Health Information Technology Advisory Committee

Transcript September 5, 2018 Virtual Meeting

<u>Operator</u> All lines are now bridged.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Good morning, everyone. And welcome to what is now our third in person meeting. It's good to see everyone. Can you hear us? All right. We'll make sure we get our audio connected. But I hope you had a nice summer break and ready to go. We will officially call the meeting to order. We'll start with roll call. Robert Wah?

Robert Wah, Co-Chair, DXC Technology Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Carolyn Peterson. Michael Adcock?

Michael Adcock, Member, University of Mississippi Medical Center Present.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Christina Caraballo?

<u>Christina Caraballo, Member, Kizmet Health</u> Present.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Tina Esposito?

<u>Tina Esposito, Member, Advocate Health Care</u> Present.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Cynthia Fisher? Not yet, okay. Brad Gescheider? Not yet? Kate Goodrich, I believe she's going to be absent today. Valerie Grey?

Valerie Grey, Member, New York eHealth Collaborative Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Anil Jain?

Anil K. Jain, Member, IBM Watson Health Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer John Kansky?

John Kansky, Member, Indiana Health Information Exchange Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Ken Kawamoto?

Kensaku Kawamoto, Member, University of Utah Health Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Steven Lane?

Steven Lane, Member, Sutter Health Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Les Lenert?

Leslie Lenert, Member, Medical University of South Carolina Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology -

Designated Federal Officer

Arien Malec?

Arien Malec, Member, Change Healthcare Good morning.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Denni McColm?

Denni McColm, Member, Citizens Memorial Healthcare Present on the phone.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Thank you. Hi, Denni. Clem McDonald?

<u>Clem McDonald, Member, National Library of Medicine</u> Here, I'm on the phone.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Thank you, Clem. Aaron Miri?

<u>Aaron Miri, Member, Imprivata</u> Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Brett Oliver?

Brett Oliver, Member, Baptist Health Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Terry O'Malley?

<u>Terrence O'Malley, Member, Massachusetts General Hospital</u> Here on the phone.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Hi, Terry. Raj Ratwani?

Raj Ratwani, Member, MedStar Health Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Steve Ready?

<u>Steve L. Ready, Member, Norton Healthcare</u> Present on the phone.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Thank you, I see. Chesley Richards? Not yet. Okay. Patrick Soon-Shiong? Not yet. Ram Sriram?

Ram Sriram, Federal Representative, National Institute of Standards and Technology Present on the phone.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Thank you, Ram. Sasha TerMaat?

Sasha TerMaat, Member, Epic

Here.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u> Lauren Thompson? I believe she's going to be late. Andy Truscott?

Andrew Truscott, Member, Accenture Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer Sheryl Turney?

Sheryl Turney, Member, Anthem Blue Cross Blue Shield Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology -Designated Federal Officer And Denise Webb2

And Denise Webb?

<u>Denise Webb – Marshfield Clinic Health System – Co-Chair</u> Present.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Okay. And for our federal representatives – oh, I think we're got those already. Oh, hi, Cynthia. You snuck in on me. And our ONC leadership team, we have Steve Posniak, director of technology; Elise Anthony,

director of policy; John Fleming and Dr. John White. And before I turn it over to Dr. White, I just have a few reminders and logistics. First of all, the meeting is recorded, just as all of our meetings are. As you can tell, we have a number of members who are on the phone. So, for those on the phone and/or the Adobe, just feel free to pipe in, whenever you have a question or comment, and we'll make sure we get you in the cue. We will continue to use our process of using the cards for a question or comment. And if you haven't already, there's a little face button on the microphone, and that's how you will turn it on and off.

Our logistic support team will advance the slides. So, for anyone who is presenting today, just ask for the slides to be advanced for you.

Clem McDonald, Member, National Library of Medicine

This is Clem. It sounds like there's wind blowing in someone's microphone, if they could mute their phone. It's hard to hear.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

And Clem, we can hardly hear you. But I think we heard there may be some background noise. So, if we could have someone's line muted. All right. With that, I would like to introduce our deputy national coordinator, Dr. John White, for opening remarks.

Dr. John White – Deputy National Coordinator

Thanks, Lauren. Good morning, everybody. The part of Dr. Rutger today will be played by a nondescript bureaucrat, myself. Don is off coordinating with the international community, at the moment. And he sends his regrets and his gratitude to everybody for being here and working with us hard today. So, welcome to the September HITAC meeting. Thank you very much for everybody who has traveled here today and those of you who are local. My grandfather was also a public servant, and we used to talk about doing the people's business. And you have really not done the people's business, until you have traveled to a meeting in Washington at 98% humidity in 90 plus degrees. Fortunately, beautiful surroundings and endlessly scintillatingly fascinating stuff for us to talk about. So, hopefully, it will be good. We've got a very full agenda for you all.

As Elise will elaborate for us later on, there is a lot of work ahead for the committee. The metaphor that came to my mind was you are on the board, and the wave is coming, and you better start paddling because it's going to be a busy fall. So, catch that wave, and it will be a great ride. Just a couple of updates for you from ONC. ONC hosted its second interoperability forum last month. Steve Posniak will be elaborating on that for you a little bit later. But it was a well-attended, well regarded event. And I think I would not be cheerleading to say that folks who attended felt like it was a really substantive discussion. So, it was good. I look forward to you all hearing a little bit more about that. We're continuing to revise our draft trusted exchange framework with the public comments that we got and the recommendations we received from all of you. We're currently working on a notice of funding opportunity for a cooperative agreement to select a recognized coordinating entity to support the trusted exchange framework and then, subsequent common agreement. So, stay tuned for that coming announcement.

The Cures Act requires us to engage in rule making, as you all know, that will help advance interoperability and the exchange of health information and to address information blocking. We're undertaking the developing of the notes to proposed rule making to outline proposed policies related to certain provisions in the 21st Century Cures Act. These proposed policies are going to focus on implementing provisions for conditions and maintenance of certification requirements for health IT developers under the ONC Health

IT Certification Program. The voluntary certification is health IT for use by pediatric healthcare providers and other specialty care and practice settings and provisions related to information blocking and establishing definitions for reasonable and necessary activities that do not constitute information blocking. So, again, we are in the process of rule making. It is, at times, not as fast as everybody would like.

But I promise you, there are amazing folks working on it, and they are moving with all deliberative speed that they can. All of these provisions that we've talked about, we firmly believe are going to advance interoperability and support the access and exchange and use of health information through open application programming interfaces and transparent and uninhibited data sharing. So, we're really excited to be working on these and to be able to kind of lay this all out for folks in the very near future. We do still anticipate publication of the MPRN in the fall of this year. We're also, in another cures provision implemented, preparing to launch the EHR reporting program, which includes stakeholder convening to develop reporting criteria that would eventually be included in the certification program. A request for information was released in late August. Sorry, not certification program, in the reporting program.

A request for information was released in late August generating a reasonable amount of interest to provide early input. We do expect to award a contract to support the stakeholder convening to develop reporting criteria in the coming weeks. And you'll hear more about that later on today. So, again, thank you for being here. I do want to give Dr. Fleming an opportunity to speak about some of the burden reduction efforts that we have been undertaking, which is just as important to us as interoperability. So, John?

Dr. John Fleming

Okay. Thank you, John. My project, while at ONC, has been to work towards physician administrative burden relief. And a number of articles have come out, over the last couple of years, discussing that. and one area – well, really, our job has been bifurcate to two areas. One is to report to congress about suggested benefits and tactics that could improve that. The other has been to work with CMS to look at the problematic issue of documentation burden, specifically, which is generated by pay for text, which is, essentially, what's been going on for 20 years, which has been worsened by the electronic era. And as you know, proposed rule came out in July. It, basically, sets a weighted average single amount of payment for Levels 2 through 5. And it leaves the documentation to Level 2. And, hopefully, we get providers back into the business of providing documentation for the benefit of the patient rather than for the benefit of the billing.

So, I think comments close on the 10th of this month, and then, we go to final discussions and finalization of the rule. So, anyway, that's not specifically in your purview, but I thought you might be interested in what's going on there. Thank you, John.

Dr. John White – Deputy National Coordinator

All right. And with that, I would like, next, to turn it over to our executive director of policy at ONC, Elise Anthony.

Elise Anthony – Director of Policy - ONC

Good morning, everyone. So, one, thank you so much for coming all the way to DC during this wonderful weather season that we have. As John said, there's a couple of things I wanted to start with. One is I wanted to thank you for your work that you've been doing, not only coming to the meetings and this being our third in person, but all of the work that happens throughout each month on the work groups to

develop and get the draft recommendations and engagement in the states to actually bring it to these meetings. So, it's very much appreciated. I've had the opportunity to join many of those calls. And, in that regard, I want to thank all of the ONC SME leads who assist with the work groups in that work that happens behind the scenes and getting ready with the co-chairs, as well as supporting the meetings that are actually occurring.

And, of course, to Lauren Richie, to Seth Pasinski, to Ms. Cop, and the rest of the ONC team that works on a daily basis to make sure that the FACA meetings are running smoothly behind the scenes as well as kind of when we all get together. So, with that, there's a couple of things that I just wanted to highlight, in addition to what John and John said. One is, as you can see, we have a pretty full agenda today. Some of the things that we're going to be discussing are some updates, which we start out earlier on and then, a little bit more of a deep dive in the EHR reporting program, RFI, in terms of what it includes, and getting some initial feedback from the committee. From there, the goal of that RFI is to get public input to engage with the public, in terms of understanding what they think would be helpful, in terms of setting up the EHR reporting program, what type of criteria would be helpful to them, as end users, for example, in the purchasing of EHR and health IT systems.

Once we've received the comment that comes in from the public, and we get the initial feedback from the FACA here today, we'll be putting that together, sharing with the contractors that we're hoping to award in the coming weeks. And then, at that point, we would be coming back to the Federal Advisory Committee to engage on as part of the development of the actual reporting criteria. So, it's a little bit of a staged process. We want to make sure that we kind of give you not only the best opportunity to engage but that you have some of the public input at your hands as well, in terms of what we've heard. So, we'll be coming back and doing another presentation summarizing some of the comments and, obviously, making those comments available to you as well. So, that's a little bit of a start. And then, stay tuned, as we engage a little bit later on in the development. But we're really excited about being able to kick off some of the first steps related to the EHR reporting program and the key provision that congress has asked us to do under Cures.

A couple of additional things to note, in terms of the work that's been going on, the ISP Taskforce and the Annual Report Work Group, they will be continuing their work going into the fall. Both of these components are direct provisions included in Cures. The ISP Taskforce, obviously, is working on the standards use cases, and then, the Annual Report Work Group is working on the report that congress calls on the FACA to develop. Both of those work groups have been going wonderfully, and I want to thank all who have been engaged in them. It is definitely a lot of work, continuous work, to get it to the stage where we can actually bring it forward for consideration before FACA. All right. So, in addition, we talked about the EHR reporting program. And then, the interoperability forum that was held earlier this August, the point of this afternoon will really be a deep dive engagement with the FACA. What are your thoughts regarding pieces of the interoperability conversation?

Where can we think about focusing our work? What are some of the things that would be helpful for the Office of Technology, in particular, to think about, as we are kind of going forward with the interoperability agenda? And then, a couple of updates just thinking holistically about ONC and the Cures rule and the work that we're doing there. Obviously, the rule is, obviously, front and center in many folks' minds. As John said, we are working diligently on moving that through the process. In addition, there are other areas that we have engaged on and that there's been some progress on as well, which is 1) the EHR Reporting Program and starting that work. And that's a key provision that's included as well. In addition, 4006 is another component, which focuses on patient access and education. We've done a lot of work with OCR as well as folks like SAMSA, in terms of engaging with the public to make sure information about how to

access information from the patient perspective is available.

We've done some work sheets around Part 2 and how Part 2 can work in a health IT environment. And those have been available and are available on our website, as well as SAMSA's. And then, similarly, with OCR, we've been working with them on the initiatives around 4006, thinking about patient access, engaging with stakeholders who are committed to the patient access kind of agenda and goals. And in addition, we recently released the Get It, Check It, Use It resource, which I will continue to talk about because I think it's important that everyone that's able can share this information with their stakeholder communities. Whether you are a hospital, and you're able to share it with patients. Whether you are a actually also share it with your patients.

I think it's a really important tool because what it does is it provides an easy way for patients to understand how to actually get their information, how to update it, provide their input into it, patient amendments and so forth, and then, to use it as part of their care. The way it's set up, it's set up to be used on a phone. We've heard Dr. Rutger talk a lot about the importance of mobile technology and smart phones as part of the healthcare environment. So, in developing it, we really worked to make sure that the tool could be thumbed through, as it were. And there's also question in there about HIPAA application and so forth that are put together in a very easy to read way. So, I encourage folks to use that. ONC will continue to push that out as a resource and continue to work on 4006 and that element. I think that's also important, as we talk a little bit later, about some of the activities of the HITAC, one of the key areas that congress has asked the HITAC to look at and to think about is around patient access. And it's one of the priority target areas.

So, we will continue to keep you updated on some of the progress that we've made and some of the things that we're working on to help inform your work going forward. In addition, I wanted to talk a little bit about two other pieces. One is one that's in the rule. And I just want to give folks – I talk about this at the interoperability forum and got a lot of positive feedback, in terms of understanding some of the conditions of certification. Now, while I can't go in depth into the conditions of certification, which are included in the Cures rule, in terms of kind of how we're thinking about it, I did want to highlight some of them that are in there. And that's kind of, I think, an overarching view of how congress thought about the importance of certification are included in the Cares Act in Title 4. And it focuses on ONC updating the program to address these particular areas.

Things like information blocking and sharing that folks that are under the program are not taking actions regarding information blocking. It includes provisions around communication and making sure that you're not prohibiting or restricting communication about the products. One area that we've talked a lot about, and Dr. Rutger has released a great blog talking about APIs that I would encourage folks to read is it talks about special effort and ensuring that there's not special effort associated with the exchange or use of electronic health information. All of these things together, and there are several other conditions as well, are part of what we are thinking through, as we put together the rule. There are other provisions, as John has noted as well, including information blocking. These are all components that we've been working very closely to think through, develop, and taking the feedback we've heard from stakeholders along the way for many years.

So, we thank you for all that you've done, in that regard. And I think part of what John had said, in terms of being prepared for what is to come, there's a pretty full agenda coming your way, once some of these

pieces are out the door. And then, the last is the trusted exchange framework. We want to thank you, again, for all of the work that you did. Seeing the work that's been going on behind the scenes and been working, Steve and I, as well as across ONC leadership to think through the suggestions that we received back, not only from the HITAC but also from across the board, in terms of stakeholders, as we think through and get the versions ready for further discussion and engagement. So, thank you so much for all that you've done and for all that is to come. Thank you.

Robert Wah, Co-Chair, DXC Technology

Good morning, everyone. On behalf of Carolyn and myself as your co-chairs, welcome to our third in person HITAC meeting. I also want to acknowledge the public that's here in the room and also on the phone. Welcome to our HITAC meeting as well. I want to thank the ONC team for all of their help. Carolyn and I appreciate that, as we work through some of the issues of the committee. And you all have seen all of the work that has been done, specifically, for this meeting. We tried to have the material sent out to you, in a relatively timely fashion. It was challenging right before a big holiday weekend to get the materials out. And we wanted to get them to you a little bit in advance, so you had a chance to review them. We also sent a note out, I got it out a little bit late, talking a little bit about two areas that we wanted to highlight in this particular meeting. One is the interoperability discussion that's already been mentioned a couple of times.

But I'll also restate the end of that, which is that, as I've said a number of times, this federal advisory committee is different than most, in that we've had a very, I would say, proscriptive, legislative agenda given to us, which is unusual for the Advisory Committee process. And we've talked about a number of times about where can we start having a discussion about the things that we're all hearing from the travels that we have, in our separate worlds. And how can we bring those issues and interests to the HITAC committee process. So, at the end of the day, we have some time squared out for that. We may use some of the interoperability discussion time for that discussion. But I think that's an important thing that we discuss as a committee. We will not make any decisions about where we're going to go, in terms of directions, but I want to have a little bit of an open discussion hearing from all of you as HITAC members about what issues are we not talking about, from the 21st Century Cures legislation in the area of health information technology.

So, just keep that in mind, at the end of the day, we're going to have that discussion. I hope you had a chance to think a little bit about both the interoperability discussion as well as that more open discussion, at the end of the day. So, I also have the duty, I guess, to have the minutes approved. Those were distributed in the packages that went out with you on email. First, I'll say are there any corrections, additions, suggestions, edits to the materials you saw in the materials sent out? Seeing none, I'll have a motion for approval, oppose minutes. Okay. I'll just make that motion, I guess, rather than doing this big, formal thing. All of those in favor of approving the minutes, as distributed, please say aye.

<u>All</u>

Aye.

Robert Wah, Co-Chair, DXC Technology

All of those against say nay. All right. They are approved. That takes care of our administrative requirement of the minutes. And with that, I'll just say, again, thank you all for your participation and your work on the committee, particularly those of you that have taken on the responsibility to either lead or work on a taskforce. As we talked about in our first meeting in January, the taskforces are the place where much of the work of the committee gets done. It should be acknowledged how much work that really is. And we thank you for those efforts. And so, with that, I will turn it over, speaking of work groups, to our first interoperability and standards priority taskforce update, and our two chairs, Ken and Steven, I think, will lead that discussion. Will they do it from their seats? They're going to move over to the – I guess, we'll have you move over to the center stage for that.

And, again, thank you for your efforts to both the chairs as well as the members of the taskforce. But welcome, again. And with that, we'll turn it over to the taskforce leaders.

Steven Lane, Member, Sutter Health

Well, thank you so much for the opportunity to address the entire committee. We're very excited and pleased to be working on this taskforce. We've pulled together a really exciting group of members of the committee, as well as members of the public. They're represented here on this slide. As you can see, we've got a lot of different stakeholder communities represented from patient advocates to new entrance into health IT realm, and then, a lot of the folks who are represented here as well. So, we've gotten a lively start to the group and really great participation. Next slide. This reminder is the charge of our taskforce, to make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses. So, it's rather a broad charge. It's not super specific, in terms of what we are expected to do.

And we have lots of time to do it. So, we've really been starting w trying to understand the charge and understand really the interests of the participants who have come to the table to contribute. So, we have started with the task of looking at priority uses of health IT. The Cures Act specifies a list of priority uses. We spent our first meeting exploring those and discussing with the taskforce members their perspective on those uses. And then, we started to look for an initial area of focus. Kind of looking, based on the interests that were expressed by the taskforce members and trying to identify where we thought we could have the greatest impact. Our task then, as we start to work through those prioritized uses, will be to look at the standards and implementation specifications that exist, look for opportunities where those standards might be evolved or made more clear, look at the implementation of those standards. How have they or haven't they been implemented within the vendor community and our implementations?

And then, our goal is to come up, at the end, with a set of recommendations for ONC. I think we'll bring them back here, initially, and then, to ONC for industry and government action. So, that's the general approach. On the next slide, what you see is that list of 10 priority areas that we're supposed to be focused on. We did spend some time, in our second meeting, understanding Priority Area 1. That is to say, those uses that arise from the implementation of the incentive programs and the various regulatory requirements. So, we had a great presentation from CMS on that. On the next slide, that is just how we kicked off. CMS, Elizabeth Meyers, came at the end of July and gave us an excellent presentation to better understand that. And then, we began to focus in on uses or domains of use that we thought warranted the initial focus of the task force. We are considering separating into smaller work groups, in order to be able to focus on more domains of use.

But we decided to start out together. So, we did lump together various use domains. On the next slide, you can see here the initial domains that we balloted amongst the group. And we asked everyone to vote on the area that they'd like to work on first, as a collective taskforce. And as you can see, we kind of broke things into general categories. Orders and results, medication and pharmacy data, to include medication reconciliation, evidence based care for common chronic conditions, the idea of making information available, so that patients and providers can select the most appropriate care. Closed loop referrals, as we'll hear later, was a big focus at the interoperability forum. And great progress is being made in that

area. And I think it's one that, potentially, the taskforce could offer some encouragement to see that move forward. Social determinants of health, again, an important area for patients and providers and other caregivers is one where progress has been made, but the standards perhaps are not completely established or implemented in our health IT systems.

And cost transparency, both to the patients and the providers, is clearly a key issue that we've looked at. So, we, again, not to say that any of these is not important, but we wanted to start somewhere. And, again, we did a balloting process. And orders and results floated to the top. So, that's the area that we've started in initially. Obviously, that's, itself, a very broad area. One can order and have results for everything from laboratory to imaging to cardiac to pulmonary to neuro, medications. In some sense, prescriptions are a type of order. But we separated those out. And we decided, again, to start with where we thought the light was the brightest and the potential for impact could be the greatest. So, we decided to focus in, initially, on laboratory. That's an area that many of us struggle with to move discrete laboratory data with semantic interoperability between systems.

We've heard from the taskforce members, many of whom are here today, that there are real barriers, whether you're talking about the small office practice, the large system that's trying to exchange challenges with patients getting access to their results and being able to derive meaning from that. So, we think that there's a lot of opportunity there. What we are doing, presently, in the taskforce is we're collecting from the taskforce members where they see the largest problems, with regard to orders and results. We have a number of ideas where we think that we could really add value. Issues related to LOINK coding, for example, consistent use of the existing standards has arisen as an opportunity for improvement, challenges with having standardized orderables across the different domains of orders.

So, there are a number of opportunities that we see, but we're collecting the input of the taskforce, and then, we're also going to be working closely with the ONC staff to take a deeper dive into the existing standards, understanding those in a detailed way, and looking for opportunities to provide input on that.

Kensaku Kawamoto, Member, University of Utah Health

Steven, if I could add, too. So, I think this shows the initial first pass of the taskforce members giving their initial sense, after brief discussion of where the focus might be placed. But we're very interested in everyone's thoughts on what are the problems that folks are facing with interoperability and import clinical use cases, and what are potential solutions. Keeping in mind that some of the large levers that were available in prior eras of meaningful use, etc., are not ones that we'll be really reaching to. So, we'd really welcome thoughts, not only on problems, but really practical solutions that we can move forward on. I think that will be a big win, if we can find things that we can do to solve some of these problems we're facing.

Steven Lane, Member, Sutter Health

Absolutely. And I don't recall if there's one more slide here. There we go. So, again, the determination by the group was to start with orders and results to use the entire taskforce collectively to do that to develop an initial methodology for approach. So, we're going to be looking, over the next few meetings, at that. And then, looking at the potential of perhaps taking two of the next domain areas and separating out into smaller groups, and similarly, working through them. So, we're certainly open to input, questions from the HITAC and would welcome any feedback on the direction that we're taking.

Robert Wah, Co-Chair, DXC Technology

Comments, questions for the taskforce leaders? Arien?

Arien Malec, Member, Change Healthcare

A comment. In my time working with ONC and on a variety of federal advisory committees, I've seen the health IT community be able to make significant progress by focusing in a few areas and working in collaboration with the broad community, particular health IT developers, provider organizations, working in conjunction with specific policy levers from ONC and CMS. We can do a lot of work. Where we get into trouble, sometimes, our appetite is bigger than our stomach. So, where we get in trouble is where we try to take on too much. So, I really commend the work of the taskforce urge us as a community and a federal advisory committee to narrow our focus. And another consideration, the Standards Priority Taskforce is really looking at new standards development or high priority areas. We've got a number of areas that are in flight that need some finishing. In particular, the move to ban the facts or can the facts or whatever the hash tag is, axe the facts, thank you.

We took on some of that work with directs. We are definitely not there. We have some significant issues with the overall end to end usability of existing forms of exchange, particularly receipt of the infamous 45 page consolidated CDA and the need to have more focused clinical notes in the context of exchanges of information. So, this is more just an editorial that 1) we're better off narrowing a focus on a few priority areas, in convening the entire stakeholder community, in particular, the developers who need to implement them and the provider organizations who need to use them around those few priorities. And 2) in some areas that are high priority, for the nation, we've got some work in flight that warrants finishing and warrants some targeted improvement in order to better score the goal that we were in flight kicking the ball down the field on. Thank you.

Steven Lane, Member, Sutter Health

Arien, if I can just respond. I think, depending on the domain, we're going to see the needs as being quite different. Certainly, in the area of social determinants of health, that's an area where the standards really are not well developed. There have been IOM reports, and vendors have been starting in on that. But I think we are, as you said, talking about potentially new standards. In other areas, it's really about well established standards like direct that need to be evolved, for example, to support the referrals work flows in the direction that 360X is already moving. And then, in the orders and results, it's kind of a combination where we have a lot of very well established standards that simply need to be implemented more consistently. So, I think it's really going to depend on the area, as to what we find. I also wanted to make another comment that we left out earlier, which is that Terry O'Malley was one of the co-chairs of the USCDI task force, which is now on hiatus.

And he is on our task force as well. And we really have discussed the fact that the data elements, that is to say with the focus of the USCDI, is very important. And the standards really work in parallel, the standards for what's being transported and how and then, the individual elements that need to be transported. So, we're really trying to make sure that those task forces don't overlap too much but that they stay aligned. And that the work that we're doing in the standards task force will, hopefully, support future work by USCDI.

Kensaku Kawamoto, Member, University of Utah Health

Maybe I can add to that. I completely agree with the prioritization. I think we're looking at the task force and members of the HITAC to help guide that. I think a year will go by really quickly. And part of the reason why we only have three meetings scheduled for orders and results is really to give us the sense that we really need to come up with something that is very achievable quickly. I'll take one domain, and I think I'll follow up on the thought of prioritization. So, for example, the notion of evidence based care for common chronic conditions, that can be a lot of things. Diabetes, hypertension, etc. But I think we really want to focus and look at what's achievable. So, if you look at something like lung cancer deaths, the No. 1 cause of death for both men and women from cancer, in order to prevent it, there's a screening called lung cancer, low dose CT screening, which is projected to save more lives than mammograms for breast cancer but currently has less than a 5% adoption rate in the US.

And part of it is because, I think, in order to tell who is eligible, you need to know who many pack years people are smoking. But the current US core data set only includes whether a patient is a smoker, not how pack years they've been smoking, even if it's been collected on record. So, I think we can find low hanging, achievable areas like that to say this is a really important use. All we need to do is share the information that you're already collecting in your EHRs can be shared. So, I use that as just one example. But if you can use those kinds of examples as these kinds of very granular, achievable priorities, and we mix that with sort of more generic priorities, I think we can come up with things that I think are very achievable, within our scope.

Robert Wah, Co-Chair, DXC Technology

Other comments or questions for the task force? I also want to make sure we remember the folks on the phone, if you have questions or comments, please speak up as well. Okay. All right. Seeing none, I guess we'll take it back over to talk about the annual report. Is that what we're going to do? So, thank you both, Ken and Steven. And we're going to change chairs here a little bit to the chairs of the committee on the annual report work group, Aaron and Carolyn. Thank you both, again, for chairing this. And I'll turn it over to you, Carolyn and Aaron.

Aaron Miri, Member, Imprivata

Fantastic. Good morning. Thank you. I'm Aaron Miri. I'm here with my esteemed colleague, Carolyn to talk through the annual report. And so, what we want to do today is sort of walk you through kind of what the team has been working through, sort of what the membership looks like, the scope of what we're charged with doing. The priority target areas are the objectives and benchmarks for this year, where we are to date, and kind of what our work plan and schedule is. Being that it's the first pass at doing the annual report, a lot of things, as we iterate and meet and talk through things, things change, but this is where we stand, as of today. Next slide. All right. So, our membership. This is a work group. I've been on a lot of task forces before. This is limited really to the HITAC members, as well as ONC staff. I do want to up front say thank you to the ONC staff.

They have been amazing at helping giving us guidance through this. Again, this is the first time this group has ever been convened. So, we're also all learning things from each other as much as possible. But good representation and great discussion with the members here all represented on this page. Next slide. So, our scope, overarching. The work group will inform, contribute, and review the draft and final versions of the HITAC Annual Report to be submitted to the secretary and congress via our national coordinator. As part of their report, the work group will track ongoing HITAC progress. Think of it as a benchmark and report card. How are we measuring up against what we set out to achieve? In detail, we're going to provide specific feedback on the content as required of the 21st Century Cures, including an analysis of our progress, our assessment on the health IT infrastructure, and advancements in priority target areas. Analysis of any gaps in policies and resources.

And, of course, something that Robert had mentioned a little earlier today, the ideas for potential HITAC activities to address any identified gaps that we, as a committee, feel is appropriate to go ask that we go after. Next slide. So, as noted in Section 403 of 21st Century Cures, we're supposed to look at the following

areas. 1) Interoperability, making sure that we do achieve health information technology infrastructure that allows for electronic access in exchange and use of health IT and health information. 2) Subjects that are really near and dear to my heart, privacy and security. The promotion and protection of privacy and security and health information and health IT and continuing to further that work. 3) Patient access and the facilitation of secure access by an individual and their caregivers to individuals' protected health information.

And, again, 4) we're going to keep touching upon this concept of any other target area, to the above target areas, that the HITAC identifies as an appropriate area to be considered on a temporary basis, with adequate notice of congress. Next slide. All right. So, this is a little bit busier slide, but this is kind of a great visualization depiction that, again, kudos to the ONC team for helping us come up with this, as we talk through it. But really, how this works is ONC charges HITAC in a priority target area. We talk about it. We work through it. We deliver our recommendations. ONC considers those recommendations and activities. Then, we assess the advancements in the priority target areas, including federal, state, and private sector. HITAC identifies any gaps in policy and resources. Again, what are those opportunities out there. And then, HITAC, we know, annual report then informs any charges to the HITAC.

So, it's kind of this circle of fulfillment annually, where we're continually looking at topics, bringing it to goal, further advancement and consideration, and really showing the work this committee is doing. There's a number of very complicated subjects and topics out there. So, we don't want to try to boil the ocean. We want to be very specific to what the letter of the law states. But we also want to be able that we're able to tackle some of these very immediate topics out there. Next slide. All right. So, if you look at this from a 2D crosswalk, again, hats off to ONC for the great help visualizing this. But really, what we're trying to do is come up with a way of you look on the left hand side there, from the objectives, what are ONC objectives? Publish proposed regulation, publish the draft TEF, consider standards and specifications, some benchmarks. And we're going to go into detail about all of these, the ONC benchmarks, proposed regulation published, draft TEF published, standards and specifications considered, and, of course, the charges from the HITAC.

Did we look at and talk about the trusted exchange framework? Have we dealt with the USCDI and talked about it? Have we talked about interoperability standards and priorities? And, again, additional initiatives. And then, on each of those, we're looking at an impact sort of that high, medium, low. How are we doing? Is the work we're doing actually making meaningful impact and helping us progress down the road? Next slide. So, to make it even further complicated, the way to really look at this, when you start taking all of the various input from the industry, is sort of a Rubik's Cube. Each access representing what are the target areas, what are the recommendations, and then, the stakeholders. We spent some time, as a group, talking about the various stakeholders to really look at this. And it was a lot of good discussion from several folks about that an emerging voice today may be somebody very key in the future. So, we have to make sure that we consider even the emerging voices within health IT, so that we capture full dimension and full spec of what's really going on out there.

What are the topics? What are the challenges? What are those issues we need to work through? So, I encourage all of us, as a larger HITAC, as we talk about these things, to really think about it from that global perspective as to are there less represented industries out there or less represented voices out there within our industry that we want to make sure we capture their thoughts. And, at this point, I'll turn it to Carolyn.

Carolyn Petersen, Co-Chair, Individual

Thanks, Aaron. So, now, we start back into the slides full of text and bullet points, our favorites. The next slide, please. We'll be looking here at the ONC objectives and benchmarks. One thing to be aware of is this language issue we have. As we go through all of the slides, and when you look at the legislation, it uses the word benchmarks. And so, we have to use that, in all of our materials. This year, we're actually doing baselines because it's the first year. So, don't be confused, but we have to follow what's in the law. So, for the purpose of HITAC Annual Report, Section 403 states that the national coordinator, in collaboration with the secretary, shall establish and update as appropriate objectives and benchmarks for advancing and measuring the advancement of the priority target areas. That's kind of the formal way of talking about what Aaron's been talking about.

ONC sets the objectives and the benchmarks that we're looking to use in the development of this report. These will align with the priority target areas. And ONC is to establish a consistent measurement process over time. But we can choose to update the objectives and the benchmarks, if that's needed. ONC is open to feedback from HITAC members about the objectives in benchmarks. And we actually encourage your full participation in that discussion, something we'll be touching on this afternoon. This is not sort of a procedural formality. We really do want your feedback. ONC's objectives, on the next slide, for fiscal year 2018, ONC has several. First, to publish proposed regulation for the implementation of the health IT provisions of the 21st Century Cures Act. This would be the advancing proposals related to application program interfaces and identifying behaviors that are not considered information blocking.

The second objective, to publish the draft trusted exchange framework to improve data sharing across health information networks. And the third objective, to consider standards and implementation specifications to support priority uses of health IT, based on the HITAC recommendations, encouraging everyone to implement and use as applicable to whatever their interoperability needs are. Next slide, please. With regard to the benchmarks/baselines for fiscal year 2018, we have also several benchmarks. We proposed regulation covering APIs, info blocking, and other health IT topics to be published, a publication of the draft trusted exchange framework, and standards and specifications to promote priority uses considered. And, again, the sub bullet points just kind of address all of those things we've been talking about all year. Next slide, please. So, here's a structure that we're proposing for the annual report. Let's start with an executive summary and provide an overview. Describe what HITAC has done this fiscal year.

Do a landscape analysis of the health IT infrastructure followed by a gap analysis of the infrastructure. Will provide recommendations for addressing health IT infrastructure gaps. Will include suggestions for additional HITAC initiatives. There will be a conclusion. And then, we'll have some appendices that include things like definitions and a restatement of gathering, so to speak, of information and resources that ONC has previously published. Things like the tool kits and other documents that might be of use to HITAC, to congress, and to other providers, and the general public going forward in future years. Next slide, please. So, on this landscape analysis, the structure will be an overview looking at our legislative requirements and current ONC and HITAC priorities. And then, for each target priority target area, background and the current state, looking at some recent progress and various topics, and showing examples from stakeholder groups.

Next slide, please. On the proposed gap analysis structure, for each of the priority target areas, the gaps identified, opportunities identified, and then, recommendations for addressing these gaps and opportunities. Next slide, thank you. So, this is a very complicated way of looking at all of the meetings and how we're addressing this work plan. The bottom line is that we're doing it in a flow, cascade kind of approach starting in the beginning and giving the full HITAC opportunities to review things as we're working on the next ones. If we could look at the next slide, we could break this out in ways that are a

little easier to understand. For our work group itself, we've already had three meetings talking about the overall structure in the landscape analysis and gap analysis. Later this month, we'll be talking about the landscape analysis. In October, we have the gap analysis and the outline of HITAC's work this year. In November, further work on the year-end review and the overall report outline. In December, we're expecting to review and work through the final draft.

And then, in the spring, we'll be working on the fiscal year 2019 annual report. Next slide, please. So, the work for HITAC is really included on this slide. This is your review schedule. Today, we're just talking, generally, about how we're approaching this task. At our meeting next month, you'll have the opportunity to review and discuss the landscape analysis and the gap analysis. In November, we'll be describing our work in progress, our work for fiscal year 2018, looking at what we've done for the year. In January, you'll have a chance to review the annual report. We know you're busy in December, so we're not going to try to push it or do more, even though we'll be busy paddling behind the scenes. And then, in the winter and spring, the HITAC will be reviewing and we hope approving this annual report. It will be submitted to the HHS secretary, and then, eventually, to congress.

And now, we'd like to take any questions or comments you have briefly, recognizing that we have opportunities for a fuller discussion this afternoon and also that you can attend our work group meetings because that information is public and you're able to call in and do that.

Robert Wah, Co-Chair, DXC Technology

John?

Dr. John White – Deputy National Coordinator

Thank you. Recognizing that the task force hasn't had the opportunity yet to talk about the landscape gap analysis, can you comment at all what you're envisioning will define the desired future state and, therefore, the gaps?

Carolyn Petersen, Co-Chair, Individual

I wouldn't say that we defined an ideal future state, at this point, or looked particularly at a goal that we think the whole committee should be at. At this point, we are looking at items that have been identified broadly through the committee work during the year and looking for things that haven't been achieved or areas we feel that further progress is necessary to further ONC and congress's broad goals and objectives.

Aaron Miri, Member, Imprivata

Yeah. I would also say that we're sort of in the information gathering stage right now, as well as ONC is doing some great background work, right now, for us pulling up through comments they've received or research and others they've gone into to figure out those dimensions of the vertical that need to be further addressed. But that goes back to the importance of, as members of HITAC, for each of you to please let us know, let the committee know, speak up and say hey, near and dear and passionate to me is interoperability. And here's where I see it in the future and how it could benefit health exchange. Those types of insight and those expert opinions each of you have and bring to the table is precisely what we need to inform this report, which, ultimately, will help envision what this should look like at the end.

Carolyn Petersen, Co-Chair, Individual

And that's why we have built into the future meetings this fall opportunities to review and comment on drafts of things because we really do see it as a committee project and committee product that we are

kind of quarterbacking, but it represents the committee's perspective, as a whole.

Robert Wah, Co-Chair, DXC Technology Elise?

Elise Anthony – Director of Policy - ONC

Thank you. So, I just wanted to thank you again for this work. I think it's critically important. And to Michelle Murray who is the ONC staff support for this work. One of the things just to keep in mind, as we're doing this, is not only the importance of the annual report and the gap analysis that will inform the annual report to our current work, this year, next year that ONC is doing, but it's importance to our work on a going forward basis five, six years down the line, when we think about strategic planning as an organization and Dr. Rutger and Dr. White are thinking through what needs to happen to move interoperability forward, to move patient access, to support general exchange. The work of the annual report will help us think about that on a longer scale. So, I want to thank you for that work, and the gap analysis I think will be key to that.

The other point I wanted to make was I think the materials and how you set it up is going to be really helpful. Identifying how the benchmarks crosswalk to the priority areas is really important I think not only for the work group as they're thinking this through but also for ONC. When we are working on things like the rule or TEFCA, for example, we think about are we touching on the target areas that congress has identified as critical? Are we hitting on patient access? Are we touching on privacy and security and exchange and interoperability? So, we try to make sure we're hitting all of those pieces. And as Dr. Rutger moves towards the final for TEFCA, for example, those are things that I know continue to be prioritized as his goals. So, when you're eventually checking or deciding whether to check or not to check on those boxes, that also helps us to know, for us, in terms of whether we've hit those marks. So, thank you.

Robert Wah, Co-Chair, DXC Technology

I didn't see the order, but I'll go to Ken first. Maybe Denise, were you first? Go ahead. A little red light comes on. That little raisin next to it, or not.

Denise Webb – Marshfield Clinic Health System – Co-Chair

Thank you. Denise Webb. Thank you for all of your work on this. And the structure makes sense and the approach. The one area that's challenging me though is around that term benchmark because, when I think about benchmarks, I think about metrics or measurements. And so, ONC clearly has to have a set of objectives around the priority areas. But it seems to me that congress would be interested in measurements around how are we moving the needle in each of those areas. And the benchmarks that were listed in the slides seem more to me like, as far as our work as a committee, more in terms of meeting certain work plan milestones. So, that's just some constructive feedback. I'm not sure how we address that. But I think we need to have some concrete measurement, in terms of baseline and then, targets on where we're going in each of those priority areas. And maybe that will come out of the landscape assessment and gap analysis. Thank you.

Aaron Miri, Member, Imprivata

I think, Denise, you're spot on with your comments there. I do know that, as Carolyn mentioned, this is kind of that baseline activity for the first pass. And to your point, benchmark is a word that we talked about extensively, but it's called out specifically. So, we have to use that same language. But to your point, what does it actually mean? And so, love to get your feedback, particularly as this evolves and iterates, does this pass the sniff test, and does this really make sense to show and really demonstrate that we are

moving the needle of the landscape because that is what we, ultimately, want to do as a committee is show iterative progress. So, great comments.

Robert Wah, Co-Chair, DXC Technology Ken?

Kensaku Kawamoto, Member, University of Utah Health

Thanks. I think the support is great. And I think the really interesting part is what is the future vision. And I don't know exactly where that should work. Maybe it's another activity for the HITAC. But I think that's really important. I think, in the ISP task force, we've been focused a lot on what's achievable, which sometimes takes us away from the vision. And I think it is the job of this committee to discuss those kinds of things. And we can leverage other things, for example, going on in the National Academy of Medicine, envision the future of EHR, etc. But I would really like to advocate for that. I think it's in our minds. It's things like clinicians, caregivers. It's a joy to use the EHR. You're just amazed at what it can do because it makes what you want to do so easy. And you don't have to redo things. And it's not a source of frustration. It's a source of joy that you look forward to using that.

Patients get all of the care that's the best evidence in this country is identified as needed, and nobody dies because our current statistics of about half of the care that we should be getting we're not getting. There's a lot of good evidence about those kinds of things. And I think we have that vision. And I think it would be very useful if we can set that vision that maybe it's not achievable in a year or two years, but hopefully, it won't be another 15 years from now we're saying, again, how do we get there.

Robert Wah, Co-Chair, DXC Technology

Any other comments? Andrew?

Andrew Truscott, Member, Accenture

The other thing was off. Hey, guys. Great job. Thanks for taking this forward. It takes a lot of gusto to actually want to take on a job like this one that's going to be very much in the public eye, so thank you. A couple of points. First up, with the current landscape, much has been written about current landscape over many, many years. Not much seems to change between each of those reports. I wouldn't focus too much effort on those. It's about the gaps. It's about where we need to make progress. And the second point, when it comes to targets, I think Denise is starting to get there, let's just be clear about what we think is realistic and what's a stretch target. And, actually, give ourselves something empirical to measure against, as opposed to it would be nice if – well, we could have received that, etc.

And let's be critical of ourselves because we, as a community, are really good about making aspirational statements and really good about not hitting them.

Carolyn Petersen, Co-Chair, Individual Points well taken. Thank you.

<u>Clem McDonald, Member, National Library of Medicine</u> This is Clem. Could I get my hand up?

<u>Robert Wah, Co-Chair, DXC Technology</u> Sure, Clem. Just hold on one second. We've got one more here in the room. Sheryl?

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

Thank you, Sheryl Turney. I would like to say I think that you've laid out a great structure for the development of the annual report. The one thing I would like to sort of challenge the group to quantify maybe a little bit better or provide a better picture, it's because of something that I did within my own organization. I represent Anthem. And we're part of the Blue Cross Blue Shield Association. And one of the interesting things is that when you talk about interoperability, everyone we work with defines it differently. And it's based on their interaction in the healthcare model. So, I do think that, from the perspective of this annual report, we should define interoperability the way we're delivering the solutions because I think that's going to be very important. And interestingly, just to bring up a point, when I asked various people in my stakeholder group to define interoperability, there were many pictures that looked very different.

And the solution that would apply to any one of those pictures is going to be very different. And one of the things that was common though among all of them was that the patient ended up having to deal with hundreds of connections in the healthcare landscape, which I don't think is the delivery that we're looking for. And what I tried to clarify because that was a point I wanted to make in my exercise, is that interoperability really should be patient centric. And from the patient's perspective, hopefully, in the future, it will be immaterial like the web where it comes from. But I'll be able to get the right information to deal with my problem with my doctor in one place. To me, that should be all of our goals because that satisfies all of the plains. But then, at the same time, physicians need to be properly compensated for the work that they have to do. And, personally, I can bring to the table where I've had physicians support my daughter's condition who went unpaid because there was no code, there was no process for physicians from Yale, UCI, and Mayo Clinic to work together on something because, currently, in today's world that wasn't compensated.

And we had many conference calls discussing a particular condition. I was very happy to see, in the CMS rules, more of that coming forward for the future because that is necessary. And also, in terms of research. We need to embrace and demonstrate, with the interoperability picture that we show, the importance of research. I've spoken about this before, and I'll speak about it again, because it's very pertinent. The more participants participate in research, the more solutions they will have in their lifetime for their issue. And I have use cases that demonstrate that as well. But then, they need to be concerned that the information they're providing protects their identity but still is used for that. So, in the interoperability picture, really where does that all fit in? There's still such a struggle between what data people can use and what data they cannot use, based on protecting individual's identity. And I think that needs to have a place, in this picture.

And today, it's not clear. We still have many challenges that we deal with within our own company and our research arm, in terms of what we are allowed to do with the data, what we can do, even with patient's permission. There's constant struggles. So, I do think that's something, as well, that needs to be in that picture.

Carolyn Petersen, Co-Chair, Individual

Thanks, Sheryl. I think that your point about the definition of interoperability and the importance of HITAC kind of figuring out what it means for us and how we use it as a starting point is really a good point well taken. I know, in one of our calls, we kind of joked that, since there are so many definitions of interoperability, maybe one of the appendices should be a list of all of the different definitions and to kind of show some of the implications and the breadth of all of that work and really how much there is to be accomplished, frankly. I think, with regard to more of your comments about interoperability itself, I'm

going to put that on hold, until at least we've had Steve review the interoperability forum. And I think that's a potentially really good topic for this afternoon's discussions as a group. We're trying to capture what's happening, rather than to make action itself through the annual report.

Aaron Miri, Member, Imprivata

Yeah. Spot on comments, and I will also further add, and it's something that's near and dear to my heart that I've served on a lot of different FACAs over the years, is making sure some of those work products that came out of those other task forces somehow make it into or are referenced in the annual report. Case and point, even the play book that was put together by the ONC is excellent. But a lot of people who may be new don't realize oh, this is out there as a resource. So, we can start tying back to some of those work products and show hey, this is out there. If you're curious, this is what the API task force came up with a great guidance from the ONC and the OCR about what is considered under HIPAA, what's not under HIPAA, those kinds of things. All of these different bullets to go look at. It really starts giving a true comprehensive picture of the work that's been done. So, great comments. Thank you for them.

Robert Wah, Co-Chair, DXC Technology

Clem, I appreciate your patience. Elise had a quick comment in response to Sheryl. So, I'll go to that first, and then, we'll come back to Clem.

Elise Anthony – Director of Policy - ONC

Yes, I just want to quickly note, in 4003, there is a definition that congress has laid out for interoperability. And I'm happy to share that with the full committee. It's a three pronged definition. First, part focuses on enabling the secured exchange of electronic health information. The second part allows for complete access exchange and use. And the third part focuses on not constituting information blocking. So, that's what congress has laid out. It's in 4003, and I did definitely give the short version. There's a little bit more text attached to that. But I did want to make sure that the committee was aware of that provision as well.

Carolyn Petersen, Co-Chair, Individual

Thanks, Elise.

Robert Wah, Co-Chair, DXC Technology

This is what happens, when you put this under your pillow every night. Clem?

Clem McDonald, Member, National Library of Medicine

Well, I'd like to not try to define anything because interoperability is such a big space. But I'd like to propose that our goal, a goal, would be to push data to all patients as it's done, all test results to patients as it's done in a fileable form, which means it needs some minimal structure and some minimal coding. And I think we can make people happy that way, and I think it's doable. Is my voice heard?

Robert Wah, Co-Chair, DXC Technology Yes, Clem.

<u>Clem McDonald, Member, National Library of Medicine</u> Okay. That's all I wanted to say.

Robert Wah, Co-Chair, DXC Technology Thanks, Clem.

Carolyn Petersen, Co-Chair, Individual

Let's key it up for the afternoon, Robert.

Robert Wah, Co-Chair, DXC Technology

Yeah. I think that part of the discussion might well be also served under the discussion of the interoperability forum and/or the interoperability longer discussion in the afternoon, but thank you for that, Clem. Any other comments from our chairs?

Aaron Miri, Member, Imprivata Thanks for your time.

Carolyn Petersen, Co-Chair, Individual

Thank you.

Robert Wah, Co-Chair, DXC Technology

All right. Again, thank you for your work on this. We're a little bit off the schedule that we had proposed. I don't feel completely necessary that we have to, by the minute, follow our schedule. But we're just a little bit behind. So, I'll turn it over to Lauren to introduce our next set of speakers.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> Designated Federal Officer

Great. Thank you, Robert. So, at this point, we will hear form Seth Pasinski who is the director of strategic planning and coordination division at ONC, and Michael Whitty who is the program lead for the EHR reporting program.

Seth Pasinski – Director of Strategic Planning and Coordination Division - ONC

Hello. Thank you. Hello, thanks for the opportunity to present and looking forward to the discussion. My name is Seth Pasinski, as Lauren mentioned, the director of strategic planning and coordination division at ONC presenting with Michael Whitty who is the EHR reporting program lead. So, the intent really is just to introduce you to this new program that we're taking a first step to implement. We released a request for information to begin to gather public input. So, we look forward to getting your initial feedback today on some of the questions we asked in the request for information but anticipate our ongoing engagement interaction with you throughout the development of the EHR reporting criteria, which is our first phase of the program. As Elise mentioned at the beginning of the meeting, we're implementing the 21st Century Cures Act.

And one of the points of emphasis in the act is transparency around information on interoperability, usability, and security. And in particular, through two mechanisms. One is the rule making on conditions of certifications that, again, Elise mentioned. And the other is through engaging stakeholders to develop and implement the EHR reporting program. And the intent of that program is to make available public information comparing certified health IT and the information form the source that would include both users of the technology as well as developers of certified health IT. A point of emphasis in the request for information, as we think about how to implement the program, is around making sure that we leverage existing sources of data and also get feedback on ways to minimize any potential burden in participating in the program on both the behalf of certified health IT users and developers. And, again, we're taking a first step in implementing the program and looking forward to getting your feedback on it today.

With that, I'll turn it over to Michael Whitty who is going to just give us an overview of the request for

information.

Michael Whitty – Program Lead EHR Reporting Program

Hi, thank you very much, Seth. So, as we've been discussing, ONC is very focused on implementing the provisions of the Cures Act that are designed to improve health IT and interoperability and to reduce provider burden. There's a number of topics in the Cures Act, as we've discussed, in terms of patient access and burden reduction and enhancing the certification progress. But there's also the specific thing, Section 4002C that calls for the creation of an EHR reporting program to provide publicly available comparative information about certified health IT products. The program is going to, ultimately, reflect input from the developers of certified health IT and voluntary input from users, providers, patients, etc., about criteria related to security, usability, interoperability, conformance certification, and other areas that stakeholders say are appropriate.

The Cures Act requires that ONC engage the public in a transparent process to develop what those criteria should, ultimately, be and how the program should work. Next slide, please. So, the real background is that, in 2016, there was a report for congress on feasibility of mechanisms to assist providers in comparing and selecting certified EHR technology products, which is based on market analysis and subject matter research and including a task force of the then HIT advisory committees, the certified technology comparison task force. So, we went ahead, and we released the RFI recently, which is, as I've said, the first step in developing these criteria and receiving inputs from the public on what would be useful and implementable from the perspective both of users and purchase and acquisition decision makers and also on the part of developers to avoid being overly burdensome to them. We will be – the Cures Act requires – next slide, please.

Yeah. So, the RFI is seeking input on reporting criteria that have the characteristics that you see on the screen in front of you. They want to be – we want to show distinct, measurable differences between products and describe functionalities that stakeholders are interested in looking at, how is this going to help me do my job, that are going to be timely and reliable and comparable across products and not overly burdensome to any developer but especially to small and start up developers. And that inform not only the acquisition, upgrade, and customization decisions but also allow some trending, so that we can see where the industry is moving and where, from a more strategic perspective, things are going and can be led better. Next slide, please. So, the request for information is in a number of different topic areas, including we have two sections, basically. One is these cross cutting areas that you see in front of you that are really about the overall conceptual frameworks of how the reporting criteria should be designed, what they should look like.

And what are existing data sources that we can use that already exist that we can repurpose for this program? What data should be reported or contributed by whom? And how they should look. Then, there's the categories for the reporting program, and those are the categories that you see in front of you that are listed in the Cures Act. Security, usability, and user centered design, interoperability, conformance certification testing, and other categories, as we said, that are appropriate to measure the performance of these technologies. Next slide, please. So, the Cures Act requires a number of steps. First of all, it requires that we do this stakeholder driven process. And it requires that we let a contract or fund an independent entity to develop these criteria using stakeholder input and to convene stakeholders and to develop draft criteria that will then be published for formal public comment. So, we have next steps here for the HITAC, which is that initial feedback.

We're talking to you all today, and we hope to hear from your initial thoughts and feedback. And then, as

you can see here, we're going to provide you a summary later of, as Elise mentioned, the comments that come in on the RFI that went out and of the public feedback that the independent entity that we're going to fund will receive over the next many months. This is going to be a long process. Once those comments from the public and the stakeholder engagement process goes through, the independent entity is going to come up with some draft criteria proposals. And we're going to come back to the HITAC, and we're going to present that whole process to you all again, including those draft criteria. And that's when we're going to seek your recommendations on what those draft criteria look like, with the context of all that stakeholder engagement that has been done before. And we will seek your comments, at the same time that the public are providing their comments to finalize those draft criteria that will then be incorporated into what becomes the EHR reporting program.

I think that the next slide is, just to sum up, really this is the first step right now that we're doing in the RFI. The broadest possible public input before the independent ND goes and takes a deeper dive into what folks need out in the world. And you can see the information as to where you can find the RFI and submit public comments and the due date there. I think Seth is going to take you back through a little bit of the mechanics of that.

Seth Pasinski – Director of Strategic Planning and Coordination Division - ONC

So, just to make folks aware of the deadline for comments is October 17. And, certainly, in addition to any feedback or comments discussed today, at this meeting, members are welcome to, as individuals, submit for yourself or on behalf of your organizations through the formal RFI comment process as well. And I think, with that, we'll turn it back to the chairs to take us through some time for discussion and comments.

Robert Wah, Co-Chair, DXC Technology

Great. Thanks for that. I saw three hands go up all at once over there. I don't know if I got it in the right order or not. I'll start with John. I think you were first, but I'm not sure.

Dr. John White – Deputy National Coordinator

So, it's, obviously, not congress's intent that the federal government take the position on one product being better than another stating that. I'm trying to ask how would you describe, kind of at a cocktail party, the intent of this. And sorry for the naïve question and maybe silly to ask a bunch of health IT people, but is anybody aware of a precedent in another agency of the federal government doing a similar analysis in another industry?

Seth Pasinski – Director of Strategic Planning and Coordination Division - ONC

I think, just on the first point, I think, in the law, and I think in general, the main point is just transparency of the information. So, to your point, not from a government position favoring one product over another. But just making available the comparative information, so that there's improved transparency. And, again, the requirement really is in those four specific categories that are listed. But, certainly, one of the things we'll be interested to hear from of those areas of interoperability as well as usability, what would be the particular areas of most interest, with regards to this program and where it potentially could address some of those transparencies or gaps in existing information.

Robert Wah, Co-Chair, DXC Technology

Thanks. Ken?

Kensaku Kawamoto, Member, University of Utah Health

It's useful along those lines to think of the analogy is this like a consumer reports kind of thing that's going

to help you buy a car. But I think we've already bought the car, for the most part, in this country. So, not maybe the opportune analogy. Maybe this is like an annual physical for us because we're not going to buy another one of us to change into. We bought what we bought, but what can we do? So, I think, along those lines, it seems like it would be most helpful, if it's not just saying this has a higher usability rating than this because we already bought ours, and we're not going to change it because of this. Maybe if it's around what you actually find. So, in users of this system, they found that this medication reconciliation screen was causing errors and issues. And it's something that you can actually use to make change because, if you do qualitative analyses, you can get to those.

So, maybe just thinking like can we get to something actionable that the vendors can use to improve their systems, rather than just saying A is better than B kind of thing?

Michael Whitty – Program Lead EHR Reporting Program

Thanks. I think that's actually part of the second part is that the first part is that informing the acquisition and upgrade decision. But I think the second part of the intent that's in there is that market trend, that trending concept. I think that's very helpful there, thank you.

Robert Wah, Co-Chair, DXC Technology

Steven?

Steven Lane, Member, Sutter Health

Yeah. I really want to thank you guys for taking on this work. I think it's really important. And I think it really can help us, not only in the acquisition decisions, again, many of which have already been made, but implementation as well. I think the providers are already using a system. And the more they know about what those capabilities are, I think will be most helpful. You make a point about avoiding burden through this, burden to providers, burden to vendors. There's going to be a burden. We can't get anything meaningful out, if we don't ask someone to do something. So, while I appreciate the appeal of that concept, I think we have to question it. I think most of us understand that the burden to providers is already pretty high. And asking providers to do something more, an unfunded mandate, is going to be tough.

With vendors, even small vendors, this is kind of the cost of doing business. So, I think that what I think makes sense is asking the vendors to bake these tools into their systems, so that it's not extra work to be able to do this but that the reporting, the metrics that support this effort, really just show up automatically in the process of use. And I think that that can be done. When you're looking at security issues, there are going to be how many breaches are there. How many data losses have there been? How many unanticipated down times have there been? There are some key metrics that you can just answer the question. It's not a burden to do that. It's just you have to do that. With usability, again, there are some key issues. How many errors occur? Ken made a point about this. If clinicians are doing the wrong thing, that suggests that the system isn't supporting them and doing the right thing. So, you can look for these artifacts, again, without creating undo burden.

I know some of the systems are already measuring how much time is a clinician spending interacting with the patient or interacting with the patient's data, as opposed to doing more kind of busy administrative work and those things. If we can develop standard metrics that we then ask all of the vendors to report on that seems very logical. And with regard to interoperability, there's no question that you couldn't ask the system how frequently do they have successful patient queries. What's the volume of the data exchanged? How much of that data is incorporated at a discrete level? And how much of it is actually used by clinicians to really impact care? And there have been other discussions about how to measure

interoperability. It seems we should apply what we've learned in those discussions into this effort. So, thank you for doing that.

Robert Wah, Co-Chair, DXC Technology Thanks, Steven. I'm going to go over here, Aaron?

Aaron Miri, Member, Imprivata

So, I'm just going to go at maybe some of the policy background that led to this program, for those who were avid 21st Century Cures watchers. Early drafts of 21st Century Cures had language about a stars rating program following the PDP and MA plan stars rating approach. The final draft of 21st Century Cures pulled out the stars raring approach and put in this language that calls on ONC or allows ONC, potentially, to work with an outside organization to establish certification criteria. So, it seems to me that there's a perspective by congress that there is some sort of market failure relating to the existing mechanisms for providing public information. There are some well known programs out there that provide information on usability ratings, user ratings, analyst ratings of EHR technology and other HIT technology.

If you look at some of the language in 21st Century Cures, it seems like some of the market failure addresses or some of the specific concerns are about access of that information to small provider organizations, as well as access to smaller developers. So, I just wanted to frame up the policy question that ONC really has a choice. I read, maybe Elise can comment, but I read the language as not locking ONC into choosing an outside agency but allowing ONC to either create a stars rating kind of approach or to pick an outside firm, and then, fix and address the market failures. So, and then, anything ONC does has to come along with a funding model, either a taxpayer based funding model or working with a private organization that has a built in funding model. And any of the work that is addressed as some of the market failures that were identified have some work within that funding model.

So, I just want to frame up maybe how ONC is thinking about the intent of congress, with regard to the RFI program and also, potentially, just frame up some of the choices that ONC has because I think, in some cases, we're rushing to a prospective that we're setting up a stars program, and it's not clear to me that that's necessarily the right approach and that we should consider policy approaches where we work with an outside firm and then, work on addressing some of the barriers, burdens, and market failure that are attached to that outside firm.

Elise Anthony – Director of Policy - ONC

There we go. So, thank you, Aaron. I appreciate the commentary. I just wanted to provide a little bit of kind of background to your point, in terms of how ONC is thinking about implementation. First, I would say we are open to implementation, and that's part of why we're putting out the RFI, to gain insight, in terms of how the public sees this provision and how it would be most helpful to them. I will say that you're absolutely right. Earlier versions of Cures did include, specifically, a star rating program in some of the drafts. However, that did not get finalized. So, we do want to make sure we're sticking close to the language that was actually finalized. And I think, in that regard, one of the big messages that you see come through the text and that's actually there in the language is around the transparency and the stakeholder engagement and the importance of having outside entities help us with the development of that process.

And that's part of why we are looking to bring on a contractor, hopefully, in the next two or three weeks or so to help with that process. At the same time, I think, if there are comments from the public and what we're hearing here today will help us to think through how we go forward with implementation on the final program.

Seth Pasinski – Director of Strategic Planning and Coordination Division - ONC

Just one point, too, on in Cures, it does specify that, for working with an independent entity. So, part of it is kind of a requirement to work with an external organization, as far as the convening and development of the reporting criteria.

Robert Wah, Co-Chair, DXC Technology

[Inaudible] [01:29:42]The number of red lights we can have at one time, so if everybody has it on.

Andrew Truscott, Member, Accenture

Thank you, Mr. Chair. It's an interoperability issue with the microphones, isn't it? So, I've got a comment, some narrative, and a question. So, first off, thanks every so much for taking this one on. You probably didn't have that much choice, but thank you for taking it on. You've chosen – you've got a subject area that's both incredibly mundane and fascinatingly contentious in equal measure. So, thank you. In terms of other logistics and to John's point, take a look at my home and the UK, Australia as well. They've got similar programs, at a national level, generally, because of the way that their healthcare system works nationally. So, that might be worth taking a look at.

I think it's important to distinguish around EHR reporting the difference between product capabilities and implementation capacity just because not all products were created equal, but also, not all implementations of the same product, same versions, were created equal. And there are other people around this table who get to live that day in and day out, as much of a burden as it is to them. And to Steve's point, he raises a good one around burden. I don't have a problem with burden. I think burden is important provided that it's reasonable. You used the word meaningful around what we're doing, Steve. And I'm going to add useful to that. I know it's another set of descriptors there. But the fact is this reporting should not just be a check box on a piece of paper. Whether we like it or not, this will be used as a proxy for competency and the ability of an organization to correctly curate and care for patients and their information, whether we like it or not.

So, actually having it as there's something I have to do here, there's actually checks and balances that need to be put in place. I don't think we should shy away from that. We should just make sure that it's not an undue burden. Now, work out some way to make it, as Aaron was mentioning, manifest so that, actually, it's not undue on a smaller organization. Whereas a bigger, larger, more complicated organization actually has more checks and balances you need to go through and put in place to make it successful. Consider that. And then, onto my question. What can we do? You're sitting there. You've got surrounding you here people whoa re in the middle of this industry in many different facets and forms. How can we help you get there?

Michael Whitty – Program Lead EHR Reporting Program

Just quickly, thank you. I think that's great. I think you just helped me by suggesting looking at the UK and Australia and systems and seeing if there's things we can learn there. Didn't think of that before. But also, I think, first and foremost, of course, is for everyone to please have a look at that RFI. And if you feel inspired, submit some comments into that process. But also, either there or here, help us think through what are the pitfalls, perhaps, in doing this. What are the necessary burdens? What is an undue burden? Thinking about that and really framing, as we go through, as the independent entity that we fund goes through developing criteria and engaging stakeholders, are there things to keep in mind, whether it's past experiences with something, if not similar, at least somehow analogous in another field or topic? Or is there something we should avoid?

Is there something that we should make sure to do? Are there weird nooks, crannies, corners of some experience that we might not know about?

Andrew Truscott, Member, Accenture

Just a quick follow up. I hear you. You said, in your remarks, this is a long process. It cannot be a long process. There is a desolation and a need for this. And you could well get it wrong the first cut. But get the first cut out there, and then, we can move and change things. But in a vacuum, we will not be successful with our mission.

Robert Wah, Co-Chair, DXC Technology

Thanks. Raj, I think you're next.

Raj Ratwani, Member, MedStar Health

Great. Thank you. Michael, Seth, thank you both. So, I sort of have a lot of comments, as you can imagine, given that it's usability stuff. So, I'll try and rattle through them pretty quickly. So, the first one is you talked about user centered design, and you talked about usability. And I think the really big focus needs to be on the usability side, not the user centered design side. When it comes to user centered design, every vendor is going to raise their hand and say they do it. If you push them to say show me evidence, they're going to show you evidence. And it's actually really difficult to detect variability in user centered design process.

So, I put much of the focus on the core usability. When it comes to core usability, there is the easy, and this ties back to the burden points that I think Steve and Andrew were making, is it's going to be very easy for us to say let's put out a survey instrument or something like that to assess usability, which doesn't actually gets at usability. It gets at perceptions of usability. So, there's value in that, but I'd really focus on the harder part, which introduces the burden, which is getting at performance based usability. So, and that's going to be complicated, and somebody smart will figure it out. But I'd really push the point around performance based usability and making sure you're doing that in a way where you can compare apples to apples. And that's where things, I think, get a little bit complicated. Related to that, back to Ken's point, it's got to be on the implemented product. And when we do that, as Ken highlighted, most products are purchased, but they're already done.

But there's a huge variability in optimization and upgrades and so forth. And so, we've got to make sure we're capturing that context, so we can tie it back to actually usability, so that we can learn from it. So, that's the kind of second important point I want to highlight. The third is I hope we're not just talking about provider facing components of the EHR that this extends to patient portals and other pieces that patients are touching. So, making sure that that's built into the usability piece. And then, the fourth one, and I think probably the most important, is approaching this whole project or process with your usability, user centered design hat on. So, talking to the stakeholders, and I know you mentioned stakeholder feedback. But doing that iteratively. So, let's talk to providers and say what would be the most useful for you, as we talk about transparency of EHRs. And once you get a little bit of pilot data, put it back in front of them and say how would this change your decision making, or what does this actually provide you, and keep iterating through that process, so that we really get it right this time. Thanks.

Robert Wah, Co-Chair, DXC Technology

We have quite a few people that are still waiting to speak. I'm going to take prerogative here to maybe not go back to the chairs or the presenters right now. And let's just hear all of this first, and then, we'll come back to you all. So, I don't want to make you think I cut you out, but I think we've got to get all of this out, too. So, Les, I think you're next.

Leslie Lenert, Member, Medical University of South Carolina

Thanks. I just wanted to point out the importance of the aspirational nature of this. This is really where we will influence EHRs to make them what we want them to be. That that's really the goal, in the long term, is that without these benchmarks, we won't really be able to do that. The second thing I'd like to re-emphasize is, again, the usability statistics are really the effect on the whole healthcare processes as have been outlined and described really by Raj. And that includes a focus on productivity metrics coming out of the EHRs and using them, specifically, as tools to tell how the healthcare system is performing. What's the rate of rejection of insurance claims? How long does it take the average primary care visit? There's all sorts of things that we can get directly out of the EHRs that tell us more about these processes than really what user perceptions might be.

But the last point I really wanted to make about this was the notion that, as you go forward, there has to be an enormous amount of data about the organization that is linked to the EHR that is captured simultaneously. And without the organizational characteristics, qualities, other types of data, I don't think you'll be able to really interpret the results. So, what might be a four star result or system for a large organization won't work for a small one. Again, based on the particular types of activities that providers are engaged in and the culture of the organization, the quality ratings may differ. And, certainly, one number won't really satisfy everyone. So, we need to know enormous amounts about the organizations providing the data or where the data came from, when we're actually looking at the quality ratings.

Robert Wah, Co-Chair, DXC Technology

Thanks, Les. Aaron, I think you're next.

Aaron Miri, Member, Imprivata

Yeah. I'll make my comments quick because I know time is running short. So, great work, guys. Seth and Michael, great job. Two comments for you. 1) I want to kind of echo what Andrew stated. This is necessary and was needed yesterday. I would embrace the fact that it's going to be very messy, what comes out of it, in the very beginning. I think there's a lot of tribal warfare that occurs with product usage within the provider community, this is putting my provider hat on. And there's a lot of misinformation out there about what products can and can't do. So, being very specific and factual is going to be very important in eliminating all of that tribal warfare type feedback. It's going to be very important. Another comment for you is that don't be surprised, on the provider side and the CIO side of providers what can and can't be said.

It's amazing what's in contracts that limits you in your ability to talk about certain features simply because of competitive concerns. So, there's a lot of things that CIOs or organizations may not be ale to articulate back. And that's simply because of contract agreement. So, there's a lot of things like that that need to be worked through. But I think, at those circuit points, you need to be able to publish and say we could not go into these data points because of contractual limitations. Okay. That's good to know. That's good to know, if I'm evaluating products that, hey, there are certain things here I won't be able to work through or talk about with others. So, all of those data points are going to come out. But I would say embrace the messiness is needed yesterday.

Robert Wah, Co-Chair, DXC Technology

Thanks, Aaron. Cynthia, I think you're next.

Cynthia A. Fisher, Member, WaterRev, LLC

Thank you, Robert. As I sit here representing the voice of patients and caregivers, I look at what we've trying to accomplish with the valuation and check lists or stars. And, at the end of the day, isn't it really about what the patient experiences, what the caregiver experiences, some of the things Sheryl was discussing? At the beginning of this process is the practicality of how we receive and manage our healthcare. And why, if we go, us as a committee, up 30,000 feet, is it not our job to make transparency not a noun but a verb? And if you think about it, from a patient perspective, as we navigate the cost of the system, and we don't even account for the cost of lost days and time in work or parking and trying to aggregate our own information for our next specialist appointment.

But if we go and look at how this mobile world on this mobile phone works with us today, is in our banking life, in our airline life, in every other facet of our life, when we reach into the world of our data, it comes to our repository of choice, whether it's my Vanguard bank account or my app for my flight consolidations. But why is it that we, as EHR community and we that now have this incredible technology have yet to deliver it to the patient in a consolidated, human readable form that can be also machine readable and analyzed? The technology exists. I think it's our job to make it happen. So, at 30,000 feet, and \$36 billion has been applied through the hospital systems' provider networks to have the EHRs in place today, but it took me 45 minutes to get my partner's portal password, at which point, I gave up on trying to get access to my information. And even this week, my films didn't get transferred, and I was told to get a whole other scan done, which was going to cost and be more efficient because I waited two months for that specialist appointment.

So, this is the world in which we live. And, practically, many of us here sit here with children and aging parents that wouldn't it be nice to have all of their information in one place, as we manage their appointments and care. It's all doable. So, as we look to do star assessments, Seth and Michael, why not let the Amazon business models and the Yelp business models that exist today or even Uber, when I get out of that Uber X, I can rate my Uber driver. And I can even choose to pay him or her more, based upon my experience. We can do that in every other facet of our life. Why don't we empower ourselves to do that here and go up 30,000 feet? So, my recommendation is we could make this happen really soon by, essentially, saying open the APIs, open the valves, let it be free to the patient because the patient has already paid for it. The patient has paid for it through their insurance. That's, basically, giving up wage increases because their healthcare benefits keep increasing.

Wages have been flat because our healthcare benefit costs grow out of control from our employers. So, we're paying for it that way. We're paying for it through our taxes. And we're paying it through our care. So, why not use condition of participation? CMS and HHS, basically, say, okay, game on. If you want to participate in interoperability and I'd even say in net transparency of negotiated pricing throughout the healthcare system, deliver that to the patient as a condition to participate in any federal employee or federal Medicare or Medicaid benefit plan. And, finally, in order to get paid, as a condition of payment, you must deliver to the patient their information in the repository of their choice. So, the lab results, the x-ray results, the radiology, when Sheryl leaves with her daughter from her doctor's appointment, and the lab tests are done, they should be populated into her daughter's account, which she should have access to to be able to navigate to the next specialist.

And then, that physician, that provider can be paid. Why not use the levers that we already have and the tools we have at HHS and here as leaders to actually make it happen? And I'm going to tell you that, if we gave a year and said, okay, it's a condition of payment, everyone would find a way to be interoperable

and open the interfaces, so that the beautiful digital world in which we live can deliver to the patient. And the patient can, ultimately, then, rate price, performance, and quality just as we do on Amazon or Uber. And the patient and the consumer can then have choices. And, ultimately, we can then, ultimately, with price transparency, net price, not list prices posted, discharge masters. I'm sorry, you've got to have the net negotiated price and the insurers have to play in that game, too. Why should I go to a cash register and pay 300% more than another plan that negotiated an MRI at a lower price? It shouldn't happen.

We should have a thin band, and that will happen with a truly competitive market, if we take bold, brave moves here at HHS and as committee members. So, I think we need to get out of the quagmire and let the competitive market forces work on behalf of the patients because that's who we're working for. We're working for our citizens of our country, our taxpayers who are begging us to change the game in healthcare. We can do it.

Robert Wah, Co-Chair, DXC Technology

Thanks. Christina, I think you're next.

Christina Caraballo, Member, Kizmet Health

Thanks for the presentation. I just wanted to make a quick statement. I think that, when we're looking at the evaluation of the technology, I think it's really important to also consider what's actually being used in the market. So, we can certify and go through all of the test groups, and we've done it multiple times with my company. But then, what are our clients turning on, and what are hospital organizations actually using? So, when I think of patient access, the vendor communities are supporting APIs, supporting fire. But that doesn't necessarily mean the market is using it. So, to get a really good landscape of what's in use versus what's available, and I don't know if that's maybe a joint statement from providers and vendor together where I say I'm a provider. I'm using this technology. This is what is available to me, and this is what I have turned on, so that we can start actually seeing where the major challenges are and start addressing – I think it will help us address interoperability and patient access, at the same time.

Robert Wah, Co-Chair, DXC Technology

Thanks, Christina. I'm going to go to Tina, just because, Arien, you've spoken before and just to make sure to get Tina in.

Tina Esposito, Member, Advocate Health Care

No problem. And I think this piggybacks off of what Cynthia was saying. I think implicit in all of this and that we have to keep in mind is that this will also tell us, to some extent, what EMRs don't do but also what maybe they shouldn't do. So, we tend to, and I see it very much in our health system, where we always go back to the EMR, the EMR, the EMR. And sometimes, I'm just not sure that it's positioned to do what it is that we want it to do. And so, I think that shouldn't be lost, as we pursue this. And it's implicit. We can make it as explicit as possible, and it's not a knock to the EMR vendor in any way. But I think clarifying for us, particularly for the consumer, these are transactional systems. And they run very well to support our caregivers and our processes within a hospital or a medical group, etc. But they're not everything. And so, I think, to some extent, as we go through this process, understanding perhaps what they shouldn't be doing or maybe just aren't positioned to do will be just as important.

Robert Wah, Co-Chair, DXC Technology

Thanks. Arien?

Arien Malec, Member, Change Healthcare

Yeah, thank you, sir. My first comments were about the setting up the policy choices. I'm going to be a little more maybe proscriptive or opinionated in the second round of comments. The committee seems to, in some of its comments, not be aware that there are existing rating systems for EHRs. And they're pretty discriminatory, in the sense that they provide – I don't mean discriminatory, in the sense of discriminating one against classes of EHRs. But they provide pretty clear distinction between top or top three categories and bottom categories. We should have a compelling reason, if we believe that the private market rating system that currently exists is insufficient. And we need to set up, effectively, a public competitor to that private rating system.

We should be very clear that what we're providing is a materially better rating system and will be used preferentially and better to achieve the policy outcomes that we're seeking to achieve because we should also not underestimate the cost of setting up a private or public or public/private competitive rating system because there's a lot that goes into running a ratings agency, much of which is oriented around fairness transparency and addressing organizations that attempt to gain the system. So, there's a fair amount of people labor that goes into those systems. If we don't believe that we can do a significantly better job than the existing ratings agencies or organizations, then, instead, we should seek to work with really there's one organization that's out there that's sort of western in its nature. We should work with the organization that exists and seek to address what we perceive or believe as the deficiencies of that organization.

And those seem to be the two policy choices. And we need to be very deliberate about whether we set up a separate rating agency that's taxpayer funded and take on, whether it's with a third party or not, take on the administrative cost to benefit burden and taxpayer cost of setting up that agency or whether we don't believe we're going to get a materially or even better benefit. Sometimes, framing up clear policy alternatives helps guide the conversation. And it seems like we're approaching this from the perspective of believing it's green field, and we're going to dream up our magic wish list, and we're going to get all of the things that we look for. In the real world, we're either taking a rating agency and putting it out of business and sending up a public competitor to that rating agency. And if we do that, we need to be very deliberate about it. And we need to be very clear that we can take a much better approach to the market than currently exists. Thanks.

Robert Wah, Co-Chair, DXC Technology

Thanks. One of the dilemmas as chair is we want to have a robust and great discussion. So, I never want to be limiting that. We've got a couple of people that have spoken before. I also want to mention to the people on the phone, if you have comments, please speak up because it's hard for me to recognize you on the phone, unless I hear from you. With that said, I'll go ahead and have Raj and Andrew go ahead and make their comments. But if you are on the phone and want to make a comment, please speak up, and we'll get you on the cue as well. Raj?

Raj Ratwani, Member, MedStar Health

I'll be very quick. In response to Arien's comment, I think there certainly are private sector groups that are measuring or attempting to measure usability now. And having attempted this in lots of different ways, it's actually incredibly difficult to do at scale. And so, they have different ways where I think they're attempting to do it. But I don't know that they're actually measuring true usability, which is what the market wants. And so, at the very least, what we should be doing is enabling those data to be available, so that the private sector can get access to it because that's really the huge burden here. And so, as you go through that process, I think really thinking about that enabling point is going to be important. And some of that ties back to language that may be in the contracts that are signed with vendors. It may be

access to certain source data. It could be access to log data, etc. Thanks.

Robert Wah, Co-Chair, DXC Technology Andrew?

Andrew Truscott, Member, Accenture

Thanks, Mr. Chair. This one is to Arien's comments. I imagine that you went and looked at existing schemes that exist right now inside this jurisdiction before you went and issued an RFI and said, okay, what are the pros and cons, is there something that we can actually look to take on as a baseline and then, adapt from it. If, Arien, you got insight into something, which might be more appropriate to take on as a baseline, tell them. Let's try and get this acceleration and get this moving quicker.

Arien Malec, Member, Change Healthcare

Sure. If that's back to me, my perspective is that the rating system that currently exists, and I'll just name the organization, it's Class. I don't think there's any mystery about it. My perspective is we already have okay ratings that do a reasonable job of discriminating one EHR versus another, in terms of at least provider driven characteristics. And it's not clear to me A) that organizations – there's actually pretty good information on usability, okay information on interoperability. It's not clear to me that organizations use the existing rating system, in the way that we think they're going to use the rating system. If there was a magical, better rating system, we'd magically have interoperability. I don't believe that's the way that organizations end up buying product. 2) It's not clear to me. I'll say rather than use fuzzy words, I don't believe that we will be able to set up a public ratings agency or a public/private rating agency that will do a materially better job than the current one that exists.

And so, a better policy approach is to work with that agency, find the market failure points that we think are high priority. And we've heard some good suggestions, in terms of considering the patient input on the usability of portals being more standardized, in terms of how we assess usability of the EHR products do a better job of measuring interoperability. These are all good considerations that we could take to an organization that currently exists and say, hey, if you do a better job at this, this could be a good give to get. If you do a better job of this, then, there are some taxpayer funding, some links into the chapel. There's some material benefit to you to participate in this program, if only you improve these three attributes. So, I guess that would be my preferred policy stance just because I'm aware of the cost of setting up an independent organization. But I want to make sure that we're being very deliberate, as a committee, in providing good advice to ONC to either say, yeah, it's worth the taxpayer squeeze and burden and money out of our paychecks to set up a competing system.

Or we really should go where the market is and address the incremental market failures, whether that be patient usability, access to information, interoperability, or better structured information on usability. Thanks.

Robert Wah, Co-Chair, DXC Technology

Thanks, Arien. Once again, I'll call on the people on the phone. If you have comments on this issue as well, I want to make sure we include you in the conversation.

Clem McDonald, Member, National Library of Medicine

This is Clem, if you can put me on the list.

Robert Wah, Co-Chair, DXC Technology

Go ahead, Clem.

Clem McDonald, Member, National Library of Medicine

There's a couple of things. I think the rating thing is a very, very difficult, tough thing. But I'm not sure that Class, what you hear is they don't want to be too strict or tough because their customers are also the companies, to some degree. But whether we could find a couple of things narrowed down and maybe invest in developing some proven measures. And this usability, to me, it comes down to time and/or the time to learn and the time to do things. And I think you need to have a sample of people and set up a specific test for three or four things, which could be different and hard, but perhaps the government could invest in something like that that would be a fair measure of the actual time it takes to do stuff under reasonable circumstances across systems. That's one thing. The second thing, I wanted to support Cynthia on her mission.

I'm not sure that the mechanism is easy to assert to do it. But the idea of getting the data to the patients, and I use the word push because I think that's what she meant, is a very good one.

Robert Wah, Co-Chair, DXC Technology

Thanks, Clem. Other folks on the phone that want to comment on this? Okay. So, the other thing I have is a commitment that our published time for public comments is at 11:30, and we're right at that time. So, even though we have Steve coming up at what was 11:15, I'm going to ask him to hold off for just now because I want to make sure that we stay to the schedule that we published about public comment period. And I also want to thank the leaders of this discussion that we just had. And, hopefully, this information has been helpful for you. As you said, you're collecting information. And, hopefully, this is information you'll be able to find useful. Thank you.

Seth Pasinski – Director of Strategic Planning and Coordination Division - ONC

Thank you.

Michael Whitty – Program Lead EHR Reporting Program

Very helpful. Thank you all for having us.

Robert Wah, Co-Chair, DXC Technology

So, with this, I think we'll turn it over to our – I'll give it over to Lauren to orchestrate the public comments.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> Designated Federal Officer

Great. Operator, can you please open the public line for comments? And while we're doing that, we will also open the floor up for public comments for anyone in the room. If you're interested in making a public comment, just please come on up to the table, and we'll get your mic on. And if you can also state your name, please, thank you.

Tommy Floshans – Director of Government Affairs at Olympus Corporation of the Americas

Tommy Floshans, director of government affairs at Olympus Corporation of the Americas. My main question today really stems from that so much has been written about interoperability at the EHR level, yet access or the point of care has received less attention. What are the goals moving forward to outline or mandate capturing information at the point of care? And I say that based on the approach or the statements made by certain individuals in this room that maybe had to get redundant testing or certain images were lost or what have you. Again, the takeaway I've heard a lot in this conversation is it's all about

the EHRs. But the reality is outside of the EHR, there are much more benefits to capturing the information. Why are we not mandating capturing at the point of care?

Robert Wah, Co-Chair, DXC Technology

So, I think what we'll do is collect the comments. I don't think we have a direct response for your question. But thank you for that.

Tommy Floshans – Director of Government Affairs at Olympus Corporation of the Americas Thank you.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Thank you, sir. Any other commenters here in the room with us today? Okay. Seeing none, operator, do we have any comments, on the phone, at this time?

Operator

No comments, at this time.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Okay. I'll hand it back to you, Robert.

Robert Wah, Co-Chair, DXC Technology

Okay. Again, I appreciate everyone's indulgence. Because we published this time, and the public knows exactly what time we're going to have, I want to respect the fact that we made a promise to the public that we would take their comments, at a specific time, even though it sort of breaks the rhythm of our meeting. So, thank you all for your indulgence. And with that said, I also thank Steve for his indulgence. We want to get in a little bit of the discussion about interoperability. We have a lot of time, in the afternoon, also for this. So, I think it would be good to have a kickoff leading into that discussion with an induction and a summary of the interoperability form that we just recently had here in Washington. So, Steve, I'll turn it over to you. Thanks.

Steve Posniak

All right, thanks. A pleasure to be with everyone, as usual. I am now squarely between you and lunch, so I will tune my compression algorithm appropriately, since I need to recap three days in less than 30 minutes. So, I'll do my best. And, principally, what we wanted to have from my presentation here would be to give you a sense, if you weren't able to make it, which I know some of you were able to make the interoperability forum, what was discussed, the topics that were covered, issues and highlights and challenges that emerged out of the three days of conversation, and then, that will give you ample inputs and fodder to use later this afternoon as kind of part of the broader group discussion, as we go forward. so, let me make sure the mouse is working. Here we go. We're going to do a brief recap, highlights as well. One thing to note, the sequel was pretty good at the box office.

So, this is our second interoperability forum. We had a lot of engagement. I want to thank everybody that was involved in helping set it up. Two of my lead staff, Michelle and Carolyn worked with our teams of senior experts, did a Herculean effort to get everything going, as I know many of you have probably have worked and planned for public engagement sessions. It takes a lot of work behind the scenes to get

everything done. And everyone made it look really smooth for those that were participating in it as well. So, for the second interop forum, we had two goals. To learn about recent efforts to advance interoperability nationwide as well as to identify concrete actions in response to current interoperability barriers. Our speakers covered a variety of themes, improving patient access, addressing public health priorities, and looking at ways to reduce provider burden. The kind of patient aspect was really permeated throughout all of the tracks that I'll cover and many of the demos that we also had a dimension where the patient was involved in their care.

As is summarized here, we had seven tracks that happened on the second day. And I'm going to give a brief recap of each of those tracks for you. The other thing to mention, in terms of just a couple of quick changes, I won't dwell too much on this, is that we had three days instead of one. We had a mix of this track and kind of plenary session aspects. And as part of the rhythm and tempo, we had the various keynotes and other speaking opportunities. So, Dr. Rutger spoke, administrative room spoke delivering some of the remarks from a high level. We also had a demo from the Blue Button 2.0 team at CMS to highlight some of their new tech and interactivity through the CMS Blue Button API. And the National Partnership for Women and Families also released a new video about how the kind of caregivers in chief, women in the families play an important role in providing care and getting access to health information. All right.

So, just a few metrics, since we were talking about measurement and reporting earlier. We had about 400 in person attendees, over 600 over the web on Monday and Wednesday. I want to thank all of those folks that dialed in. I know we reached an international audience, if you can believe that, in terms of people tuning in form across the world. So, that was really helpful, as well, in terms of everyone's engagement. We had 21 break out sessions, numerous presenters, many panelists, and as all of us like social media, the interop forum hash tag was also trending in the DC area. So, that made us happy about our impact there. From a track perspective, we had seven tracks. I'm not going to read through the names because theyr'e going to happen to be the titles of the following slides that I'll cover. But really, the broad spectrum of different interoperability topics that vex us today and with which we spend lots of time thinking and talking about solutions, too.

So, for the first one, patient matching, we had key leaders both from the private sector as well as ONC staff help to facilitate this discussion. Key points that were raised, inaccurate matching is not just a technology problem. There's a lot of human dimensions in both in terms of work flow and data capture, data quality that can affect patient matching. And I think some important takeaway came out of this from the track participants about having a better understanding of matching definitions, metrics, being able to promote some transparency around the particular matching related aspect, duplicate patient record numbers. Equally, a better understanding of how to deal with some unique populations. So, pediatrics was discussed. These are people, as we started to look at the other matching techniques that are currently being deployed in the field, when you talk about referential matching or other things that may use historical or credit or other types of consumer interactions, my kids are hopefully not charging things that I'm unaware of, at this point.

And they don't kind of have those other dynamics. They don't have a mortgage. They don't have other things that may help provide that more well rounded picture of you as a healthcare consumer. So, from an interoperability measurement track perspective, the goals of this session were to describe the current state of interoperability measurement, identify gaps, and to look at actions taken. And I think one of the summary aspects of this is we have a limited amount of data that can be accessible to people that do this type of work. We have a limited amount of understanding of where, across the full spectrum, from the

action that's started to the outcome that we'd like to be able to measure, and all of those intermediate steps in between, and how to best get at that data via either survey methodology, if it's recorded from like black box perspective, as part of actions that are taken in health IT use. A lot of the data sources today are done through survey mechanisms or self-reported.

So, how do we look at other ways to get access to data that may be relevant to interoperability measurement and other concerns about how we can look at testing novel approaches, in a way that will help facilitate our understanding related to interoperability measurement activity? From a security perspective, no surprise, distributed ledger and blotching technology was discussed, as part of this track, as well as identity and trust. And, equally, the ability for patients to have an integral role and effective role in management and maintaining access and control of their health information, as we look to an API oriented ecosystem where there's more patient directed and patient mediated exchange. Digital identities was one of those topics that was brought up again, as well as areas for multiple stakeholders to collaborate together related to the aspects of data access and authorization.

From a content interoperability perspective, this session focused on both the US core data for interoperability, its maturity, as well as its representation in the kind of two predominant standards that we often talk about, the consolidated CDA, as well as Fire. And there was also an opportunity, through that track, to look at current content validation tech tools and explore further opportunities, as well as to look for areas for continuous improvement. So, a few notes out of this track include certification, as you all know, relates at the baseline. There was mentioned that certification is often done kind of I like to call prior to shrink wrapping. And then, it gets deployed. And, as was mentioned earlier, it's part of some of the discussion, lots of customization, additional tweaks and other adjustments are made to the systems, once they're certified.

And so, really understanding how issues are being handled, which was reported out through this track, at the developer level. So, that was encouraging that, at scale, issues that are being brought up are not just isolated to solving one particular provider's problems. It's really looking at solving any types of issues that come up from a contact perspective across the developer's deployed portfolio. Equally, expectations are increasing. And so, this is one of those aspects where, out of the track, the exchanges taking place, the data transmissions that have already been deployed and incorporated in people's work flows, now, they're wanting the next level of functionality, the next level of work flow performance that requires tighter standardization, more constraints, and other areas of opportunity for investment. Let's see what else we've got here. Interesting points that were made earlier that really jive with this track, the opinion of the participants in this track was to not to expand too quickly, or not to do too much more than what we have right now.

It's really to hunker down and finish what everyone started and to really get a firm handle on what it is that we've deployed to date. And so, I think there's a balance and trade off that I think everyone is struggling with about how – are we going really narrow and deep? Are we going really wide and shallow? What's the best approach? What's the blend there? What's the shape of kind of that aspect of how we want to take on the work that we do, in terms of do we need more data? What are the purposes for needing that more data? How is it going to be collected and integrated into the health IT systems and the standards that can be supported? We had an interesting track on clinician experience with interoperability that covered a few let's call it both long term and short term activities.

There was a demo and presentation on a project that's gone on for greater than five years called 360X, which involves kind of an amalgamation of a bunch of different standards, including direct and H27V2
messages about how to handle closing the referral loop and really automating a lot of those processes between the referring and kind of receiving providers. So, numerous health IT developers, as well as the kind of clinical teams presented both on the third day, as an encore presentation, I'll say, as well as more detail during the track, the work that's progressed associate with that. Equally, clinical decision support and the novel CDS hooks related going on associated with Fire was discussed, as well as handling some of the behavioral and mental health oriented data as well. Key actions coming out of this track were to look at ways to improve processes to ensure better data quality.

And that data was going into the right places as part of clinical work flow and in the electronic health record system, so that they could be reused, and it would be factored into other either analyses or reports or other types of services that may be connected to electronic health records. Continuing to test and focus on improving work flow, so that the effort involved in making all of this interoperability happen is as efficient as possible. And I am going to move on to the last one here. Interoperability infrastructure. This was a broader, one of the bigger rooms that we had, lots of people in there. I happened to sit in there in the morning. And we talked quite a bit about the current state of the national and nationwide health information exchange infrastructure, the kind of current trajectory and where the various networks are going. So, presentations from the Sequoia Project, E Health Exchange, Care Quality, as well as Commonwell and Chic among others that kind of were giving an update on what the current status of everyone's infrastructure was as well as the various efforts to ensure connectivity among the networks.

And we also talked about the cost and business models and modes of exchange and how to include consumer access as part of that exchange infrastructure deployment and the various ecosystem aspects, as part of including consumers in that exchange portfolio. Also, there was a discussion of the existing business models, as well as, as we look into an environment and ecosystem where consumers are using apps, those apps are connecting in via various points in the network. How there is greater assurance around the vetting or the practices, those apps that are used by consumers, and who plays a relevant role in determining the trustworthiness of those particular services that consumers are using.

And then, kind of last but not least, another refrain about focusing on existing and using existing standards, making sure that they're deployed in an efficient and effective manner, and acknowledgement that, as we look to having other data, there are some things, which I think is a point that Tina raised earlier, there are things that key charges are designed to capture and other things that have not quite been built into or expressed as a need from the clinical users. And so, when someone is able to ship that data from one point to another, being able to store that data is not always able to occur vis a vis the current functionalities that are built into the health IT systems that they have. All right. And the last one, but not least, standards to advanced research. So, the interesting set of panelists as well as contributors from Vanderbilt University, Mayo Clinic, etc. There was a kind of refrain associated with research needing a cohesive set of standards but also recognizing that clinical care requires a certain level of data accuracy and research needs a certain further data granularity.

But when it comes to the standards that are available, research doesn't necessarily need new standards. They want to be able to use and participate in the clinical ecosystem from which those standards are already being specified and born. So, I think you're seeing a lot of convergence between what the clinical users today and what those that are focused on research saying we all really overlap quite a bit. And we can use a lot of what exists today. So, the genuine interest in really collaborating from the research community. And in closing, I wanted to thank everyone, again, for your participation in the interoperability forum, whether you dialed in for a little bit of the key notes or the demos another day or you were there in person. I really appreciate your time. It looks like plans are to make this a trilogy at least to go forward

for next summer, as it has become a bit of a tradition.

The other one public service announcement to make sure that I get in is that the ONC annual meeting, which is kind of a broader scope of topics, including both kind of the policy and interoperability aspects, is scheduled for November 29 and 30. More information will certainly come out via our list serve, so make sure you sign up for that, if anyone listening is not signed up for it. And for those of you that will be traveling out of town, the usual hotel blocks and things of that nature. All right. And then, so, for this afternoon, our illustrious chairs, as well as myself and Elise and John will be helping you navigate in open discussion about a variety of these topics. And we wanted to make sure that, ahead of time, you had that kind of brief recap, the snapshot of the Cliff notes of what happened in those three days, and we'll key up some questions to help open up this afternoon's session.

But, again, thank you for your time. Hopefully, that was a whirlwind tour and helpful and just what happened in case you missed what happened on the last season of the interoperability forum. And I will conclude and let you get to your lunch now.

Robert Wah, Co-Chair, DXC Technology

Great. Thanks for the compression algorithm. And thanks for everyone's indulgence for trying to take in all of the information as quickly as he could say it. So, we're just a couple of minutes late for breaking to lunch. But I think we're going to try to get everybody back at 12:55, is that right? So, sorry, we're taking a few minutes out of your lunch time. But please enjoy your lunch break. We'll be back here, hopefully, ready to convene again at 12:55. And you'll be all ready for a robust discussion about interoperability, as well as any other future topics for our committee. Thank you, again, for the morning. And we'll see you back at 12:55. Thank you.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Can you hear me now? Operator, can you please open the public line again?

Operator

The line is open.

Carolyn Petersen, Co-Chair, Individual

Thank you. Thanks, everyone, for returning after lunch. I think we're going to commence with the afternoon's discussions now. If you could please take your seats and refocus your attention on the business at hand. Thank you. So, this morning, we went through a series of briefings and reports. We concluded with Steve Posniak's recap of the interoperability forum. We skipped the discussion that we had anticipated would follow that, in order to try and stay on schedule and get you to lunch, at a reasonable time. We're now going to continue this afternoon with those discussions as well as discussions about future topics and future work for HITAC. So, we'll start with our discussion of interoperability efforts and barriers. Do you want to lead us off, Robert? Start with a question, and see where we can –

Robert Wah, Co-Chair, DXC Technology

So, again, we thought that what we wanted to do was leave a fairly good chunk of time as the committee to talk about what we think are important issues in the area of interoperability, with the introduction that Steve had talking about how the interoperability forum went this year. But it's really our time, as a committee, to talk about those issues that we're seeing in the various lives that we lead outside of this committee, in the area of interoperability. So, we don't have a specific format in mind about this, but we

really wanted to open it up for a full and rich and robust discussion, from the committee, on the issues that we see that are barriers to interoperability, facilitators. And so, one of the issues that we think, as a committee, we need to put forward, as an advisory committee to ONC, in the area of interoperability. I think, with that as an introduction, I welcome your comments.

And as I said, we're going to use this time plus the time at the end to think about where we want to go as a committee, in terms of future directions. I don't have a bright line between the two discussions. So, if one ends up being shorter than the other, we can move into the second one. But we really wanted to make sure we had plenty of time for the committee to have input into what we think is a very important area. So, do you want to go into more on that? You can introduce that part.

Carolyn Petersen, Co-Chair, Individual

Okay. So, one topic that came up this morning, in our discussion about interoperability, was this notion of having a variety of definitions put forth by different organizations and different stakeholder groups. I'm wondering if we can start with more of an in depth presentation of how that rule is defined through ONC, the language about interoperability and the definition that you referred to earlier. And then, we can launch from that point into a discussion about our views and concerns related to definitions and how we want to try to shape our work going forward with regard to that variation.

Clem McDonald, Member, National Library of Medicine

This is Clem. Could I make a comment?

Carolyn Petersen, Co-Chair, Individual

Sure. Go ahead, Clem.

Clem McDonald, Member, National Library of Medicine

Well, I don't think we should spend our whole day worrying about the definition. There is a definition, and I think we've got to find the focus within it to get something done because that could take a lot of time.

Carolyn Petersen, Co-Chair, Individual

Well, certainly, I think probably given the very nature of experience and background and education in this committee, we could probably talk indefinitely about a lot of things. But this consideration of definitions and how it is expressed and operationalized differently among different sectors, certainly, is something that has relevance to our work going forward, as well as in the current moment. So, I think we do benefit by having at least recap where ONC is on that definition and then, having a discussion of some limited duration going in that area, since it's something that has impact for the report and for our work in future fiscal years.

Elise Anthony – Director of Policy - ONC

So, I can just read the definition. I just pulled it up. It shouldn't take me too long. It's not too long, in terms of definitional structure. But yeah, this is the definition that is laid out in the Cures Act in Section 4003. ONC is using this in our ongoing work streams. It specifically says the term interoperability, with respect to health information technology, means such health information technology that enables A) secure exchange of electronic health information with and the use of electronic health information from other health information technology, without special effort on the part of the user. B) Allows for a complete access, exchange, and use of all electronically accessible health information for authorized use with applicable state or federal law. And C) does not constitute information blocking as defined in Section 3022A.

Carolyn Petersen, Co-Chair, Individual

So, that's kind of the foundational principle that we have. Of course, there's always the way that that gets implemented and plays out operationally in the field. So, I'd like to start by taking say five minutes to, again, discuss any concerns or issues people have around the way there are differences, in terms of how people interpret interoperability. I know this morning, we talked about the concern that it's very different for patients. And there's really a need to try to streamline the focus, so that patients are simply getting their information. What are the other provider or stakeholder concerns? What other cases should we be thinking about, as we try to formulate a streamlined, effective strategy for how we deal with interoperability in the future? I see Steve has got his card up first.

Cynthia A. Fisher, Member, WaterRev, LLC

This is Cynthia Fisher. You asked other stakeholders in the process. If we look at the use of the electronic medical records, it's really the users, the end users are not only the patients and their caregivers but, primarily, their doctors and the relationships of interdisciplinary teams and specialists in assessing and working together in care. So, if we look at the usability, I think Leslie had mentioned the term use, usability, if we look at the stakeholders, is it not our role to deliver the best practices at the lowest possible price and at the most interchangeable ease for improving healthcare and mitigating cost to the consumer, to the employer, to the taxpayer across the board? And to that end, I also would add that to whatever we can do to deliver that mindset first works in the best interest throughout the healthcare system because we live in a transient world.

And let's not fool ourselves. We are in a race for big data. And big data in discovery and disease and in a world where orphan drugs is the mainstream way, at very high prices, to deliver a very significant marketplace. The providers, the insurers, the clearinghouses, the EHR vendors are all in a big data race to control that data and silo that data. And I think, as someone who is an outsider looking in to the system, it's very discouraging to me to know that our federal government tax dollars of the \$36 billion plus dollars, were used through the providers to get these EHRs in place. And now, the data even accessed technologically to the open APIs and pushing that through, there's a money game going on where the providers of the electronic information are actually looking to have ownership interests and charge significant fees to developers to get access to that aggregated patient data that's delivered to the marketplace.

Whether it's royalties per patient, whether it's interest in stock or equity in any technological vendor that wants to build and grow to the marketplace, I just think that that's wrong because then, we don't have a free system. And we're, actually, encouraging ever increasing prices. So, everybody is trying to get a bite at the apple at something that's already been paid for and should be delivered to the marketplace. What can we do at ONC to say enough is enough? Let's get the job done. Let's use, again, like I'm going to be a broken – you're going to hear this again, but conditions of payment and conditions of participation. Let's use the levers to allow for open operability, so that our doctors don't leave their jobs, and we have a shortage because they're frustrated because they can't do their jobs, and they can't get access to information to see the whole patient. And the patients and the caregivers are also dealing with ineptitude. So, I think we can do it.

Again, I encourage us to look at the whole system and look at mitigating cost to the taxpayer across the system. And I even go to what we spoke about earlier about having this whole RFI going out for the star based assessment of EHRs. What does that matter? Who cares? Really? Why spend taxpayer dollars when consumer reports could rate it for us or let the private market just rate it? But let the consumer rate it

because once we've accomplished our job, which is to deliver interoperability, we won't need any of those ratings because it will have happened. And our kids' records, our parents' records will be with us everywhere because they'll be here on our mobile device. And they'll be pushed forward, just like I can see every transaction in the rest of my life on my mobile device.

Carolyn Petersen, Co-Chair, Individual

Thank, Cynthia. Arien, your card is up.

Arien Malec, Member, Change Healthcare

Thank you. So, there's actually language in 21st Century Cures that also addresses the notion of permitted purposes. And one of the issues that we have in interoperability is that it's such a squishy and amorphous thing. And, in people's minds, it works all of the time, every time in every context. And yet, when you look at aspects of clinical medicine, it just can't because, in some cases, clinicians don't agree on what X is. I was lectured by one of the people who runs one of our major standards development organizations on how physicians can't even agree on what a problem is. Absolutely true. So, I think we need to narrow down to permitted purposes, recognize that, in the real world, we can't get every permitted purpose accomplished. And make our definition of interoperability secondary to the actual clinical work flows that those permitted purposes are embedded in.

So, as an example of this, what's required in a transition of care may not be required – may not be the same thing for what's required in an ED context of use, both under a broad treatment purpose. And neither of those may be at all the same thing as what's required for research, what's required for public health, in a variety of cases. So, this is sort of a plea for let's design the high priority purposes of use, follow clinical and research practice backwards to the data that needs to flow and the kinds of data that need to flow. And then, get interoperability working backwards from that. And then, in terms of how to measure, in general, the best measurement is one that's the most outcome driven rather than the most process driven. Although, I think multiple work groups and federal advisory committees have noted outcome driven measurements are much harder to do and maybe more process intensive. Whereas a process based metric that you an get easily and cheaply may get you 75% of the way there.

So, just measuring that X has been exchanged is a pretty easy thing to do and a pretty easy thing to report on. Measuring that X delivered clinical benefit is a lot harder but, ultimately, a lot more meaningful. So, again, just to summarize, focus in on permitted purposes. Focus in on high value permitted purposes. Make sure a definition of interoperability, what needs to be exchanged, is secondary to what's clinically important in that use case or in that purpose of use. And then, to the extent possible measure interoperability by the outcome achieved. And cheap and easy process based measures are good, too. Thanks.

Clem McDonald, Member, National Library of Medicine

This is Clem. Can I get on the list, please?

Carolyn Petersen, Co-Chair, Individual

Sure, Clem. Steve, did you have other comments? I saw you put your tent down, but I didn't want to overlook you?

Steven Lane, Member, Sutter Health

No, thank you. I think I'll just add to the discussion, in my practice, I am highly interoperable. I've benefited from making connections with other organizations in our region. We have lots of tools in place, standards

based. We have a cooperative vendor. And I come to this meeting, and I hear about all of the barriers. So, 90% plus of my patients are online. They can access their data. So, I think that there's a gap between sort of the leading practices and getting those out to everyone, whether different vendors, different sized practices, etc. I feel very fortunate to benefit from all of the interoperability that we enjoy. So, I think it's important, as we try to move forward, we look to those who have been most successful and figure out how to close that gap and bring people forward. And I think the big challenge there really is in cross vendor exchange. I think a number of the vendors have shown that they can do a lot when sharing between their own customer bases.

And when we look at the cross vendor exchange, there are very real challenges that I think standards and the work of this group can help to mitigate. The other thing that really, if we're talking about a definition, is there are all of these stages in interoperability. There's making the connections. There's laying the pipes. There's starting to push payload. But when it comes down to the actual usability of that data, and a number of people have use this term, whether you're talking about point of care or POP health management, research, we have to get down to that level of granularity and figure out where is the value that makes the data truly useful for the specific purpose in mind. So, I think big challenges, promulgating leading practices, working on cross vendor or cross network exchange, and getting down to the granular sort of molecular usability of the data that we're exchanging.

Carolyn Petersen, Co-Chair, Individual

Thank you. For the record, that was Steven Lane. For future commenters, would you please state your name first, so that everyone on the phone and also for the record of transcript, we can be sure that's correct. Next, we'll go to John Kansky.

John Kansky, Member, Indiana Health Information Exchange

Well, you stole my thunder. This is John Kansky. So, in response to concerns about the differences in the way people are thinking about interoperability, I wanted to encourage a sensitivity to balance for what I think of as two channels of interoperability. And there may be people around the table that two channels makes sense to and others that this is going to sound weird. But I see a definite focus by CMS and ONC to want to establish the patient as a channel for interoperability. Great. Wonderful idea. We absolutely need to do that. Meaning making the patient active in and a vehicle of moving their data from provider to provider, whatever it is, among the healthcare system to get things done. We should establish that channel. Meanwhile, for the last, I don't know, 30 years, the industry has been trying to build the provider to provider, payer to provider, through HIE's, Commonwell's care, quality, direct trust.

We've been trying all of these things. It's kind of the American way. Trying all of these things and figuring out what works to establish interoperability through the healthcare system channel. And there's frustration with the progress or lack thereof that we've made and the obstacles that still exist. But what I'm appealing for is not forgetting about that channel and, certainly, not making it harder for that channel to be successful. So, whatever we do, TEFCA, HITAC, we should try to make sure that both channels are promoted and advanced.

Carolyn Petersen, Co-Chair, Individual

Thanks, John. Now, we'll go to Clem.

Clem McDonald, Member, National Library of Medicine

Thank you. This is Clem McDonald, to be repetitive. So, I think we make it too complicated too often. And I agree with John's emphasis on the two channels. But if we set up the source – if we stimulate the sources

of this data to deliver in a standard format with enough coding and structure that it can be filed anywhere it goes, we'll solve everybody's problem. I think we look at the wrong end of it. We over dissect, we over analyze. But if we just said you've got to get all of your EKGs, all of your x-ray reports, all of your pulmonary spirometers, all of your lab tests, or at least 98% of them presented in this way, and I would be happy to say get it to the patient as a push. But if they do it, they can get it to anybody as a push. So, it's not that hard. And in Indiana, John's home, we connected about 30 hospitals together. But they had to put it together in little bit of a standard format.

And it took a day and a half to do the interface, typically, for each hospital. Anyway, just to push to think simply and just do it all. Along Cindy's line, just get it to the patient. If we can get it out of some system in a standard form, we can get it out in a lot of places. But to get it to the patient, that's the driving force. It's in the law. And that same organization could get it to other parts of the system that need it.

Carolyn Petersen, Co-Chair, Individual

Thanks, Clem. I believe Les was next.

Leslie Lenert, Member, Medical University of South Carolina

I'm a little concerned about unintended consequences, as we go forward. That as we design systems that move data from A to B, and there's always some minor differences in coding structure, what the level or complexity or granularity of coding. That what we wind up doing is introducing more and more information and then, partially, corrupting that information, as we move it around. And so, what I think we really need to focus on is a standard for de-duplication of data, as we're achieving interoperability. We just don't have a standardized approach for doing that right now. It's going to be one of the biggest problems we face. Just so you understand what I mean, you could have 20 CCDs from 10 organizations, and they might have 70% overlap. And you would have no idea as to where the gold is in all of that.

And so, I think that part of what we need to do is to come up with an approach to managing the natural proliferation of information as it moves and is shared around and has different sources and labels. And that really is about de-duplication. I think we could have some ideas about how to do that, but it may be good to have some ideas.

Carolyn Petersen, Co-Chair, Individual

Thank you. I believe Andy was next.

Andrew Truscott, Member, Accenture

Thanks, Madam Chair. There's a difference between accuracy and precision. And we have quite a lot of accuracy, I suppose, in the way that these things are drafted out. But we don't necessarily have the precision. And what I mean by that is all I hear from my clients quite a lot is well, we don't have meaningful use anymore. None of that stuff applies any longer. And so, nature is always a vacuum really, and this is like we've got a bit of a vacuum clearly because we haven't replaced it with anything necessarily yet. So, a lot of the things, which meaningful use put in place, organizations are saying well, we don't necessarily have to do that anymore. Actually, they kind of do. They didn't disappear. It's just there's no stick any longer. And Steven is nodding at me slightly here. And organizations are saying, well, actually, this TEFCA stuff doesn't apply to me.

It's not something I have to do. And they're getting counsel from their own legal specialists and external counsel who are saying, actually, it doesn't. So, think providing clarity to organizations actually of who is covered, what is covered, and how you demonstrate that you are compliant would be useful. As I read

the legislation, and my interpretation is actually we have scope to do that, and my interpretation is that, actually, this committee is on the hook to start making recommendations through to ONC about what those should be. That's my interpretation. I could be wrong, and I'm perfectly willing to be wrong. And let's have that conversation here. But just because MU dropped, it doesn't mean none of this stuff needs to be done. And there's a lot of organizations who will automatically drop to doing the least because there's a cost to doing anything there. We have incentives, and we have punitive measures. The act is full of punitives.

It's not much on the incentives. But punitives are still incentivizing people because there's a big stick if you get it wrong. I'd be interested to see how far along we are on the IG aspects. I think we all recognize that it's only going to take a couple of examples before actually people start complying. But it's only fair to ask people to comply with something. We have a large group of standards organizations that we've worked with, in the past, and we'll continue to work with. I think, frankly, we ask them. You've got the standards, the HL7s of this world, ask them. What should we put in here? What should we carry on and continue? And then, make recommendations for policy and move forward. It's the absence of saying anything that I think is one of the biggest barriers, right now.

Carolyn Petersen, Co-Chair, Individual

Thanks, Andy. It looks like Steven was next. Okay. We'll go to Ken.

Kensaku Kawamoto, Member, University of Utah Health

Ken Kawamoto. So, I think I heard a lot of very similar thoughts. So, one part is let's share the data around with the caveat, I agree, with the duplication problem, when we're sharing all sorts of data around, and we have no idea which one is duplicative, which ones might have been reconciled and slightly modified. I think it will become a total mess. So, maybe that's the initial gold bar. Let's share but figure out how we know that these 10 pieces of information that look really alike are actually different or the same and whatnot. And then, for the semantic interoperability part, the true interoperability beyond just knowing that two things are actually referring to the exact same thing, I think that maybe we get more target based. Obviously, it's better if we can get semantic interoperability broadly. But, in areas where that's difficult, perhaps we just start with use cases that allow for better value care.

And I completely agree with Cynthia's point that one of the elephants in the room is healthcare is so expensive in this country. And we really don't live very long. And it's like we get kind of poor value for the money we spend on it. So, maybe that's a key focus to say how can we make healthcare less expensive, so we can remain competitive just not just in healthcare but economically.

Carolyn Petersen, Co-Chair, Individual

Thanks, Ken. Now, we'll go to Sheryl.

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

Thank you, Carolyn. Sheryl Turney. So, I wanted to pile on to what Leslie had said earlier because I see these challenges, maybe it's from a little bit different perspective because we're a payer. And we not only have to abide by the rules of national, state, federal, everybody, but also our association rules. And so, interoperability becomes very complicated. And one of the venues that's been collecting data for the past few years, as a result of the ATA, are the state APCDs, which we haven't talked a lot about. But they collect data, and they use it for various purposes. And, actually, I just received a notice this morning that one of the state APCDs, Massachusetts, is, basically, challenging PCORI's new rule that they're voting on tomorrow regarding the reuse of data for health research without getting permission from the APCD for

the data use.

And representing a payer that submits data to that environment, I would agree with that because there are some uses of the data that are not prescribed, based on the laws of that particular state. So, interoperability becomes more complicated, when you're considering secondary uses. And secondary uses and unintended uses come to play every day. We get requests from clients to provide data. Their vendors want to use the data for, basically, competitive products and services, as a consequence of getting that data. Our association doesn't allow that. So, it's a complicated factor. We want to benefit all of the participants, so to use the data for the intended purpose. But I don't think there's any player in the healthcare realm that doesn't also want to monetize that some way, once they receive the data. And we can't ignore that aspect of it because it's a challenge we have to deal with. And I know I brought up, in an earlier meeting, advising patients and members in our DONC's tool on secondary uses and also understanding, when they give their data to an app, how they're going to use that.

And I see that they expanded the education to include some of this. So, I was really happy to see that. But we need to consider that, as we're talking about interoperability because everywhere we turn, there are groups, companies, organizations that want to use data for secondary purposes that, potentially, were not intended. And we need to consider that as well.

Carolyn Petersen, Co-Chair, Individual

Thanks, Sheryl. Go ahead, Steve.

Steven Lane, Member, Sutter Health

Steven Lane. So, plus one to Cynthia. I think, really, it seems to be low hanging fruit for us to bake in requirements for patients to be able to get their data automatically. To, basically, subscribe to any data source and say, when you update my data, send me a copy, whether it's in the CDDA document, whether it's on Fire, what have you. But I think, to Les's point, there is going to be a huge challenge. We feel this, in the clinical space, when once you establish these connections, once you have the data flowing automatically, you are quickly overwhelmed by that data. De-duplication, I think, is just one piece of the larger challenge of data curation, which includes prioritizing the data, sorting it, identifying gaps. There are a lot of pieces there. And I think whether we're talking about handing all of the data to the patient, whether it's on their iPhone or anywhere else, in their health data bank, or sending it to the members of their care team, you have the same challenge.

And I hope that the work that we do on this committee helps to support this notion of the app ecosystem. The idea that there are smart developers out there who, once they can get their hands on this data, will be able to utilize AI and machine learning and all of the tools of big data to start to do some of that work because, as a clinician that tries to do that manually, it takes forever to reconcile a med list and a problem list and an allergy list and an immunization history, to say nothing of the discrete laboratory results. So, I think we need to leverage technology. And I think whether it's focused on the patient having access to the data or the provider or the payer, there are these same issues that we need to put technology to work on that data, so that whichever stakeholder it is who is trying to make use of the data and derive meaning from the data can have that automated.

Clem McDonald, Member, National Library of Medicine

This is Clem. Can I get on the list again?

Carolyn Petersen, Co-Chair, Individual

Sure. Go ahead, Clem.

Clem McDonald, Member, National Library of Medicine

Well, again, I hear us kind of worrying so much, we won't maybe get to it. So, I have not been talking about, and I don't think anyone has been talking about sending it out for secondary use and sending it everywhere or sending insurance data. We've been talking about the primary data, the initial data, getting sent safe from the lab to the patients or from the x-ray reporting to the patients. Now, the CCDs add complexity. And I wasn't thinking, maybe I was wrong, it might be the easiest one to do, that being the primary delivery mechanism because there are real challenges in the passing of data from A to B to B to C. But if the originator sends it to the patient, and then, possibly to other users like the physician of record, then, we don't have that complexity. Just a thought.

Carolyn Petersen, Co-Chair, Individual

Thanks, Clem. Are there any other members on the phone who have comments to share? Okay. Back to the room, I see Arien's card is up, and then, Cynthia's.

Arien Malec, Member, Change Healthcare

Thanks. Arien Malec. The one thing we've talked about is business model issues with regard to secondary and tertiary use of data. And we haven't talked about business model issues with regard to primary drivers of interoperability. And also, something that may be surprising or controversial, but I've been doing this for quite a while, and I don't see any technological barriers to interoperability. I've built systems that have transacted multiple billions of records a year sending results to the clinicians or to them. There were no technological barriers to do that. I worked in the area of interoperability both in Direct and Commonwell. There aren't that many barriers to connecting providers. Dr. Lane mentioned some of the work that he's done. And he's been able to wire up or get the community locally wired up to the health system that he belongs to. So, the question, actually, isn't what are the barriers to interoperability or what do we need to measure more.

For me, the question is given that there aren't that many technological barriers, the remaining barriers have to be economic. And so, we really need to talk about some of the business model issues. One of the jokes I made to the then national coordinator who was asking for out of the box thinking about how to spur interoperability was to destroy the practice primary care. Of course, I didn't think that was very funny. But if you look at the way that we do interoperability in this country, we're much better at getting two large systems to talk to each other than we are at getting two primary independent care settings to talk to each other. And to me, this indicates that we've got an interoperability ecosystem that, for natural reasons, has been driven around the needs of very large systems. But we haven't gotten down to the economics that work for small and independent practices. At the same time, it's not clear to me that physicians are willing to go through some of the painful practices that are required in early days of interoperability.

Dr. Lane mentioned that once you start sharing information, you discover that they clinical utility of some of the information or the usability presentation of some of the information that you get isn't that useful. When we first started using the internet and the web, it turns out that the user interface for the early day web was kind of clunky. But people were so enthused to be able to get information that they kept working at it and kept improving the usability. The forcing function to drive us to improve usability, in this country, for health information exchange works too slowly and too inefficiently for us to get the incremental improvement that we need to. And, again, I think this is a business model issue. And it's also going back to one of the points I perseverate on. It's also an issue that this country is – the US

healthcare system is too big, too safety critical, and too distributed in its economics, in the sense that we have very large self-systems, very small independent practices, independent pharmacy, chain pharmacy, etc.

Too distributed in its practices to get all of the things done all at once in the same way that we do on the internet and in consumer electronics. And so, accordingly, we've got to pick our poison and go deliberately and slowly through these systems. But if we don't address the economics of interoperability and the business model drivers of interoperability, we're going to end up in a model that works for the very large institutions but leaves out the patient, leaves out the small and independent practices, leaves out the independent pharmacies or the small long term care organizations, and is driven by the needs of the very large organizations with the most money to spend. Thanks.

Carolyn Petersen, Co-Chair, Individual

Thanks, Arien. And then, Cynthia.

Cynthia A. Fisher, Member, WaterRev, LLC

Thank you, Arien, regarding talking about business model. Imagine, if you will, that we could look at this broken interoperability and broken healthcare system of sharing information with patents and physicians. And look at the grocery store or the restaurant world in which we live. So, we go to a restaurant, and we get to actually look at a menu and see the pricings. Why can't we do that in healthcare where we can actually know in advance of getting our procedures, a colonoscopy, for instance, what my net negotiated price is by my Blue Cross Blue Shield insurance in Boston? And it would sure be nice to know that Harvard Pilgrim might have a lower rate. Why can't I, as an employee of my company, get the same rate that maybe Harvard Pilgrim negotiated?

But I'd be able to see that on the menu. Wouldn't that be nice? And then, maybe perhaps rather than a big spread that can be 300% or 1,000% difference, based upon where you stood in line at the cash register or who negotiated what for your plan, we'd actually have a thin band of what MRIs would cost or colonoscopies. And what if we saw what the out of network bills were like who was going to be out of network? And what if we saw all of that pricing up front? And then, in fact, wouldn't our interoperability be like when we're at the restaurant, and we get our food? So, we order the food that we've chosen off of the prices with the menu. And we're not blind to it. We actually aren't blindfolded to those prices. And we actually go in with expectations. So, if it's an elective colonoscopy because I'm 50, which I'm a little bit older than that, but let's pretend, but if it's an elective procedure, I'd actually know what that colonoscopy is going to cost me out of pocket.

And if I knew in advance that the anesthesiologist was going to charge \$2,500.00, I might not have that money this year. So, think about what our role is in interoperability of delivering the information to the patient. We are the first step to actually give the goods. We're giving the food. The medical procedures is the food. And we're all in this together. And then, finally, it's the bill. Then, you come out of your care, and your bill doesn't match because it's siloed because anybody you've seen in the system ends up billing you maybe four or five months later. Maybe it's even done to a credit bureau because one of the caregivers actually went to an old address of yours and you have no idea because you never got it. And you don't know in what fact what your insurance plan has negotiated. But what if we actually were able to enable patients and physicians and all of us to see the menu, get the prices, actually get the service?

And what if we real time, as soon as that's digitally available, that means our food is up, we like to eat our food hot, what if we got real time the food of our information, it was provided and pushed to the patient

real time as soon as it becomes a digital record? Then, we're being served. And then, once we receive that digital record, whether it's labs or a medical device or the surgical procedure or whatever, once we've received it, and we've engaged in that care, then, we pay for it, just like in a restaurant or just like even how – so, we, basically, then – and then, we can see if we've been overcharged on our bill. We, actually, can compare what we went in for and expectations and see that it matches our bill. But all of these healthcare EMRs were built on billing systems. And Carolyn, in the very beginning, you mentioned the prioritization had payment systems at the top, which I argue it shouldn't be payment systems as our priority in interoperability. It should be patient and physicians' systems, systemic.

So, I put that out there to say, Arien, that the business model is really important, as we look at this, and delivering to the marketplace a competitive market that benefits our consumer and our taxpayer. And I'll leave you with an example. I have single friends that are in their 50s, and I'm their healthcare proxy because I have a little bit of insight on how to navigate the system. A friend had a new job after being unemployed for five months, very nervous to go to her new job in New York, stayed in a hotel. I get a phone call at work from an Emergency Department physician who said she had a stroke. And they found that I'm here healthcare proxy on her phone. And they said you need to determine whether we're going to issue TPA. I couldn't understand how this healthy woman who eats well and takes care of her health would have a stroke. It didn't add up. But I didn't have access to her medical records. I'm her caregiver. I rushed to get someone to get into her apartment to get the file out of her place.

I didn't have access, but I didn't have time for all of that. I had to decide on the TPA or not. In her nervousness, what I found after the fact was we issued TPA. But that decision could have killed her. What happened was she had two drugs in her prescription list, a synthetic drug for thyroid medicine, which she took two pills and Ambien. In her nervousness to go to her job, she took two 20mg of Ambien and took a hot shower at which point she then had stroke like symptoms from falling asleep. That said, she came out of the hospital. She started waking up after the issuance of TPA. Had we had the drug list, perhaps we could have put cold compresses on her and seen maybe it was a wrong drug taken and prevented all of that expense. Now, here's a woman who has been unemployed with no income nearly losing her home. And her hospitalization year for that ER visit was \$57,000.00. Out of pocket, after her insurance coverage. She wasn't going to make \$57,000.00 in that year.

Don't we want to address these issues? Don't we want to empower caregivers? Don't we want to enable interoperability? I appreciate the time you've given me. I just encourage us to do the right thing and make it happen. We've had so many great people in this agency and federal administration that are working hard to this end. It's doable. Arien said the technology has been around forever. Clem is impatient about it. I join Clem's impatience and beg us to do the right thing.

Carolyn Petersen, Co-Chair, Individual

Thanks, Cynthia. We'll go to Sheryl, to Christina, and then, to Sasha. And I think, at that point, we will move the discussion in a different direction or at least take a different approach to try to elicit some other perspectives and issues. So, Sheryl?

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

Thank you, Carolyn. Sheryl Turney. I would like to pick up on the point that Cynthia made. Actually, I would like to recommend that we separate price transparency, cost transparency from interoperability because I have seen many efforts. Again, I'm going to bring up the state APCDs because they have been there for a while. And we have vendors in various states, basically, training providers how to use APCD data in order to help them negotiate their rates for their next rate discussion with payers. That's a fact. So, with that

knowledge, then, it would seem that having data available on a price transparency basis at the state level is helping to raise prices rather than reduce them. And, basically, I have, within our organization, been the voice of both sides of the story because there are always two sides of the story. And I think, actually, there was an opinion by someone at the Attorney General level who wrote a case on the antitrust and the benefits of transparency, both positive and negative. So, to me, it's not the same question.

Interoperability is the sharing of the data. Price data is part of that. But I think we should try to keep the cost and price transparency conversation separate because it gets much more complicated. And the other thing is I see price transparency in medical not like a grocery store or a restaurant, but more like going to a lawyer. Not to bash any lawyers, but you go to a lawyer, and you might know the hourly rate, but you have no idea how long something is going to take to be resolved because you're involved in a negotiation. And there's unforeseen circumstances. That's the exact same thing that can happen in the medical field. And so, from that purpose, there may be things where I certainly don't want my doctor making decisions about my healthcare just based on price. I want those decisions based on what is needed at the time, in order to do the appropriate work. And that is more complicated. And I think we need to give credence to that. There may be some services like tests and MRIs and maybe blood work that can apply more cost transparency tools to it.

But I think services is something separate. And I think we do need to leave that discussion to the side. That's just my take. Thank you.

Carolyn Petersen, Co-Chair, Individual

Thanks, Sheryl. Christina?

Christina Caraballo, Member, Kizmet Health

Thank you. I want to echo agreement with Arien and Cynthia that we're not really looking at a technological issue with interoperability but the business cases. And I think, if we're talking about some of the barriers, we definitely need to bring up TEFCA and what we're looking at now. I'm definitely a glass is half full kind of person, and I saw TEFCA come out, and I'll be honest, it's like this is awesome, I love it. Then, I started taking a step back and listening to kind of what the industry was saying. And I heard opposition and people worried about it. So, I started just listening and making phone calls and trying to understand what I was missing. And I know that we had tried to do this 10 years ago and failed. But that's 10 years ago. Where are we today? And why are we not doing better?

So, as I started kind of talking to different groups in the industry, what I uncovered is that, again, it's not about the technology, but we've got problems that when Steve shared with us earlier, you have the state laws, business arrangements, and contracts that are being disrupted, privacy and security concerns, patient matching. We could go on and on. But those are some of the big ones. We've got some real challenges. But we're still going full speed ahead because we really want to do this. And I think that's great. But I think with some of the work we want to work on with our annual report is looking at some of those big areas and concerns that the industry has and addressing them, so that we can get all of the stakeholders that are important to interoperability together having the same conversation and move everyone forward. And I would think it would be really great, if we can give, somehow as a committee, figure out how to give ONC the funding to be able to do this.

Get out and talk to the different states and the different players in the market. So, kind of still thinking through that, but I'd love to discuss it, in more detail, with the committee. And then, when I think about it and look at the QHENs, we look at a lot of what's being done in the states at the HIE level. And I'll be

honest and maybe naïve in some points in my views on this, but when I saw the TEFCA, I thought oh, QHENs, those would be great for HIEs to play a role. They're doing some really great things in the states. And the ones that are successful are very successful, and data is being exchanged. Hospitals are sending information. Patients are able to access it. And then, if we take that a step further and look at our challenges with interoperability and patient access, imagine a world where we've got the QHENs, and then, at a higher level, there's a single access point I, as a patient, can come into a place, and it could be maybe this consumer hub within the different QHENs.

And that allows me to have a marketplace of applications where I can access all of my data and information in one space. And then, we go further with that, if we can create this infrastructure, then, providers can start prescribing different applications for patients to interact with. Patients can interact with their data the way they want. I just think that there could be some really great opportunities, if we kind of think along those lines.

Carolyn Petersen, Co-Chair, Individual

Thanks, Christina. And now, we'll go to Sasha.

Sasha TerMaat, Member, Epic

Thanks. This is Sasha TerMaat. I think it's been helpful to start off talking about sort of our interoperability priorities in context of this definition because it seems to me that we've come up, in the last half hour or so, with a lot of different, amazing opportunities as interoperability space. And different examples or anecdotes or problems or challenges that folks have brought up, all of these seem like really useful areas to focus. And I think we could spend the rest of all of our careers working on all of those in different ways. I think the most important thing for the committee will be to measure what we are going to do. And I'm not sure that I have a clear sense, from our conversation so far, of what sort of measurement we would set out to say, well, currently, we're here.

And we hope to be here in one year and here in five years to kind of assess whether the efforts that we make and the recommendations that we give to ONC and then, the work that's executed on those recommendations actually achieves the end goals that we have in mind, whether that is a flourishing app ecosystem or patients with streamlined access to every single piece of data that they have or that provider to provider channel that John was mentioning earlier, or even everyone being able to be screened for lung cancer the way that Ken mentioned in an earlier example. Each of those might have different projects behind making them happen. And all of them are really valuable projects to work on. But if we each have a different one in mind, as we work towards them, and we don't agree on some sort of centralized set of measurements that we'll use later to assess fairly whether we achieved what we set out to achieve, I think we'll each end with a disappointment in not achieving what was in our head, when each of us had something slightly different in mind.

Carolyn Petersen, Co-Chair, Individual

Thanks, Sasha. So, to kind of I wouldn't say recap, but to kind of lay out here where we are, we've had about 45 minutes of really good discussion where individuals who have strong perspectives related to interoperability are putting those thoughts out on the table for us to think about as major challenges. When I look at my list of HITAC members, I see that some individuals have spoken up, and some have been more quiet. And I think it's important that we try to get at least some perspective from all of our members because we all bring different backgrounds and different strengths and have different things to offer. So, we have 15 minutes now, and approximately an hour after our break. What I'd like to propose is that I go down the list, and each individual who has not offered some thoughts yet, just name for him

or herself what he or she perceives as the primary challenge and the primary opportunity related to interoperability.

And then, after we've gone through and had some feedback from everyone, start proposing particular focuses, foci, for our coming year, in terms of what we want to do related to interoperability. Perhaps we can come up with some resolutions today about things we really want to do. Perhaps we decide that we need to do some more thinking about that and continue that discussion, try to reach some conclusions in October or November. But I think besides giving our general feedback, we can also really benefit ONC by starting to narrow this to some goals that we can agree on, or at least some areas of work that we want to look at, in the next year. So, with that, I will start down the roll call list. And, if I call your name, if you could please present your primary challenge and your primary opportunity related to interoperability. So, Michael Adcock?

Michael Adcock, Member, University of Mississippi Medical Center

Sure, thank you. So, my primary focus is around total health. So, we're a total health center of excellence as designated by HRSA. We have 234 end points across the state of Mississippi. I don't know how many of you know, Mississippi is currently undergoing a little bit of a weather issue right now. But our 234 sites across the state, only 6 of those are actually related to the medical center. So, the rest of those, we're dealing with interoperability issues across the board. So, we're not only in medical centers, but we're also in private physicians' offices, we're in prisons, we're in schools. So, you can imagine the different types of issues that we run into, from an end point standpoint. We're also a very rural and poor state, just in case you didn't know. So, a lot of the physicians' practices that we work in don't even have EHRs.

So, we're not only dealing with an interoperability issue between EHRs or EMRs, but also dealing with interoperability issue or a communication issue with those providers' offices that don't. You add into that the 300 plus patients we have that were monitoring at home, and it becomes an even more complex issue. As the only academic medical center in the state with a statewide mission, us providing acute services are difficult enough. So, we're providing specialty services into offices across the state. We're also trying to provide chronic disease management in the homes. So, not being able to get the information that we need, we do not have a statewide health information exchange yet. There's one there, but it's just not complete enough to meet my personal needs or my professional needs. So, we're still looking at how we address those issues because I need to know when these patients, across our state, are admitted to hospitals, when they're seeing their physicians, when they go on an ambulance ride.

We're trying to track all of that data, so that we can provide the best platform we can around chronic disease management and acute services as well. So, we not only have an issue between the five or six platforms that we use to try to achieve our tele health services but also between the different health information or the EHRs across the state. So, that's, I would say, the biggest challenge that we're facing is completely around what everybody has already talked about. And we can talk about pricing. And we can talk about the consumer interface. We, certainly, focus on all of those as well. But being able to get the information that we need, both from other providers and back to other providers, not even to mention the patients that we have to communicate with, certainly, our biggest challenges. Opportunities, I think they abound. That's one of the reasons our program has grown to the size it has is Mississippi is blessed with lots of challenges.

Therefore, we have many, many opportunities to try to meet those needs. But if we can figure out how to get that information back and forth, in a way that makes sense, our providers across the state can't afford to go out and buy an EHR. And even if they do happen to find the money to go out and purchase

an EHR, them purchasing one that's going to interface with ours can be difficult. We're trying to help that the best we can. But we need the ability to be able to communicate both to and from providers and also to and from patients.

<u>Carolyn Petersen, Co-Chair, Individual</u> Thank you. Tina Esposito?

Tina Esposito, Member, Advocate Health Care

Tina Esposito, advocate of health. I support and oversee an advanced analytics capability, within the organization. We are a large accountable care organization of near a million I think attributed lives. I would say the challenges that we have, very similar to what Michael has articulated, is really pulling together as much of a picture of a patient as possible. And that includes, certainly, health information that may come from multiple EMRs outside of our network, certainly, even within our network but also claims data. And anything external to really, again, define the needs of that patient, so that we can intervene as appropriately as possible. I would say, fundamentally, the issues that exist are the quality of the information but also the ability to match all of this information to a patient, so that we know, indeed, when we're getting data that it truly reflects this particular patient.

And someone spoke to it earlier, as far as the interoperability conference, this is a fundamental issue within our healthcare system. We don't know how to sort of piece all of this together without a unique identifier. So, I would say that's fundamentally, I think, a major issue that we could discuss further. I think I just want to raise one other item that was discussed around measurement. Sasha had identified kind of the need to make sure that we can very specifically measure our outcomes and our performance. I think what's also important for the group to understand is that the point of view, in terms of the measurement, is going to be very meaningful. So, we need to identify, or at least acknowledge, that successful outcomes are going to be very different, at times, for a provider in comparison to a patient. And I think we've talked about it. we've gone around and around.

I think we can just acknowledge that, if we wanted to stay true to identifying success that outcome, that measurement would be different for a consumer than it would be for a healthcare system.

Carolyn Petersen, Co-Chair, Individual

Thanks, Tina. Is Brad Gescheider on the phone line? Okay. Valerie Grey?

Valerie Grey, Member, New York eHealth Collaborative

Thank you. I'm a relative newbie to some of this space. And so, I find myself listening and learning, as you all talk about the many issues and challenges. In New York State, we have what's called the Shiny. It's a statewide health information network at NICE. We're sort of charged with leading, governing, creating policies, and ensuring that the different local health information networks can communicate amongst themselves and sort of setting policy. And I think I would just stress a few different things. I agree with everyone. And when you sort of say can you sort of talk about the top challenge or opportunity, it's sort of hard to do. I would say a few observations. In New York, we've spent maybe the last year and a half actively trying to define what is our goal and target, in terms of really growing the HIE. And HIEs really have been trying to solve the interoperability problem for some time.

And I think that many of us have. Is there more work to do? Always. But in New York, we've got every single hospital in our system. We've got 80,000 other providers. And everybody is working very hard. And it took us a long time to even define what are the basic metrics we want to measure ourselves by. What

does participation mean? What does adoption mean? Consent is a big issue in New York. And I wish that we could spend a little bit of time talking about consent, at some point in the future, because I certainly understand the federal position that states have their own rules and their own laws. But we're not really going to get to national interoperability, until we start to sort of reconcile some of the differences and create some movement and advocacy there. So, the metrics are very important. I think the data quality and completeness we've talked about here at this table, also very important. And the need to standardize information.

I think, in some states, I don't know if I should say this out loud, I think the TEFCA is really, really important. And I think we all very much personally believe in it. But I do find that our efforts in New York State because TEFCA is sort of in play, I hear a lot from the field that certain vendors are not interested in connecting to state HIEs because there's going to be this national solution that comes. And, hopefully, that is true that that national solution comes. But, in the meantime, there's like a lot of work being done at the state level that I think may be getting a little bit slowed down, as we work through TEFCA. And it's just something to keep in mind. And I don't know if John has experienced the same thing. In terms of opportunity, I think, clearly, this whole conversation is a wonderful opportunity that I think I'm excited about. The one thing I'd like to see us talk maybe even a little more about is the opportunity that exists with social determinants of health and trying to incorporate nonclinical data into our ecosystem.

I certainly get the argument that we've got to figure out our core first and make sure we can do the clinical as well as possible. But sort of looping in some of that nonclinical is going to be very important. And I know there's plans for that. But I do think, in New York, we're actually doing some research and trying to set up a framework for legally sharing that information. So, sorry to drone on. Those are just a few thoughts. Thank you. And John, I don't know from an HIE perspective, if you wanted to add anything. Is it just the urgency of New York?

John Kansky, Member, Indiana Health Information Exchange

No, just real quick because I took my turn earlier. But to comment on Valerie, there is a – we're on a mission to preach what we call and not or to participants in our health information exchange. Meaning that it isn't us or Commonwell. It isn't us or Care Equality. It isn't us or the Health Exchange. It's us and those things. And the burden is on the health information exchange to figure out how to make that make sense. And we have to figure out how to be complementary and amplify the value of the EHR platform, not compete with it. But there's definitely a perception that we're an ignorance, and I'm using that word deliberately, an ignorance that we're pushing against because, even decision makers at high level in healthcare organizations do not understand TEFCA. They do not understand the different national interoperability approaches. And we're trying to educate on this campaign of and not or.

Valerie Grey, Member, New York eHealth Collaborative

Yeah. It's really all about how can we use the HIEs to leverage whatever we're creating here. And I think they are – I know in New York's case, we're more than happy and can't wait to do that.

Carolyn Petersen, Co-Chair, Individual Thank you. Anil?

Anil K. Jain, Member, IBM Watson Health

Yeah, great. Thank you. Anil Jain, IBM Watson Health. From our perspective, many of the folks around the table right now in your industries are customers. We work with providers. We work with payers, government, with the industry who are generating new and novel therapies. And so, for us, some of the

challenges that we see in providing solutions to them, and IBM Watson Health is really around aggregating data, doing advanced analytics, machine learning, and then, cognitive AI to solve some of the challenges that simply putting data in front of people or putting analytics in front of people aren't going to solve some of the more complex challenges. The challenges that we see our stakeholders have, as well as us, is that we see a lot of misaligned business cases. The opportunity to share, even when the technical underpinnings are there becomes a little bit daunting, when not everyone sees the same value.

There is also a significant amount of inconsistent implementation of technology and inconsistent use of standards, even when they exist. So, there's a high cost, a high tax burden, if you will, for getting people to just communicate, even when they believe their systems are interoperable. There are barriers to getting access to data of all flavors. And when they do have access to the traditional sources, the question they ask us is can you help us get some nontraditional data sources, the exogenous data, the wearables, all of that. And we have a gap there right now in terms of how we're approaching that. When we think about some of the other challenges around the people process of enabling technology, we see a big burn out area. So, the simple answer could be let's just get clinicians to collect more data. That's simply not going to work. Let's get the health systems to make things a little bit more interoperable. That's asking every single health system to do the same thing over and over again.

So, we believe there's an ecosystem solution where we try to focus on some of -1 think I heard some of the comments earlier. Focusing on things that are going to get us moving sort of quickly but not try to boil the ocean with this. The opportunities that we see to making this a little bit less of a challenge is to really focus on the open APIs and get us focusing on getting the data to bring them to insights and using those insights to push the case for interoperability. So, we're actually solving the problems that clinicians are having, solving the problems that other stakeholders are having rather than simply moving data around for the sake of moving data around. But what problems are we actually solving? And how do we use the free, unfettered movement of data to create the value propositions and bring the business cases more aligned. So, within Watson Health, because we have so many stakeholders across the industry, we're focused on those types of issues.

Carolyn Petersen, Co-Chair, Individual

Thank you. We'll next go to Denni McColm on the phone.

Denni McColm, Member, Citizens Memorial Healthcare

Hi. This is Denni McColm, and I am hopefully not echoing as much there as I am to myself on the phone. I represent a rural healthcare provider with hospitals, physician practices, homecare, long term care, just to give you some framework. And our biggest challenge is that our providers haven't been able to get the information that they need from the state HIE or any HIE that we've tried to participate in. Either they don't really know information should be available, or the patient hasn't opted in, maybe they weren't even asked to opt in, or maybe the other organization isn't sharing all of the information, particularly documents like lab reports and discharge summaries. So, they give up. And then, they have their nurse call the provider to fax over the exact information that they need. So, that's the biggest challenge. and we've pondered, in our state, how to resolve that issue.

The biggest opportunity I think we have is that our state is proposing to move to a consent to access approach to speak to someone else's suggestion that consent would be a good topic for us. And it looks like it's going to be adopted and could be a lot more successful. So, what we hope it will do is allow our providers to access all of the patient's information because, at the time they check in to see our provider, they say yes, you can access all of the information at that other provider or on the whole network and exchange. So, that's our perspective.

Carolyn Petersen, Co-Chair, Individual Thanks, Denni. Aaron?

Aaron Miri, Member, Imprivata

Yes, thank you. All right. So, a couple of quick stories from previous slides, I think, is the best way to talk about it. Oh, Aaron Miri, sorry, thank you. A couple of quick stories to help kind of give perspective on some of the challenges there with interoperability. The first story I'm going to give you really revolved around a large number of triage cases that were coming in to my hospital with patients that would show up with a CD with images on it or whatnot. Whether it was from priors or whatever else. And the doctor would pop in the CD, and sure enough, they couldn't read the images. Or there was a proprietary reader that had to be installed and, of course, there were not rights on the computer to install a proprietary reader, so you couldn't read the images. It was a big issue.

And as we dug more into it, it turns out that these images, depending where they were coming from, depending on the vendor of the manufacture of like an x-ray machine or an MRI or whatever else, they put a proprietary basically wrap around the image, so it had to be read by their reader. So, there was a big challenge there, in terms of these very proprietary formats and that not being something that's very universally presentable and able to be adopted. So, that's one story. The second story for you really is around work flow. A large number of my physicians were affiliates. And they would come into my hospital, but they also practiced at other hospitals. So, they would touch two, three, four different EMRs, in addition to their own clinic.

And so, they would often be sitting down doing their notes, from one work station, closing out charts. But then, they would VPN into another organization and open up medical records there. Or they may be comparing some priors of the same patient who maybe was at a different hospital .and often times, I would ask the doctor what are you doing. What is the interface? The interface is only going to send me the results data of whatever you're sending across. There's other stuff in the record that I need to know and look at. And it's a lot easier for me just to remote in and VPN in and see that on a totally different EMR. They're like how can I cut and paste there. And I'm like you can't cut and paste from one organization to another. Don't do that. So, there's a lot of work flow challenges to interoperability beyond just the data being interoperable and really understanding that. The third story I'm going to give you is around security. We had a large organization from another country reach out to us wanting to access our specialists via tele medicine and also enter in data to our EMR.

We looked at the situation. We talked to an organization it was very much in need for specialist access. But the security risk was too great, given that the EMR could be maybe perhaps intercepted, even with a secure VPN. Somebody could go in there, mess with the data. There could be a number of issues, and our board voted against it. So, again, it's not so much things not being interoperable but other challenges that forbid and impeded progress of things being easily to be seen and data to be shared from one point to another for purposes of care. So, I say there were three opportunities. 1) I think we can really look at tech standards, which we are, with a minimum floor there, both security as well as operational. Get away from these proprietary formats. Use more universal type formats that everybody really needs to adopt and that's part of it, along with security standards that really enforce that minimum floor, so that there's some responsibility given, in terms of what a device can or can't do and what kind of data.

Is it going to be malicious or not? 2) Really encouraging the organizations to share records beyond just

having a doctor VPN in, whether it's a carrot and stick model, whatever it takes. There needs to be a lot more there. So, it's not really a tech challenge. There's a lot more to it. And 3) as I said earlier, was security. Beyond the nation, state, organization that really reached out to us, a number of our affiliates in the community, especially in rural parts of Texas, they just don't have security standards. But there's always the risk you get from your compliance folks saying you're violating Stark by assisting them. So, there's a lot of things to look at that are outside of the realm of it just simply being a tech issue that I think we should collectively talk about and address, in some form or fashion.

Carolyn Petersen, Co-Chair, Individual

Thanks, Aaron. Just a housekeeping note. We are pushing a bit into the break. I've conferred with my cochair, and we've determined that we'll use our prerogative to keep going with this part of the discussion, and then, take a break after we finish up the last few individuals to speak. Thank you. So, Brett?

Brett Oliver, Member, Baptist Health

Brett Oliver. I'm a practicing family physician and CMIO for a moderate self-care system. And I think I'm kind of in the Clarence Thomas mode when I'm here. I'm learning, listening, and compiling my thoughts, not commenting a lot publicly. But the biggest issue for me is I really represent providers, physicians and nurses, the end users on the healthcare side is really with usability and value of the data that's being pushed forward. I've certainly seen things that are interoperable in getting data that really doesn't move the clinical needle but is celebrated from vendors, celebrated from interoperability exchange organizations high fiving each other. And yet, really, the end result is nothing. With our CIN, that's where we've struggled the most, as an organization. We have one of the large vendors in our own organization, and that exchange is fabulous, only to find out that the CCD information doesn't exchange with other vendors or it's 70%. That's a problem that should be easy to solve. The data is there.

There's not a technical barrier. But as we've enumerated a number of different ways, the barriers that exist there. So, before we – there's wonderful comments about patients getting their data. If I can order a pizza on my phone, why can't I – I get that. But I think we kind of put the cart before the horse just a little bit. Right now, the data that I receive in interoperability as a provider doesn't bring value all of the time. And until we can consistently get that, I'm afraid about what we start pushing because we've used that term a lot today, pushing data to people without it having proven value. And, granted, I understand those definitions vary by the person you're pushing it to as a provider or a patient, whatever. I just would like to see some standards in that at least offered up before we have this free flow of data. Listen, my providers are afraid to get an email message from – we've got Steven. We've got Anil. We've got these high functioning interoperable physicians.

I'm also dealing with the physician culture that's burned out, that is way over to the left side on interoperability and information exchange and all of that. Please take that into consideration, as we're opting changes. You have to take your time, in this culture, or you're going to get a considerable percentage of providers abandoning the profession because they can't take anymore. We jokingly talked this morning at breakfast about get rid of the fact, axe the fax. And we can all laugh about it here. But there are people, as we said this morning, they'll die in their cold, dead hands with that fax before they give it up. It's just the culture that's out there right now. So, I want to make sure, before we add another thing to do, and it's been said a number of different times, for a provider and nurse to provide data or what have you that it brings value to patient care. I can sell that. I can tell my colleagues, listen, this analytics that we ran on your patient's Fit Bit data can show that they're at risk for depression.

That's valuable. Bring that to me. Don't give me the gross downloaded Fit Bit data. We can celebrate that,

but that doesn't do me – I don't want it, quite frankly. And then, am I liable for it, etc.? So, I think if we could have those basic standards set on basic stuff first, and then, give organizations a road map about where we were headed, so we can start laying the ground work both technically and culturally within our organization, start moving that needle to the other direction, I think that would be most helpful. Thanks.

Carolyn Petersen, Co-Chair, Individual

Thanks, Brett. Let's go to Terry O'Malley, on the phone. Maybe not, okay. I'm next on the list, Carolyn Peterson.

Terrence O'Malley, Member, Massachusetts General Hospital

Hello, I'm sorry. I was starting to chat away on mute. So, I'm another clinician with a large healthcare system in Boston, Partners Healthcare. I'm a geriatrician. So, my interest in interoperability is really about how it makes my work better and safer for my patients. And what strikes me about a lot of our discussion, we have tremendous shiny objects that we can go after. And there are some very complex information exchanges and data aggregation and reuse that have tremendous value. But I think I'm going to echo Clem and just say we really need to make this much more simple and focus on some basics because, as much as we want to run, we haven't quite gotten to the crawl stage yet. And the basics, I think, are well known. And we're working on them all. But unique patient identifier has got to be solved, and that's a national standard.

You've got to have permitted use and authorization to recognize they're going to be state specific, but there's got to be an overlap that all states agree on. And that becomes another national standard. And then, finally, we need to then focus, once we have those things in place, really focus on some very specific, high value use cases where the simplicity comes in. And I think what Ken and Steven outlined on the interoperability standards priorities task force piece focusing on results is a great example of a very focused, very high value use case. And if we can figure out results and how to make them standardized and then, how to push them or move them or share them, we will have gone a huge way in improving the safety and quality of care. But it really starts with just looking at this very, very narrow use case. And I think what I've learned today from folks, with the emphasis on the business case and the policy, is that we're probably going to need to build the policy and sort of build the business case in parallel to building the standards that we need to support the interoperability.

So, it's really the convergence of high value use case with the standards required to support it, in parallel with the business case. And the last piece is that I think interoperability, by and large, is a local issue. I think it's a care community. It's a care ecosystem issue before it's a national issue. I would also say, in the spirit of simplicity, is to really let local care providers help determine what their priorities are. But if we can present them with a very high value use case like sharing results, that, too, could be sort of a national experiment in adopting a standard. So, thank you.

Carolyn Petersen, Co-Chair, Individual

Thanks, Terry. I'm on the list next. Carolyn Peterson. I would think a big challenge around interoperability is the heterogeneity of patients. That when we talk about what patients want and about giving patients the data and making sure they have what they need and what they want to use, there's, sometimes, a tendency to think that all patients are the same. And everybody wants to be doing something with data. But when I think about the patient advocates I've worked with and groups that I am aware of and speak with on occasion, there are some distinct groups that really feel like they're pretty full, in terms of managing their disease and not really looking for new tasks and new responsibilities related to their healthcare. They just want to go get their care, not have to do all of this other stuff with tech and data

and problems they can't work out because they don't have a help desk.

So, I'm seeing as a challenge how we can find ways to use interoperability to help them as well, even when they're not really looking to use data. On the opportunity side, I'm very interested in looking for ways to use data and the flow of data to help patients who are in specific atypical situations. They can be people with rare diseases, people who live in places where they don't have good bandwidth, so they're not really comfortable downloading lots of things and sending stuff back and forth, people who don't have a good community around them because they're isolated, in some way. If we can move data, we may able to pool information and to learn new things about treatment or care or self-care that help people manage their health day to day separate from the stuff that happens at the clinic from the medical procedures and the interventions. Perhaps some of you might think of that as the operationalization of adherence and compliance using what other patients have learned and what we know to try to do better for yourself within the medical framework. And now, we'll go to Raj.

Raj Ratwani, Member, MedStar Health

Thank you. As we get to the end of the alphabet here, I'll try and be really quick. So, I'm Raj Ratwani with MedStar Health, and I say this as part of the MedStar **[inaudible] [05:01:29]** renovation. One of the big concerns of ours is the usefulness of the data and the relation of usefulness and the financial barriers. So, as we see challenges with interoperability, we're looking for innovative solutions. And as we've recently seen, the cost associated with APIs, from some of the vendor organizations, frankly, they're shocking. So, I think that's a really big concern from our side. As for the focus, I really like Sasha's point earlier about thinking about what we're measuring and how we're going to see advancement for whatever direction or directions we choose. Thanks.

Carolyn Petersen, Co-Chair, Individual

Thanks, Raj. Let's go to the phone to hear from Steve. Steve, are you on mute? We're not able to hear you. Okay. It sounds like we're not going to get that. Let's go to Patrick who is also on the phone. And let's go to Ram. Okay. How about Lauren? And that brings us to Robert.

Robert Wah, Co-Chair, DXC Technology

Thanks. So, I'm trying to figure out what the best way is to contribute to this. I think one is the business barriers that have already been mentioned. I think it's worth being more explicit about this. I think there's two business barriers that I've seen, in my work, in interoperability. One is that there is a strong belief that there's a connection to patients, based on the data we have on them. And most people view patients as revenue sources, if they're a provider of care. And so, this idea of interoperability makes them nervous, frankly, because, if they are to share data about their patients with other organizations, that's a potential leakage of their patients and their revenue. I think we ought to be very clear about that that that's something we have to identify and address. I don't necessarily have the answer to that. But I think we've sort of danced around it in our comments that there's a business barrier.

But to me, that's one of the most significant business barriers is that hospitals, physicians see their patients as sources of revenue. And the data that they have on them are direct connections of that source of revenue. So, any idea of sharing that makes them nervous. And there has to be some decision or some policy or some mechanism by which we can address that discomfort that people are having. And I say the other business barrier, frankly, is that the vendors in the space have some belief that it's sort of like I used to refer to it as a cell phone mentality. When we first had cell phones, it was very hard to call from one network to another. There was a let's keep everybody in the corral mentality. And so, if you were on one network of cell phone, you couldn't call the other network of cell phones, without it being expensive or

difficult. And I would submit that the cell phone industry, through a number of different mechanisms, recognized that there was a need for more interoperability.

And I would submit that everybody's boat floated much higher after the interoperability occurred. Now, how do we get the industry to have that same leap of faith now about interoperability across networks and not have this corral mentality? I'm not sure I know that. But, again, I would say identifying it is a first step. And then, we need to address that. So, those are the two biggest business barriers that I see, in terms of interoperability. And then, in terms of solutions, I would say I come from a large system integrator. So, I'll relate to some of the challenges that we've been asked to address in interoperability. So, we have a large hospital system that has grown larger by buying multiple hospitals that are on multipole different systems. And so, their interoperability issue is about an enterprise level, how do they take data from multiple sources and make it look like it's one enterprise source of data. And so, we've built a platform.

We call it Open Health Connect. But I will tell you about it only as a way to address some of the things that we've seen. One is we layer it out. So, the first layer is system of record. We think there's a need for interoperability at the data level. And that requires a large library of APIs to build this system of record. And so, that's interoperability at the data level. But to go beyond that is to then build a layer of insight on top of that because having all of that data together is not useful, unless you can analyze it, do some interesting things with it. We've already heard some examples of where that's being done. But I think without the layer of insight, you don't really get any value out of the interoperability. So, we have a layer we call layer of insight. And then, the last layer is what we call layer of engagement.

And this is where getting the data to the right person at the right time is critical, whether that be a provider, a payer, a government, or a patient. Making sure that the data is available, the insights from the data are available to those patients, providers, governments, payers, and researchers is really the last key part. And so, I'd offer that as a way of framing out how we want to proceed beyond just interoperability. We want to have insights and then have those insights delivered to people, in a way that they could use it. And so, that would be my observation about this issue from my perspective. And then, I'd say also, globally, what I've seen most recently is outside of the US, there's this big thing called GDPR, which some people refer to as HIPAA on steroids. But I think it's really outside the healthcare industry. It's all industries talking about privacy of data. And I think we have to be very mindful of where society is right now about access to data.

And it's raised a ton of questions about secondary use, monetization of data. If you click on a website outside of the United States now, the first thing they ask you about is permission to use cookies that you never saw before. That's the first visible sign of GDPR. But I think you're going to see a ton of downstream consequences of this new law that's sort of the law of the land across the EU that has some significant financial consequences of violation. So, I'll give you that.

Carolyn Petersen, Co-Chair, Individual

Thank you. And let's go to Denise.

Denise Webb – Marshfield Clinic Health System – Co-Chair

Denise Webb, Marshfield Clinic Health System. I can probably echo a lot of the comments of Brett and Aaron and Robert and Steven all from provider organizations. And in our situation, Marshfield Clinic Health System is in the rural part of Wisconsin. And we're a large provider led health system with 1,200 providers, about 700 physicians. And the clinic is 102 years old, multispecialty practice, 86 specialties.

Prior to me coming to the health system, the environment in the healthcare market was quite different where there was a collegiality amongst the competitive healthcare organizations around us because they were primarily hospital based organizations. And they relied on our physicians. And so, when Marshfield Clinic Health System decided that it was the right direction to go to become involved in owning and running hospitals as part of their strategy that really sort of changed the dynamics.

We actually had a combined medical record with two of our major competitors in the area. And that all got kind of disconnected in the process of the competitive market forces. And we're really challenged, in our area. We have over 55 sites in the central northwest area of Wisconsin. And in terms of payer mix, it's about 5 to 1 government covered patients versus a commercial patient, a working person. And that creates tremendous pressure, in terms of managing the cost of care. And so, in this process of our strategy and where we're going, by the end of the year, we'll have six hospitals. And they're not all going to be on the same electronic health record system. We're extremely challenged, when it comes to exchange of health information across vendor products. I myself moved from the Madison area 16 years with a health system. And I have to echo some of the other comments I heard that we need to solve the issue of getting the patient's data, my data, from the previous provider to my new provider before I really care about having it myself, I want my provider to have the data.

So, that's been extremely challenging to get that data exchanged. Even though there were functions and features in place on both sides, it didn't work. I don't know why it didn't work. I think that the challenge is in two areas, and I'm probably echoing others' comments. It's really exchange across vendor products. It's not so much a technical issue per se. I know there's political and competitive force issues. That's a major challenge. And I think the other is that, in the rural area of our state, while there has been a lot of investment in broadband and providing access, it's still not necessarily affordable for a number of people in our area. And we have patients traveling upwards of two and three hours to get care. And we would really like to have the ability to serve them through tele health, hospital, at home, and those various methods of providing care.

So, I see a tremendous opportunity in the work with the USCDI and actually having some standard core data sets for the prevalent, prominent use cases around transitions of care, referrals, and also, to providing patients access to their data and the apps of their choice because, if all else fails, if the patient at least has their data with them, if we can solve the de-duplication matter, then, that will help them or their caregivers to ensure that at least their provider would have the information. So, I think that is pretty much my thoughts on this.

Carolyn Petersen, Co-Chair, Individual

Thanks, Denise. Well, we have now had a chance for everyone to speak with regard to this interoperability issue. I think we will take our break and come back at 3:00 p.m. Thank you. All right. Thanks for returning. We've got one last hour. And we will make it interesting and enjoyable and get you on your way. So, were going to start this last little segment with regard to interoperability with some reflections from Steve Posniak.

Steve Posniak

Deep thoughts from Steve Posniak, right? Thanks very much. So, the earlier discussion was great. I appreciate everybody's perspectives. And one of the reasons that we're privileged to have you here in person for one of these meetings, and what Dr. Rutger really wanted out of it, is also to give you an opportunity to learn from each other's perspectives and to hear your experiences on the ground. So, one of the interesting components of listening to this and then, reflecting back to, maybe double reflection

then, in that case, to the interoperability forum, as part of the measurement track as well, and I think some of Sasha's points reminded me of this, in other policy spaces where we look to identify how much progress we've made, one of them is like broadband access. And so, we have a rough sense of people have broadband access or they don't.

And we use that as a proxy for when you have broadband access, you can innovate. You can invest in new businesses. You can do new things. You can connect to the world and the internet in a different way that people without broadband access can't. And are we talking from our interoperability construct at the super high level of we want people to have broadband access because we think all sorts of cool things are going to happen, and people are going to be able to engage in healthcare in a different way? Or are we really getting down to a specific use case, the lung cancer one that Ken mentioned earlier, and that's between one foot off the ground, which may be that example, and broadband access is just super high. We need to find those impactful kind of measurement points for our progress and being able to understand how to get those. And then, equally, struggling with, as perhaps another reflection, the answer that we all give because I'm one of them is yes.

All of these. They're very important. They're all important. We want to solve them all right now. And thus, we shall and so, identifying. And there really isn't a clear, right tradeoff between prioritizing about sending data, prioritizing about how to improve the receipt of the data, the incorporation and the use of it, being able to find it, being able to access it, if you're on the patient side, and how to really accomplish all of those at the same time. And keeping in mind, I think, Arien's points earlier about being humble about where we are and how long it takes these turns of the crank for our environment to really incorporate the changes that we aspire to see.

So, I think, as we look to the progress that the advisory committee can make and the recommendations that you can provide, helping set clear goals and outcomes that you'd like the industry and the ecosystem at large to accomplish that don't move, in order to allow some of that predictability, road maps that you've heard being mentioned, the planning in advance, being able to help deal with I won't say ignorance from my perspective, but the educational challenges that we have to reach outside of the beltway and explain what our policies are about and what they're meant to achieve. And then, I between those kind of north stars, there can be more than one, helping to increment, along the way, what are our check points and how we can best achieve some of those goals. Admittedly, it will need to cross multiple stakeholders in that spectrum that we have. So, I think we've heard quite a bit. And maybe I'll think back to when we previously had two federal advisor committees, which was twice the fun, the standards committee and the policy committee.

We spent a lot of time on the technical side, as I did helping the standards committee. And roughly, now, we can move data from Point A to Point B. The data can be received by the recipient system or sent and traverse across the wire. And it's really how we put it to use that has become more of the challenge and the interest in greater expectations for how we can improve the care delivery that is using the data that we have available to us. So, a lot of the pivots that we're seeing in real time is the shift from some of the comments that Robert reflected on and I think Arien's earlier points that we can do a lot of the stuff that we want to achieve today. It's really best how to align it with the market and the business ecosystem that we're currently I don't want to say stuck with for lack of a better word, but a part of and how to make those shifts, at the same time, as we're trying to make technological shifts and change policy and culture and behavior as well.

So, there are a lot of dimensions involved in this, which I think is probably the bottom line. All of you have

a different perspective to provide relative to how those dimensions can be best addressed. And so, as we focus on our strengths and the contributions that you can provide, please keep that in mind. End of reflections.

Carolyn Petersen, Co-Chair, Individual

Thanks, Steve. We appreciate that. So, at this point, we are at about 3:07. We still have a discussion about future topics, things for HITAC to consider going into next year. We definitely want to have a good discussion about that. At the same time, I did see a table tent come up towards the end of our previous comment period. And I'm thinking we have a very few minutes, in case there is anyone who has a different perspective or comment that hasn't come up or something that they absolutely feel really needs to be said before we close out the interoperability discussion.

Clem McDonald, Member, National Library of Medicine

This is Clem, if there is a minute.

Carolyn Petersen, Co-Chair, Individual

Go ahead, Clem.

Clem McDonald, Member, National Library of Medicine

Well, I think, if you worry about everything at once, we'll get paralyzed. And so, I think we've heard this already. We've got to pick and focus. But this is maybe wrong and simple minded, but Google now has a product that can take in medical data as identified. And I don't know the details. But I suspect that's a place patients could ship their data to. And I think our big problem is the data isn't free and fungible. It is yeah, people are sending it around, but it's all different ways. So, fungible means it's got to be a fairly standard way, so you can move it between places that use it. And that's, principally, being a code on the – and I'm focused on test results because we have gotten almost nowhere on that, despite Steve's positivity. There's no formality yet about sending radiology reports or EKGs. These things are just common. And patients should be able to get them.

So, I think, if we focus on getting it out, who makes it, the rest will take care of itself. The market will grab in there and use it to make money or to serve patients or do whatever. But right now, you really can't get it out easily. This isn't data blocking. It's just that it doesn't come out in a very usable form always.

Carolyn Petersen, Co-Chair, Individual

Thanks, Clem. Any other comments from any other members of HITAC? Anything else? Sheryl? Keep it brief, please.

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

I pressed the wrong button. Can you still hear me? Okay. Sheryl Turney. I represent Anthem. I think that, from the discussion that we've had today, what I focus on is really for our work next year, what levers or incentives or recommendations can we make that's, basically, going to further improvement of that work flow problem, the business model problem, around interoperability? Because if we say it's not technical and, certainly, there are some technical issues that need to be addressed, and we have a lot of work already going on with technical standards, but really not a lot around the work flow business model issues. So, maybe that could be one of our priorities for the 2019 work. And then, what forum do we have, in order to make recommendations around those issues?

Carolyn Petersen, Co-Chair, Individual

Thanks, Sheryl. So, we've had quite a robust discussion this afternoon. And we're now going to hear briefly from the ONC about how they will use our feedback and what they see going forward.

Steve Posniak

Back to me, Steve Posniak, again. So, if there's one thing I can attest for the office as a whole, we are astute listeners. And so, all of the comments from earlier this morning related to the EHR reporting program, requests for information, just the general feedback and discussion related to the task forces, as well as the overall kind of open discussion that you had earlier today, which, again, we wanted to give an opportunity, since you all have not yet hit your first birthday, give an opportunity for you to really have some free flowing discussion and understand each other's perspectives. But, at the same time, in real time, we are listening. We are taking notes, jotting down particular points that align with where we may be shaping and crafting policy proposals or other programmatic activities that we work on, as well as our internal strategic planning as a whole.

So, in terms of the open discussion that we had this afternoon, the takeaways for us, largely, Elise and I are here, John is here, so you, basically, have ONC's executive leadership team from a programmatic perspective all present and accounted for, in terms of running the operations day to day. And so, we also are figuring out ways to incorporate your points of feedback, as well as how we communicate and convey the advisory committee's perspectives to our colleagues across the department. So, some things are, certainly, not activities that ONC alone can address that you have particular concerns or policy wishes for. Others are areas of authority that our sister agencies have that we don't have, but we certainly talk with them on a daily basis. So, to the degree that salient points come out of the conversation earlier today, which there were many, and others that come out of your future conversations, we're always on the look out to bring those back and school our colleagues across the department, as the saying may go, about what's happening in the field and where we can do better.

Carolyn Petersen, Co-Chair, Individual

Thanks, Steve. And with that, we will see, out of our two hour sojourn through interoperability and into a discussion of future topics, which Robert will lead for us. Thanks for your very engaged participation and really appreciate the good discussion with all involved this afternoon.

Robert Wah, Co-Chair, DXC Technology

Thanks, Carolyn. So, I think we've already heard one comment from Sheryl about maybe where future directions are going to be. And those of you that know me, if nothing else, I'm persistent. So, this has been an issue that I've been pressing for some time that I think we, as a HITAC, should have an opportunity to have a more open discussion about where we see the future use of this committee going. As I said before, we have been given a menu of things we needed to do, by legislation, which is unusual for an advisory committee. And that's fine. And we're standing up for that, and we're doing it. But I think we also need to square out some time to have this discussion about where we as members think we should be heading, as a HITAC. I will give you the caveat that just because we say it doesn't mean we're going to do it. So, to make the ONC team less nervous, this is going to lead to new directions that they weren't ready for. So, this is, right now, a discussion.

And by no means are we going to come to a conclusion about what we're going to do. But I think we need to have the discussion. And it would be valuable for us to have this discussion about what we all think we would like to see this committee and our work result in. So, by no means is it binding. I want to make sure that's clear to everybody. And I'll speak on behalf of the ONC team about that. But I think it will be useful for us to have an opportunity to have this discussion. So, we've got, as I always say, we've made a

commitment to the public that we will allow public comments at 3:45. So, regardless of where we re in the discussion, I'm going to try to honor that contract with the public because they've all scheduled their day and their time for that. So, but that gives us about a half an hour here at least to have a discussion about where we, as a committee, would like to see us go in the future. So, with that, I'll start with Steven.

Steven Lane, Member, Sutter Health

Thank you. Steven Lane. I guess, I'd just turn the question around a little bit and say what can we do. We all have lots of aspirations and things we'd like to see happen and levers we'd like to see pulled. But, truly, I think we all want to invest our time wisely. So, and maybe this has been asked and answered. But I think the key place to start is what do the ONC staff feel that they can accept from us and make actionable because we shouldn't waste our time doing the things that are outside of those guardrails.

Robert Wah, Co-Chair, DXC Technology

Yeah. I think everyone has a balance that they try to strike between what I call the pragmatic world and the optimistic world. And so, we, obviously, have to find the right balance there between optimism and pragmatism. But I don't want to necessarily limit it early. So, I'm going to let it run a little bit on the optimistic side. There's always plenty of time to bring in pragmatism. And so, I guess, my balance would be to start on the optimistic side, and then, we'll bring in the pragmatism as we need to. So, like I said, I know ONC is nervous about the optimistic side running a little wild. But that's okay. I think we've got a little room here. Arien?

Arien Malec, Member, Change Healthcare

You keep saying that, Robert. We're not that nervous. It's okay. I don't think this is an or question or a but question. I go back to the quote that goes something like everyone overestimates what can be achieved in a year and underestimates what can be achieved in 10. A lot of this is, if we try to go everywhere at once, we'll go nowhere. But if we set ourselves specific deliverables, limit the work that we have at any one particular time, and actually be successful at it, we'll make a huge amount of progress over 10 years. And I think we can look back at many of our careers and look at what we can do now that we couldn't do eight years ago or ten years ago and see proof points and evidence there. So, I keep coming back to let's finish what we started. Let's take on one, two maybe focused new things, convene industry, including HIE developers and provider organizations as well as government conveners.

And steadily and maybe more slowly than we'd like move the ball down the field. I think that's the only thing that's been successful, in this industry, and that has a proven track record.

Robert Wah, Co-Chair, DXC Technology

Thanks. I don't know if you guys are in order, but I'll go to John.

John Kansky, Member, Indiana Health Information Exchange

With apology, I think this is in the pragmatic category. The way the question was teed up, I feel like anything related to TEFCA should be assumed, and that's not what we're talking about. Yet, I have to say something about TEFCA is that I feel like once TEFCA is out there, and it's the new ecosystem, the interoperability for the country, not everything – we're not going to get everything right. It's not going to play out exactly like the ONC envisions. So, it will be very important for us to focus on the obstacles to that ecosystem working well and to attack those obstacles. I'll try and wrap it up quickly. So, TEFCA will be the new way that we have designed for the country to interoperate. And there will be challenges. And I think this group should absolutely focus on attacking the obstacles to making that successful.

<u>Robert Wah, Co-Chair, DXC Technology</u> Andrew?

Andrew Truscott, Member, Accenture

Thanks. Something we were charged with in 21st Century Cures, which we haven't really touched upon, is around privacy and security and the opportunity to assist in the definition around privacy enhancing technologies, etc. I think that would be useful for us to bring forward, on our agenda. And it kind of ties in with the third charge of focus of area we had around enabling proxies, for want of a better word, to gain access to information about third parties. So, whether you're a caregiver, etc., there are some cited examples of iterative circumstances. And they kind of tie in together around protecting privacy of law, so allowing access where appropriate. So, I think that would be an appropriate area for us to investigate further.

Clem McDonald, Member, National Library of Medicine

This is Clem. I just want to get on the list.

Robert Wah, Co-Chair, DXC Technology

Okay, Clem. You're on. Les?

Leslie Lenert, Member, Medical University of South Carolina

Thank you. I think that it would be important for us to begin to discuss the population health, regional health, and public health opportunities raised by interoperability, and the creation of the new types of both push and pull networks that are under consideration here at TEFCA and those issues. We are at risk with pandemics still. We do not have an actual strategy for dealing with that, in this country. We have numerous opportunities to create regional systems to cross our healthcare organizations that take out the risk of healthcare. It's my dream, one day, healthcare can be as safe as flying on an airplane. But until we can really anticipate the problems that are going to happen for people and develop backup systems that look regionally at a problem like when someone has lost a follow up for a lab test or a mammogram how the system responds.

We're going to have issues with that. And then, lastly, I think we have so much that we can do with our population health efforts and organizations here. We really haven't talked about what the guidelines should be, what the boundaries should be for that, and how we can create systems that are really synergistic. So, I see these areas of starting at the national needs that we have to address and the state and the local needs for public health. But then, moving beyond just traditional public health to talk about systems that protect patients from harm. And then, moving on to also how we collaborate on population health across organizations. These are issues that are the opportunities that are being raised by our TEFCA and other technical approaches.

Robert Wah, Co-Chair, DXC Technology Raj?

<u>Terrence O'Malley, Member, Massachusetts General Hospital</u> Robert, this is Terry. Could you put me on the list, too? Thanks.

Robert Wah, Co-Chair, DXC Technology Okay, great.

Raj Ratwani, Member, MedStar Health

Mine is definitely more on the practical side. And it's somewhere in the ONC's wheelhouse now. But the pediatric certification program, I think, is one area where I'd love to see a small group of us really focus on how we could support that effort.

Robert Wah, Co-Chair, DXC Technology

Thanks, Raj. Sheryl?

Sheryl Turney, Member, Anthem Blue Cross Blue Shield

Sheryl Turney with Anthem. So, you said bring up whatever, so this might be a little bit out there. But my question would be, with TEFCA representing the pathway forward, would it be possible to issue a challenge or to have a pilot of TEFCA in some small capacity that allows a broad group of stakeholders to participate to work out the business model issues, sort of bringing transparency and knowledge to it and, potentially, addressing how the current HIEs are going to bridge from their current process and how they work, which is all different to a future model. To me, that is some quantifiable focused project that could provide so much value that I would like to endorse that that's the recommendation we go forward. Find something that would support that.

Robert Wah, Co-Chair, DXC Technology

Good, thanks. Clem?

Clem McDonald, Member, National Library of Medicine

A couple of things, and this may be sort of a mealy mouthed question. But if we haven't finished UCDI, which was our original goal, we ought to at least do that and stick to that out there. And maybe we have, I just didn't notice. But then, the second thing relates to getting the data to the patient. So, there's two sides to it. There's a sender side to say that the hospital or the clinic or whatever would argue that, when a patient checks in, there should be a field or fields which say where they want it to go to. Now, there's some technical things we've got to deal with there. And then, the second side is the patient, on the receiver's side, we should stimulate or discuss some mechanism, machinery, etc., for building tools or connecting two personal health records, so that they've got a place to receive and organize it. That's really the political push for getting this done is the patient. And it's also what's in the bill. So, I think – and it would spread, if we could get it to the patient.

Robert Wah, Co-Chair, DXC Technology

Thanks, Clem. There was somebody on the phone that followed to ask to get on the list, and I've already forgotten who it was. Oh, Terry.

Terrence O'Malley, Member, Massachusetts General Hospital Do I have the floor?

Robert Wah, Co-Chair, DXC Technology Yeah.

Terrence O'Malley, Member, Massachusetts General Hospital

So, just a thought about how we can intertwine the policy and payment lovers with all of our work. And it's really a question, I guess, for Steve and the gang. Is there a CMS ONC work group where ONC tries to meet some of CMS's data exchange needs and extracts from them some policy support, some conditions of participation support to help drive interoperability? But anyway, if not, I'm out.

Robert Wah, Co-Chair, DXC Technology

Elise has a couple of comments about several of the people's comments. So, let's go to her first.

Elise Anthony – Director of Policy - ONC

Okay. And then, I can pass on. We'll tag team, as usual. So, just one. I know the conversation is still ongoing. But I do want to stop and say this is great to hear and I think very much aligns with a lot of the things we have going on and are prepping for at ONC. So, just a couple of notes that I would say. Sheryl, all the way back to your comment I think at the end of the last session, in terms of thinking about some of the business drivers, that's part of what's contemplated in the conditions of certifications, in terms of how it's structured. It's thinking more broadly about health IT and the fact that, even if the technical capacity is there, whether the business practices are impeding what should be happening.

And the conditions of certification talks about some of the communication and allowing information to move between folks who are using the health IT and I think also in information blocking similarly, thinking about what are those things that are impeding the flow of information, even when the technical abilities might be there. So, because those things are part of what we said would be in the rule, I think there will definitely be an opportunity for the committee to inform some of that work. Now, I can't say whether it would be specifically some of the things that you talked about, but definitely some of the business pieces that attach to health IT. So, once the rule comes out, I think there will be an opportunity for you to engage in some of those conversations as well. Raj, you talked about the pediatric settings. Similarly, thinking about health IT and pediatrics is something that ONC has been doing on an ongoing basis, particularly, the provision in Cures, as you noted.

That is something we plan to address in the rules. And we said that publicly. So, when that comes out, there will be an opportunity for the FACA to engage in that as well. TEFCA implementation, I think that's something that we've said on an ongoing basis that it will be a continuous conversation that we do plan to share with the committee, as we start to do implementation of TEFCA. The pilot piece, I also wanted to touch on a little bit. There is a provision in the TEFCA section of Cures that talks about pilots associated with TEFCA. So, that's something that, as ONC, again, moves towards the implementation of TEFCA that we will be thinking about what pilots could support continued implementation and what that would look like. And then, on the CMS question, in terms of coordination, we absolutely coordinate with them on an ongoing basis. Not only Steve and myself, but many other aspects or parts of our team, including Andy Gettinger who works with CMS on provider burden, for example.

So, yes, we have that. We also have a number of more formal mechanisms that ONC kind of leads on behalf of the secretary, in terms of engagement on health IT across different offices and different agencies. And CMS is involved with that. But I can tell you, on an ongoing basis, we spend a fair amount of time working with and coordinating with CMS as they are thinking through the policies on their side of the behavior associated with health IT and what providers are held to and others are held to, in terms of programs. Whether it's more on kind of the new programs associated with innovation regarding payment, or whether it's more on the MIP side of the equation as well. But let me turn it over to Steve who can add a little bit more, if I left anything out.

Steve Posniak

The pleasure that I have of working with Elise is that she usually covers 99% of what I want to say. Just to add on the CMS coordination part is that they have, I would say, many more statutes for which they are responsible, many more than we can count. ONC is perhaps lucky that we just have the HITAC Act and

Cures. CMS has all sorts of modifications of the Social Security Act, as well as other kinds of laws like the Impact Act and others that relate to their line of work. And so, to the degree that they have statutory and other programmatic implementation issues, we have a really good working relationship now with them across many of the centers, both on the Medicare and Medicaid side, for some of Elise's staff work directly on the Medicaid stuff. And we're always kind of in this constant cycle of providing feedback, advice, getting requests from them relative to technical maturity and readiness and other sorts of items that are of mutual interest.

Robert Wah, Co-Chair, DXC Technology

Great, thanks. I'm going to go to Ken and then, Aaron and then, back over the Steven, I think.

Kensaku Kawamoto, Member, University of Utah Health

Ken Kawamoto. So, I really appreciate Arien's comment about we tend to overestimate what we can do in a year and underestimate what we can do in 10. I do think it's good that we're focusing a lot on what we can do in the next year or two. I do think that we should start laying out the vision for what's achievable in 10 as well. I think one thing that I haven't really seen, being on this committee, is that vision of this is what being a patient, being a provider, being a caregiver will look like in 10, 15 years. And I think there's a lot of exciting possibilities that I would really like to see happen. And it's one of the things that we can do, as a committee. It doesn't require a ton of resources to say what should that future look like. And I think we should do that. I think we should envision a world where we're healthier and healthcare is not bankrupting the country. I think there's a feasible path towards that. And I think we should start laying that out.

Robert Wah, Co-Chair, DXC Technology

Thanks. Aaron?

Aaron Miri, Member, Imprivata

Thank you. A couple of points here. So, two of my points are going to be on privacy and security. First of all, I think there's an opportunity, especially as it relates to TEFCA, and I believe we did speak about it a little bit in the TEF work group around how do we accurately identify patients and providers and others accessing the TEF network. What does that look like? So, strategy around patient identification. The second bullet point here also could be the interoperability challenge. And I'll give you a real world example. There were a number of times my organization wanted to exchange data with a separate organization, but we couldn't really validate where they were on the security model. Did they accurately secure their data? Has it been modified? Do we want to take that risk on or not? And the question I always got back from my compliance and legal teams was it doesn't matter if we have a breach. We're still going to be held liable, and we still have to deal with the OCR. Okay.

Even if I'm doing all of the right things, and something happens because of this connection that we know is with maybe somebody that's not up to spec as we are, we're still liable, yes. Okay. So, is there a potential safe harbor consideration, if you're doing some sort of minimal floor of effort from a security perspective, to allow for interoperability and allow for folks to take that I'll call it opportunity risk, that measured risk and say, okay, I'm going to exchange data because it's the right thing to do to provide care knowing that something may happen. Nothing is 100%, but at least I'm not going to have the world falling down on my head. Two other bullet points here. Three, I want to give a lot of kudos the ONC with the hackathon. I think more of that could be done. How do we, as a group, encourage vendor community and provider community to work together and do more mini hackathons all around and try to solve these types of IT challenges. If you look at the students coming up now out of college and even if I look at my children,

they're smarter than me, when I was their age.

Folks are figuring out ways to look at small problems that we just simply haven't thought of. So, let's tap into that resource. And it ties into my last bullet point, which is a little bit outside of the scope but was identified in 21st Century Cures, but I think it's important that we've all been talking about, which is workforce development. How do we continue to help push the ecosystem along? Is it partnerships with universities? Is it partnerships with various schools? What is it going to take to build the next generation of health IT talent because there's a deficit, right now, in the community that we need.

Robert Wah, Co-Chair, DXC Technology

Thanks. Steve, I'm going to just jump ahead to John real quick and then, come back to you. John?

Dr. John White – Deputy National Coordinator

Spare coordinator's privilege. So, I wanted to offer just two quick thoughts. I'm absolutely mostly on listening mode. So, the first is I just want to say that I appreciate the spectrum from kind of major tempered recommendations to, be practical now people, to the wild eyed, hair on fire, John Brown's among you who want change and they want it now. Both kinds of recommendations are important, I think. And both kinds of topic wrestlings are important. They help – sometimes, advisory committees are like yes, that's nice. But we, generally, actually, want your advice. And we have an immense amount of respect for all of you, for your expertise and your experience but also for your passion and your values that you bring to it. So, I really would like to hear both kinds from everybody. You would sometimes be amazed at how much we share some of the irrational, wild eyed aspirations. We, subsequently, have to deal with how do you actually get that done, but that's okay because we need that kind of idealism to drive us forward.

So, that's just in terms of the kinds of things that you all think about. I did want to offer you a perspective of somebody who has been around slightly longer than Steve Posniak. Only by like a year though, right? Wasn't it a year, 2005 when you hit ONC? Yeah. So, a year longer than Steve in the federal government. And this gets to the underestimating or overestimating one year and underestimating in ten. So, what I found is that, yes, that is absolutely true. But I'd ask you to consider why it's true. And it's not because – and, yes, there is importance to sustained effort over a long period of time. But the world changes around you over 10 years. That's kind of what's happened to us, in a lot of different ways. And that means that 10 years from now, some of the stuff that we're talking about now is going to be like well, that was quaint. And some of the stuff is just like oh, wow, we actually got there, even though we didn't expect there was any way.

And it was awesome not because of something that we did but something was happening in parallel or something was unexpected. It's good to make 10 year plans. It's not a bad thing, to the extent that you can anticipate some of the other things that are happening out there in parallel, great. But be prepared for the unexpected. So, thanks.

Robert Wah, Co-Chair, DXC Technology Thanks, John. Steve?

Steve Posniak

I don't know who it was now who mentioned USCDI earlier in the conversation. But I want to make sure that we don't lose track of that. I think that the draft that was put out earlier in the year was great. We got a lot of public comment. We did have one round of work group that added some real dimension to

that effort. But I think we would be remiss, if we don't keep the fire on that one and move it along. It's a great opportunity for us to do real good.

Robert Wah, Co-Chair, DXC Technology

Thanks. I don't see any other tent cards. I guess I will invite those that have not made a comment to think about, if there's something that you'd like to add to this conversation. We've heard from a number of folks. I'm not going to do Carolyn's go down the list of people who haven't said anything. But I just want to put out an open invitation to those of you who may have not had a chance to comment on this area. Like I said, I had no particular design or plan to this discussion. But I did want to have this opportunity to have your input about where we can go as a committee that's outside of the direction that we were given by legislation within the 21st Century Cures Act. So, again, I'm not going to put anybody on the spot. But I'm offering an open invitation to those of you who may have not said anything to add to the conversation here because I think this is an important part. We've got just a few minutes before I have our contract with our public to have their comments come in soon. Cynthia?

Cynthia A. Fisher, Member, WaterRev, LLC

Yes. I think, if we also look at the delivery of the information to the patient where the whole privacy issue can be actually addressed by the patient where the patient is mobile in their care, they're guaranteed to be the one to be there. And they're going to want to share it with the appropriate caregivers. And in that moment of time, it may be a friend. It maybe a family member. It may be some advocate to accompany them. And envision, if you will, that like I can share my contact on my phone, why couldn't I share my health IT data to the next physician I'm going to see? Even across dentistry specialists, between the periodontist and the prosthodontist and all of these disciplines to be able to go back and forth between these disciplines and share films, share your data. And, okay, if anybody has teenagers, and you track them through Find My Friends or Life 360, you know that you can do location services, and it can time out.

So, if your kids are at a rock concert, for instance, you can actually see where they are in the crowd. And they can share that information with you. And after a certain time, you can, as a friend or they'll do it with their friends in that scenario, so they can find each other. But then, they can time it out after two hours. They can go back to privacy. All of these types of apps exist today. I would even beg us, if you all opened your location services, you'd be surprised to see applications that you didn't even know follow you are following you, including the Boston Globe or CNN or whatever. But you have the option to say no, don't follow me all of the time. Follow me only when I go into your site or application, and I'll let you do that. So, all of these things are totally doable and can be shared across the system.

And Robert, I go back to what you said earlier is we need to get to the openness of the confidence of providers being able to – and their vendors to be able to share this data, so we have the best health system delivered to the patient community. And all of that privacy can be controlled by us, the end user, and with our physician sets as well. So, I just throw that out there that if we could add a way to think about the future and enable it.

Robert Wah, Co-Chair, DXC Technology

Thanks. Other comments on this issue? I don't think it has to be an end discussion of this, obviously. I think it's something we ought to have somewhere in our thoughts about this committee all of the time. So, as we continue to work through the committee's charges that we've gotten from the legislation, we should continue to think about what other areas we want to put forward as a committee, both to the ONC but also to ourselves. So, by no means do I think this is a one and done kind of conversation. But I

appreciate that you all had some thoughts about where we can go with this. And, like I said, I think this is going to be an ongoing process through the time that we're together as a committee. But thank you for your indulgence in having this time. And, hopefully, we'll be able to use this to inform the committee itself but also the ONC about where we want to go. Aaron?

Aaron Miri, Member, Imprivata

Just a quick question, actually. I recall one of the previous health IT policy committee meetings that we had, something that stuck in my mind that was very powerful, and I'm wondering if it would be maybe helpful here, is I remember a discussion by the then, one of the leaders in the CDC talking about Zika and explaining some of the disparity there because pregnancy status wasn't a required field and how difficult that was for the CDC to be able to track that from a surveillance perspective and those sorts of things. Is it possible perhaps to have leaders from different agencies under HHS to speak to us about some of those challenges that currently exist today, like that one, because I think that may impress upon us other dimensions in our walks of life that we're coming from and say hey, let's think about these topics.

Robert Wah, Co-Chair, DXC Technology

Thanks. One thing you did remind me of, when you brought that up, is that we did have a presentation from the NCDHS, I can never say those five letters. Anyway, there's another federal advisory committee that's been around for a long time that's also working on some very similar issues. And so, we, certainly, as a leadership, have had some conversations across the two committees. And we're looking for opportunities, when it's appropriate to have either a joint discussion or certainly another presentation. So, that's one example of that. But to your point, and I think this links into what Les said, too, about thinking about population health and preventative medicine issues that maybe we haven't fully thought about, in terms of opportunities for the use of information technology in those areas. That's just one example of where outside organizations can be brought in.

Elise Anthony – Director of Policy - ONC

So, just to add to that, yeah, absolutely. I think there's wonderful opportunities. We work very closely. We mentioned CMS a lot because we tend to get asked about them a lot. But we work with not only CMS but everyone from HRSA to SAMSA to ARC and to CDC. And the work you're talking about, I remember it very clearly. My team worked on it. And the work that 1) CDC bringing that issue and sharing it with us, and we have a public health team at ONC who works on these issues, and then, bringing it to that advisory committee then led to actually inclusion in some of our work at ONC, including an interoperability standards advisory. So, I think, absolutely.

There's ongoing opportunity for us to not only focus on kind of the long game, in terms of what are we thinking about interoperability, where should things be in five to ten years, how do we support the rule, TEFCA, etc., but also where there are those kind of pressing issues that come up. How do we enable a space for the HITAC to get involved quickly and help inform the work related to standards, etc.? So, yes.

Robert Wah, Co-Chair, DXC Technology

Well, I gave you the constraint that we had a contract with the public that we would allow public commentary at 3:45. And you very nicely came right on that schedule, right? I'm sorry, we've got one more comment on the phone. Ram, did you have a comment on the phone? Maybe not? Maybe he's on mute?

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Ram, are you on the line?

Robert Wah, Co-Chair, DXC Technology

Okay. Lauren, I'm going to turn it over to you to open it up to the public commentary.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Great, thanks. Okay. At this time, operator, can you please open the public line for comment?

Operator

Yes. If you would like to make a public comment, please press Star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press Star 2, if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. And we do have one public comment from Julia Skapik with Cognitive Medical Systems. Please proceed.

Julia Skapik – Cognitive Medical Systems

Yes, thank you. I appreciate very much the discussion about metrics for interoperability. In that vein, I think ONC is in an excellent position to be able to gather much richer metrics about interoperability. For example, what information is actually viewed. What information can be confirmed by a receiver that they actually received it? These are pieces of information that are generated just in the point of the exchange and don't actually add any burden. That being said, it's very exciting that there's going to be availability of the 2015 edition, more rich narrative content in gold, co-concerned, **[inaudible] [06:16:56]** and assessment sections. And I certainly encourage ONC to reach out to the community to find out is that content going to be made available to users immediately. And if not, why not? And can they do some sort of tracking of systems to make sure users are actually getting that information exchanged.

From the standpoint of users and usability, I can tell you what I perceive the priority of my vendor to be on my user feedback, when it takes me over 20 minutes of clinical time to sit on hold and provide them with feedback. Yesterday, I bought used auto parts online, and there was a person live waiting to help me in live chat. And I think the other thing that ONC can really do that would make a difference is require the availability of feedback from users on a myriad of issues. They see usability, functionality, interoperability as the point of the use of the system to report those metrics and also how things are being adjudicated by the vendor. But at least we'll give a user some sense that they can reasonably, without taking an hour out of their day, provide feedback to the system and that someone is listening. And that also, it may help to add some additional information to the kind of subjective usability metrics that are being generated in the private sector. Thank you.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> Designated Federal Officer

Thank you for your comment. Operator, do we have any other comments on the phone, at this time?

Operator

There are no other public comments, at this time.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

Great. Now, we'll transition to those in the room. Anyone who would like to provide a public comment, at this time, please come forward to the table and state your name. Seeing none, I will hand it back to our co-chairs.

Robert Wah, Co-Chair, DXC Technology

Thanks, Lauren. I want to make sure we didn't miss Ram on the phone. I thought we had a note that he was wanting to speak.

Ram Sriram, Federal Representative, National Institute of Standards and Technology Hi. Can you hear me?

Robert Wah, Co-Chair, DXC Technology Yeah, great.

Ram Sriram, Federal Representative, National Institute of Standards and Technology Can you hear me?

Robert Wah, Co-Chair, DXC Technology

Yes, we can.

Ram Sriram, Federal Representative, National Institute of Standards and Technology

Essentially, I was just telling that if you're looking to the future, you also have to look into interoperability of EHRs along with medical devices and other sensors, which are going to give out lots of information like you have all of these implants and all kinds of sensors in there. I just put a comment on the chat anyway because right now, a lot of concentration is on interoperability of EHRs, per se and getting information out of EHRs and what to do with them. But there's lots and lots of data, which is going to be generated from other kinds of sources. Actually, including social networks.

Robert Wah, Co-Chair, DXC Technology

Thank you. So, I think we've wrapped through our fairly ambitious agenda through the day. Again, I guess from my point of view, as one of your co-chairs, and I hopefully speak on behalf of Carolyn as well, we appreciate everyone's efforts to come to this meeting and all of the meetings prepared. There's a lot of material to go through. And, hopefully, we've been able to steer the conversation in a way that's productive for all of you. Always looking for suggestions on how to make that better. Please send them along in whatever means you'd like through direct email or smoke signals or whatever. But I'd like to say that, since our first meeting in January, I think the group has come together pretty well. And, certainly, I've seen no reluctance on anybody's part to speak up, which is a good thing. So, from my perception, I think that's a good thing that we're at a good place as a committee. But like I said, there's always opportunities to make it better.

So, if you have suggestions, please pass them along. Once again, I want to thank the ONC team for their support and their help in making this work successful. There are a lot of things to do. Certainly, the task forces are where a lot of the work is being done. And I know that you all are working hard to contribute to those as well. Thank you for that work. Carolyn, do you have any other comments you want to make?

Carolyn Petersen, Co-Chair, Individual

No, I'm just happy to take the opportunity to reiterate all of Robert's points about your great involvement in our discussions today, your efforts to travel and willingness to engage in some discussions that

sometimes it feels like we've been having forever and are not moving forward, even though we actually do but slowly. I want to thank the ONC staff for all of their help in organizing the meeting and making it possible for us to come and do productive work and their work with the task forces and work groups to help us in those areas also. Thank you.

<u>Lauren Richie – Office of the National Coordinator for Health Information Technology -</u> <u>Designated Federal Officer</u>

So, with that, just a couple of reminders before we adjourn. First, our next full HITAC meeting is October 17, which you should have on your calendars. And then, even before that, we'll have at least a couple of task force and work group meetings. So, for the public members listening in, you can find the calendar of those meetings, as well as all of the meeting materials on healthit.gov. And with that, we will adjourn for the day. Thank you all.