of buckets can we put some of these problems into so we can address them according to the best way to address them depending on which bucket the problem falls into.

We would also like to define and identify what specific deliverables and outcomes would be desired from the HITAC this year, as well as those that the HITAC would like ONC to accomplish and deliver this year. And then, talking about some initial, just where do we start? So, was this me? Oops. Sorry. Someone's helping me out. Okay. Clear.

So, I offer these questions for the HITAC to begin the discussion. Not to solve the problem today for sure, but just to begin the discussion, get your feedback, and see where we can go from here and how ONC can help get there. So, the HITAC during the course of last year had defined a number of different areas of integrating external data and specific examples are including image, video, and audio files that may be coming in from outside sources, duplication of data that's coming in from outside sources,

whether it's multiple instances of the same piece of data from the same source or multiple sources. Secondary data that another organization has that both of which are sending to a receiving organization. And then there's the topic of unusable data from outside sources, and the example given for that was what do we do with this thing coming in called family history? Do we know enough about the data that is coming in that's called family history that we can make use of an utilize?

Additional outside data, including patient-generated health data, is another area that was identified by the HITAC. And so, that begins to discuss what sorts of data are we trying to exchange and integrate? Are there particular knowledge gaps? And by that we mean are there things that a variety of people don't know, don't understand about the use of this outside data, and data types, and that includes groups like developers, implementers, providers, as well as the policy folks like us. Specifically, with those examples and others that you identify, we would like to hear more about some more details perhaps about the use cases in particular.

And then, I thought it would be helpful – these are the buckets that we discussed – is this problem with external data a problem with standards? Is it a problem with the way that the workflow handles the data and collects it and sends it on? How is the implementation of a particular use of a data type worked into the Health IT system and into the actual healthcare system itself, and whether or not some of these problems are areas that should be covered or at least addressed in the certification for existing Health IT functionality in our certification program. And then, the question is, what does the HITAC want to do this year? What do they feel like is a reasonable deliverable or a reasonable outcome as a result of work to be done this year? And the same question for ONC. What would the HITAC like ONC to do or try and do this year in order to help address and solve some of these problems? So, I'd like to open it up for questions, comments, from everybody.

Carolyn Petersen

Okay. It is now 2:25 p.m., and we are adjourning at 3:00 p.m., and we have a public comment period. So, in handling this, I would like to ask that each individual keep your response to a minute. Not try to cover every aspect of every problem but be very focused in your feedback. I will also work through the individuals who want to comment based on who has spoken the least today. So, those who have not had that chance to be so involved can do so now. So, with that said, let's start with Jim.

Jim Jirjis

Yeah, I think that this is an important area. It's almost like we're the dogs that caught the fire truck, right? Suddenly all this information is exchanged. Within ACA, I know as we received these CCDs, what we find is that it is a difficult-to-manage problem, and part of it has to do with the various implementations of the same standards and how people interpret them semantically, syntactically. And it leads to a lot of challenge and manual effort to try to make that machine usable. The second problem is these massive CCDs that are just unwieldy and unusable to the clinicians, particularly when you can't parse and process them. And the last piece is the ability to reconcile. It's a very arduous process to reconcile clinical information into the workflow. And so, from our point of view, efforts to address the variation in implementations of how people interpret, or quite frankly how well they adhere, would be a grey area of focus.

Now, I say that too, I love the Sequoia team, the health exchange. Our experience was a common recognition that the variation and adherence to standards and implementation of those standards is creating this enormous problem. I think that was a little over a minute.

Carolyn Petersen

Thank you. Let's go to Arien.

Arien Malec

Thank you. Nicely framed. I think part of the issue here, though, is framing things as outside data and inside data. If we framed it instead as the patient's data, and the job of physicians and hospitals as putting together a comprehensive view of the patient's data, this notion of the difficulty of receiving "outside data" would be somewhat really framed. And as a proof point, back 15 years ago – so long ago that I can't really remember – I was involved in creating a comprehensive medication record that incorporated sources from PBMs and from other physician practices. It is hard. It requires good design, and there are cases where the standards are insufficient. But the biggest obstacle by far is the perspective that as a physician, as a hospital, it is not my job to integrate outside sources. It is my job to document the patient and their encounter and this "outside data" is a distraction to my job. So, I just submit if we framed this problem somewhat differently and framed the job of a physician and their staff somewhat differently, we might frame the solution somewhat differently as well. Thank you.

Carolyn Petersen

Thank you. Let's go to Steve.

Steven Lane

Thank you. Stephen Lane. Thanks, Al, for setting this up. I've given this a lot of thought; I've lived this hell for years. I'm going to try to speak quickly to get some thoughts into the record, **[audio cuts out]** work with you on this. But I think you can break down the challenges into a number of different buckets. There are clearly technical challenges that we face. One of the biggest ones that came up in our Interoperability Standards Priority task force was the challenges related to mapping discrete laboratory result data in order to bring that and share that between systems. I don't think we have a good solution for doing that and I think that is an area that ONC really should ideally spend time working on. There are challenges of volume of data. When I connect my Apple watch up to my EHR, it tries to download all of the heartrate data, and it crashes the system. So, there are real challenges with patient-generated data and volumes and trying to figure out how to analyze or pre-analyze that data before presenting it to clinicians and filing it to the record.

There are lots of usability challenges with outside data. I'm sorry that Dr. McDonald left, but he's pointed this out repeatedly over the last couple years of our committee work, the challenges of being overwhelmed by the data, how to get providers to be able to visualize the signal inside the noise of outside data, and then the concerns about liability which he raise earlier today, concerns that if this data is available or has been downloaded to your system, that the provider is somehow liable for having looked at all that data. There are clear privacy concerns that relate to this outside data when privacy restrictions have been applied at the source system whether they have to do with adolescent privacy, with self-pay restrictions, with release restrictions that have been agreed to. And then, that

data is shared. How do we get that privacy meta-data to come across with the data and then have it be respected in the receiving system?

There are challenges related to definitions of the legal medical record, which I understand should include all the data that's been used to make clinical decisions on a patient, but none of that data was locally generated. So, we have challenges with outside data that needs to be somehow tagged as having being viewed or having been used to make medical decisions, and then how do we make decisions about rerelease of that data? If it's officially been used to make a decision, shouldn't that be released as part of the legal medical record? I don't think our HIN colleagues have figured out that challenge. And then, the real challenge of duration. As I think Arien said, this is the patient's data. We have different ways of getting at it, different ways of maintaining a copy of it, that needs to be curated on an ongoing basis.

As a PCP, I try to do that for my small panel of patients, but really we have to think about other ways to leverage machine learning, augmented intelligence, and then to leverage the patient and caregivers to let them play a greater role in curating their data wherever it lives and making sure it is accurate. So, "Oh, fun. You made it back. I'm so glad." But I think there are a number of really important questions here that we need to look at and I would love to see this group, whether it is a task force or some other group within ONC take this on.

Carolyn Petersen

Thank you. So, I have one comment also with regard to these questions. We hear a lot about the concerns that providers have in terms of getting a large chunk of data that is essentially useless from patients. For example, Fitbit data, or other kinds of tracker information, where you are looking at a lot of data points that don't add up to some knowledge that is useful. And I think also from the patient side, it's concerning to wonder what's really happening with all that information and whether it gets used and even looked at.

One aspect that I think will be critical in terms of integrating and using external data is the importance of a negotiation between clinicians and patients as to what the data will be and how it will be used, and a shared understanding on both sides that there are rights and responsibilities and there are rules of the road in terms of what people do and how they handle that data to facilitate its use for improving outcomes and genuinely managing health. One thing that ONC can be a leader in is in helping to formulate and promulgate the shared understanding. What are the components, what are the ethical aspects of behavior by both parties? How does that come together around health improvement? Rather than just movement of data in one or the other direction. Are there other comments or responses from other members of the HITAC? Please put your tents up. We do have a bit of time still to continue the discussion. Denise?

Denise Webb

Denise Webb. So, one of the things I think about as we discussed this topic, I think it is important to be able to share data with our providers, patient-generated data, but the concern I have – like for instance the smart watch I have on, what are the algorithms in this watch? What standards does it

conform to? It's not regulated as a device by the FDA, so how much trust can the provider have in the data to integrate it and use it? So, that is a whole other area to be explored.

Carolyn Petersen

Thank you. And Clem?

Clem McDonald

I sent something as requested – sorry, I apologize. My boss insisted I be on this call. But the thing is I don't think we can just open a gate and say that you're right. We need to find the rules of the road, but I think we should be clear. There should be some mutual agreement about this in some fashion. I know there are a whole lot of cases and I listed some of them on the slide that I sent you. I don't know if you finally got it or not. You said you had trouble with the first one.

Carolyn Petersen

For the HITAC's understanding, Clem had put some additional information into another couple of slides of his presentation and forwarded that to me. I tried to open it over the lunch break and was unable to, so I asked that he resend it. I haven't checked it since because the meeting's underway. But we will be sure that that gets distributed to everyone in the HITAC.

Clem McDonald

Well, I mean, the issue is I think ideally, if it's data you asked for, "Please send me this," or "I requested that," or "I wanted you to fill out this form," those are all clean. It's this other open-ended stuff. There is middle ground, like, "Call me when anything goes wrong," or they will. And how do you do that? Should that be through a human? So, at your office rather than just electronic where you may not be looking at it? And then there's these huge troves of stuff that frankly I don't think that anybody wants except if they need it. I mean, in other words, it is just too sparse with useful information in everything from the watches they can give you 10 megabytes of data in a second and/or your 45 pounds of charts from the past. There is no way to go through that stuff in a reasonable amount of time.

Now the other side, the emergency room sends you stuff, and you want it. But there should be understanding there that they're not sending it to you to dump the papers on you, all the responsibilities on you that minute, because you may not look at it for a week. And they probably ought to send more than they usually do, a carbon copy that you can hardly read. But give the lab data and imaging studies so that you know something. So, I think there should be a whole bunch of scenarios discussed, and then we have to worry about this becoming as spam attractants like faxes are and emails and even phones. Whatever kind of electronic thing is going to be an address, and you might just get junk mail from not the patient or who knows from all kinds of sources. So, I think the idea that comes out is, "Oh, yeah. We should open that all up." I think we've got to be very careful to make it be done right and appropriately and with the right balance so that both sides get what they need out of it.

Carolyn Petersen

Thanks, Clem. Let's go to James.

James Pantelas

I think I am coming at this from the exact opposite direction, and that's that I'm a firm believer in epidemiological data, and I think we ought to be gathering as much information as we can. I'm coming out of the lung cancer world. In the lung cancer world, we stopped asking questions about smoking in 1965. You either smoke or you don't, and if you've got lung cancer, you smoked. And I have had oncologists tell me that anybody that told them they didn't smoke is lying. So, we stopped gathering the information about where did you live, where did you go to school, what were you exposed to? Data is incredibly valuable, and storing it is incredibly cheap. What we need is some kind of pathway to create it. And that can be through questionnaires, just simple questionnaires of former smokers about how long it took them to quit, how many times did they quit, and what actually worked for them. Or when they first saw themselves as a smoker. That would help us to define cessation programs that might be more tailored to specific smokers.

Knowing that lung cancer is far more prevalent in the Ohio Valley or in the upper peninsula of Michigan than in most places in the country. This seems to imply that dirty air has a lot to do with whether or not we get lung cancer. And from a Fitbit standpoint, there are some radiologists in the lung cancer world that are now starting to see and correlate data that shows that people that go through radiation therapy and lung cancer do far better if they increase their steps. The more steps they take a day, the more likely they are to respond to radiation. Again, it's data. And we just have to have a way of asking the right questions to get the data to be meaningful. We could be asking questions about family history that can be stored in a meaningful fashion. We can be asking questions about where people went to school, where they worked, what they were exposed to, that can create meaningful information. We've got a guy here from CDC, and his organization just believes in large part to big data. They're kings at it. I really think that we need to be thinking about what causes the diseases that we're dealing with and the only way we get there is by understanding where people come from.

Carolyn Petersen

Okay, thanks, James. Alexis?

Alexis Snyder

Yeah, I think in terms of gathering as much information as we can, it makes sense as long as we think about accuracy. And speaking in terms of accuracy, I'm talking on both sides. So, we have the Fitbit-happy information we've been talking about, and is the data that patients sending providers accurate enough to be entered into the electronic health records and then be shared? And then, I think when we talk from the provider end, too, oftentimes patients may be seeing a specialist and information gets dictated from memory wrong and/or transcribed wrong. And then, that record not only is wrong on that end, but then is shared to a primary care doctor and then is entered in their electronic health system. And so, there's a lot of room for error in how to make systems accurate, and I think that patients with the patients and not for the patients comes in, and they need to play a part in being able to police, so to speak, their records before they get shared, so it's more than one database in the electronic health record system.

And then, how do we reconcile the information when it's different in multiple systems? So, it's hard enough to correct it within the one system where the incorrect information was entered to begin with.

It's even more difficult, yet possibly impossible, to then correct it when that provider has then shared it with another system. So, I think those are some big gaps that need to be worked on as well.

Carolyn Petersen

Thanks, Alexis. We're coming up to public comment, so let's do Les's comment, and...

Donald Rucker

Just quickly to second the remarks that **[audio cuts out]** the data we have to understand and carry the provenance of the data with it. And so, our role might be helping to clarify the standards for that provenance of the data. And just the pace that we are seeing electronic records proliferating missing information, we need to know when a fact is truly a new fact or a duplication fact that has come from another source that has already been repudiated. So, I think these are very tough questions but it sort of says for everything we are thinking about incorporating, we'd better have a unique identifier for that data and to track that as we go forward if we are really going to really think about a composite EHR that has data from everywhere, and without running into this problem we heard of reintroducing new errors every time.

Carolyn Petersen

One minute? Okay. We'll do Steve. He says it's a one-minute comment.

Steve Posnack

I just wanted to reiterate a piece of what I said earlier about the concerns of providers regarding legal liability as we move into an era of TEFCA and broadcast queries, and I think we all agree, the more data the better. I would love to have access to all of the data for every one of my patients, but even though it is cheap, it is not zero cost to store that. If you had a copy of the entire lifetime health data for every patient we ever touch, that is a lot of storage. So, we have to solve that technically, but I really think there's an opportunity for ONC to potentially reach out to the OCR or to another legal body to come up with some sort of a legal statement about what is the standard of practice. If we want people to interoperate, we want people to get data, they can't be afraid that they're going to get hurt by having that information. They shouldn't be afraid of interoperating because they think they're going to get sued.

I've been hearing this for 25 years, since the dawn of EHRs, "Don't give me all this data, because then I am liable for it." And I think we need to work together with legal experts to try to reassure people that it's okay to interoperate, we're not going to sue you for that.

Carolyn Petersen

With that, I see we have one last comment from Sheryl, and then we will go to public comment.

Sheryl Turney

Thank you, I'll be quick. I want to agree on data collected that other data definitely needs to have work so that we're all comfortable with the data provenance. But also, I do think that there needs to be some discussion about how that data would be used and what obligations we have once we use it for certain purposes. If that data is collected and then it's used for AI decision-making, there should be a

requirement related to the individuals that that impacts, that the data was used for that purpose. And today, that's not clear. Even using social determinants of health data, it is not clear in terms of what should be disclosed to the patient and what should not.

Carolyn Petersen

Thank you. I see you have your flag up, Clem. One minute? Just a minute? Okay.

Clem McDonald

Well, I just wanted to reinforce what Steve said, and clarify I think getting data if you want it and you need it for patient care, that wasn't what I was talking about. I was talking about the push from whatever source, because you don't know you're getting it, and then all of the sudden, you have responsibility and you may not be able to absorb it. There's no office visit for it, there's no staff, etc., etc. So, it's a challenge. I think there should be some, ideally, mutually agreement.

Carolyn Petersen

Okay. Thank you. Dr. Taylor, was that helpful? Is this the sort of feedback you're looking for?

Al Taylor

It was great, very concise. No, I think it gives us a lot to work with so that we can organize the feedback that we've gotten and line it up with the previous comments and previous concerns from HITAC from last year. What we will do is we can come up with maybe some suggestions about some specific pieces of work that can be done. Some were already laid out very specifically here, but we can come back with maybe an initial game plan.

Carolyn Petersen

Great. Thank you. We welcome your coming back with further discussion and another opportunity to refine things we've talked about today and see how we can integrate it in our work. Thank you

Lauren Richie

Okay, at this time, this is the last opportunity for the day. If there are any public comments from individuals in the room, we will certainly take those first, and we welcome you to the presenters' table. And if there aren't any comments from the room, operator, can we open the public line on the phone?

Public Comment (04:09:45)

Operator

Yes. If you would like to make a public comment, please press "*1" on your telephone keypad. A confirmation tone –

Lauren Richie

It's a little hard to hear.

Operator

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" if you would like to remove your comment. For participants using speaker equipment, it may be necessary to pick up the handset before pressing the star keys. We will pause for a brief moment to poll for comments. There are no comments at this time.

Lauren Richie

Okay, I do believe that wraps it up, but I will turn to Carolyn and Dr. Rucker to see if there are any final closing remarks.

Closing Remarks and Adjourn (04:10:45)

Carolyn Petersen

Thanks, Lauren. And thanks everyone for your attention and your excellent participation in today's meeting. We've had several really good discussions with a lot of feedback that will help our colleagues at ONC further their work. I hope we will also be able to further some of the discussions we had today around interest in future activities. We will have a draft of the Annual Report ready for your review and hopefully vote at the next meeting. Please do submit your comments in writing to us by the 21st. And I think, Robert are you on the line now?

Robert Wah

Yes, Carolyn, I'm here, and thanks for letting me chime in one last time. Thank you for taking care of the meeting in my absence. I think it was a great meeting, and again, Happy New Year to everyone and thank you for your hard work on behalf of our patients and citizens to improve their health with technology. I look forward to our next meeting and as always, Carolyn and I welcome your comments to improve the HITAC and to explore new areas that are important for our patients and constituents. I hope everyone has safe travels home and the beginning of a great new year, thanks a lot.

Lauren Richie

Thanks, Robert. And I just wanted to acknowledge, we have one public comment on the phone, so if we can go back to the line for a second. Operator?

Operator

Yes. Marni Carey with the Association of Independent Doctors. You may proceed.

Marni Jameson Carey

Hi. Yes, I had a little technical trouble getting in the queue. So, yeah, this is Marni Jameson Carey. I am the Executive Director of the Association of Independent Doctors, and I'm speaking out today on behalf of the more than 1,000 independent doctors nationwide who have joined us, but also I think independent doctors in general. And there have been a lot of wonderful comments in this meeting today. I've been listening and I appreciate there's so many voices that are being shared. But I did want to share the independent doctors' point of view. And actually, there are a couple of concerns that I would like the Health IT committee to consider as they move forward with the changes that you are all talking about.

You are all well aware that private practices are burdened by the amount of time it takes to enter patient data. A lot of the time, it doesn't really benefit the doctor or the patient, but it mainly benefits third-party payors, and that's very frustrating to independent doctors, and it cuts into the time they're spending with doctors. Whatever you can do to ease that obviously is going to enhance patient care. But moreover, independent doctors feel like they are sort of on the outside of a wall because of the lack of interoperability among the EHR systems. A lot of independent doctors are often uncertain about which EHR system to buy, they are worried their investment won't mesh with the health systems in their community. This drives them to move into employment models, and we believe that it's well-documented that consolidation drives up healthcare and drives down competition, and we want to preserve, and this administration has gone on the record saying that it too wants to preserve independent practices.

But cumbersome EHR, a lack of interoperability, APIs that don't move freely or flow are a hindrance to that and are actually working against the independent doctor. So, either inadvertently or by design, EHR today is one of the drivers behind this consolidation, and it's a leading driver behind higher healthcare costs. So, I would like to really hope that we can work on interface that benefits the health system, not just the insurers and IT companies, because sometimes it comes at the expense of patients and doctors.

Just in closing up, as everyone in this room agrees, and as I believe Peter Karras pointed out earlier, better access to health information leads to better health. And on behalf of independent doctors, I would like to ask that we get a less burdensome system with greater interoperability, ease for use for both doctors and patients, and like most in this room, we want the benefit of a Health IT system that is easy to use, completely interoperable, that puts price and outcome data in the patient's hands. This of course would empower them and steer them towards lower cost, higher value care, much of which is offered by independent doctors, but they don't know the price and they can't compare, and they can't tell they're going to save a lot of money going into independent providers until they get that information right in their hands.

And it's possible. So, I just respectfully ask the committee as you work towards reforming Health IT, that you work towards a result that would promote physician autonomy, not consolidation, that would promote transparency, access, and choice, and that doesn't deliberately cloud it, and that it empowers both patients and those who care for them, and maybe less emphasis on the health systems and the insurers and the IT companies providing all this infrastructure. So, I believe Health IT will and should play a great positive role, and I want to make sure that the independent doctors and the patients are at the center of all of that. So, I know you are wrapping up and I am probably all that stands between you and a beer somewhere, so please go and thank you for listening to my two cents.

Lauren Richie

Thank you again for your comments. Operator, any other comments in the queue?

Operator

There are no more comments in the queue.

Lauren Richie

Okay. With that, just a quick reminder. Our next meeting is February 19th. It is a virtual meeting. The Annual Report Work Group will be meeting next week on the 24th. Also, if you are interested in volunteering for the Clinical and Administrative Data task force, please let me know. I'll also send out a reminder before the end of the week. And if you don't have any of the materials from today, let me know. You can also find it on HealthIT.gov. I want to thank you again for your time today, and we will talk soon. And we are adjourned. Thank you all.

Adjourn (04:17:06)