Health Information Technology Advisory Committee

Transcript
June 19, 2019
Virtual Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Individual	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	WaterRev, LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member

Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member

Federal Representatives		
Name	**Organization**	**Role**
Terry Adirim	Department of Defense	Member
Laura Conn	Centers for Disease Control and Prevention	Member
Kate Goodrich	Centers for Medicare and Medicaid Services	Member
Mark Roche	Centers for Medicare and Medicaid Services	Member
Ram Sriram	National Institute of Standards and Technology	Member

ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Cassandra Hadley	ONC	HITAC Support
Steve Posnack	ONC	Executive Director, Office of Technology
Zoe Barner	ONC	Staff Lead

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome back. I hope you are enjoying your summer so far and enjoyed a bit of a break from our recent group of meetings for the proposed rule. We are ready to turn our attention to the TEFCA with the first set of draft recommendations today. With that, we will jump into it starting with roll call. Carolyn Peterson?

Carolyn Petersen – Individual – Co-Chair
Good morning.

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

Robert Wah – Individual – Co-Chair
Good morning. Present.

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

Michael Adcock – Individual – Member
Present.

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

Christina Caraballo – Audacious Inquiry – Member
Present.

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

Tina Esposito – Advocate Aurora Health - Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher? Okay. Valerie Grey, I believe she is going to be absent today. Anil Jain?

Anil Jain – IBM Watson Health - Member
Present.

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

Designated Federal Officer
John Kansky?

John Kansky – Indiana Health Information Exchange – Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Ken Kawamoto? I believe we have Ken on. Steven Lane?

Steven Lane – Sutter Health - Member
Good morning.

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

Arien Malec – Change Healthcare - Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Denni McColm?

Denni McColm – Citizens Memorial Healthcare – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Clem McDonald? Not yet. Aaron Miri?

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Good morning.

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

Brett Oliver – Baptist Health – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good morning. Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Raj Ratwani? I believe he's on. Steve Ready?

Steve Ready – Norton Healthcare – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Sasha TerMaat?

Sasha TerMaat – Epic – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Andrew Truscott? I believe he may be absent as well. Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Ram Sriram?

Ram Sriram – National Institute of Standards and Technology – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Terry Adirim? Not here? Okay. With us from ONC, we have Elise Sweeney Anthony, Steve Posnack, Seth Pazinski, and myself. I will now turn it over to our National Coordinator, Dr. Rucker.

Donald Rucker - Office of the National Coordinator for Health Information Technology – National Coordinator
Hello, everybody. Welcome. I want to again thank everyone for all of the work on the rules and recommendations. I know it took a ton of time. It took a while to read, actually. I did read all of it. I want to thank you. I want to thank Carolyn and Robert for bringing this to the finish line. I did want to give one HITAC member update. Patrick Soon-Shiong has resigned from HITAC. We would like to thank him for throwing his hat into the public fray here. We will be working with the relevant nominating entity, who I believe is a ranking member, McCarthy, for that appointment. We will do that for a replacement. The only other reminder is we are anticipating the final recommendations on the trust exchange framework on common agreement on July 11. I think we will have some of that today to start. I will turn it over to Carolyn and Robert. Thank you.

Carolyn Petersen – Individual – Co-Chair
Good morning.

Robert Wah – Individual – Co-Chair
Good morning, everyone. Thanks for joining in again. For those of you on the West Coast, I know it is super early. Carolyn is also on the West Coast. Thanks to the entire HITAC for all of the work you have done to get the comments in for the proposed rule as the national coordinator mentioned. We look

forward to a robust discussion today of the TEFCA recommendations that we are putting forward. I will turn it over to Carolyn for her comments.

Carolyn Petersen – Individual – Co-Chair
Thank you. Good morning, everyone. It is great to see us all here after a few weeks of rest from the NPRM work. We are looking forward to getting started on our TEFCA discussions today. We will start out initially, we will review where the Annual Report Workgroup is, followed by the TEFCA discussion. We do need to approve the meeting minutes from the May 13 and May 22nd meetings. May I have a motion, please?

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Motion.

Carolyn Petersen – Individual – Co-Chair
Is there a second?

Denise Webb – Individual – Member
Second.

Carolyn Petersen – Individual – Co-Chair
Will all those in favor of approving the minutes from the May 13 and May 22nd meetings please signify by saying aye?

John Kansky – Indiana Health Information Exchange – Member
Aye.

Arien Malec – Change Healthcare – Member
Aye

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Aye.

Carolyn Petersen – Individual – Co-Chair
All those opposed, say nay.

[Silence]

Carolyn Petersen – Individual – Co-Chair
Are there any abstentions? Okay. It looks like we have approved the minutes for the May 13 and May 22nd meetings. I have no further comment, unless you do, Robert. If not, we can move into the Annual Report update.

Robert Wah – Individual – Co-Chair
That sounds good.

Carolyn Petersen – Individual – Co-Chair
Great. Thank you. Like last year, Aaron Miri and I are cochairing this workgroup. Aaron, I believe, is traveling in a car right now. I will take us to the slides and then we will jointly host any discussion about it. Good morning, Aaron. Safe travels.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you.

Carolyn Petersen – Individual – Co-Chair
This is just our basic update. We will go through the membership and scope. We will review meeting schedules and update you as to where we are with our planning for the fiscal year 2019 report. May have the next slide, please?

Our membership is myself and Aaron, Christina Carabello, and Brett Oliver. We have several staff members from ONC working with us to prepare the report, as well as some contractor resources to help with research and writing. Can I have the next slide, please?

Our overarching scope is to inform, contribute to and review the draft and final versions of the HITAC Annual Report that is submitted to the HHS Secretary and Congress each year. As part of that report, we will help track ongoing HITAC Progress. That is something we did not do last year because we were in our first year. It will be a new section in our report this year. Turn to the next slide.

Going into more detail, our report should involve an analysis of HITAC Progress, assessment of health I.T. infrastructure and advancements, analysis of existing gaps in policies and resources and ideas for potential HITAC activities. All of this is required by the 21st Century Cures Act. Turn to the next slide, please?

We will look now at our meeting schedules. The workgroup itself has already met in April and June. We are currently scheduling dates for our work in July, August, and September, then into the fall as well. We will continue to discuss topics and outline the reports of the summer. In the fall we will begin drafting and bringing information to the full HITAC for review and discussion. Our goal is to finalize the fiscal year Annual Report and pass it on to the national coordinator for review to Congress and HHS in February. We are looking at being a little bit ahead of where we were last year because we were able to get an earlier start. Turn to the next slide, please.

We are updating you today on our review schedule for the full committee. We don't expect to do any updating in July. We don't meet in August. In September, we will come back to discuss topics in the outline for the Annual Report. In October and November, we will update you on where we are with progress. There is no meeting in December, we hope. In January, we will bring forward the review draft to the full HITAC. In February, we look to approve the final version and again, move that onto the national coordinator.

Next slide, please. Now we get into the planning portion. Next slide. This is our draft outline for the Annual Report for fiscal year ‘19. It is pretty much the format that we used for the fiscal year ‘18 direct support, except we have added in a section on the HITAC Progress. As you can see here, we are bringing that after the forward and overview and the head of the landscape and gap analyses and the other information. We are really bringing that to the front to draw the eye to the work we have done to date. The next slide, please.

There is a list of potential topics for the Annual Report. Since we prepared and passed on the fiscal year ‘18 report in April, we had been meeting to look at what is happening in the field and the industry and also revisiting items that were carried over from last year's discussion. The carryover items for the Annual Report would be ONC's Cures Act regulations. That is information blocking, certification

enhancements, and implementation of APIs. There is a trusted exchange framework in common agreement. We are still working through that. There are implications of privacy legislation, cybersecurity framework adoption, and concerns beyond the scope of HIPAA coverage. We have measurement ideas from report recommendations and for usability, patient control data collection, access and sharing, the reality gap between the perception of what has been certified for a system and what is truly interoperable in the field, research data ecosystem, and governance, and social determinants of health, patient-generated health data and the Internet of things. Next slide, please.

Based on comments we have received from HITAC members during the review of the Annual Report for fiscal year '18, we have some additional topics. Those topics would be challenges with incorporating and reconciling data received from various external sources, cross-state data exchange and privacy considerations, for example, the exchange of imaging reports and images, highlights of data quality initiatives, that would be things like with the Veterans' Health Administration and what they are doing, patient matching and patients electronic address information, policy and trust issues related for open APIs, and price transparency and patient access to price information. Next slide, please.

Some of the ideas that the Annual Report workgroup has come up with to date include consumer access to immunization data, data segmentation direction and impact, digiceuticals and digital therapeutics, the apps used as treatment, integration of prescription drug monitoring programs with EHRs, provider of burden reduction opportunities – of course, that is a priority for ONC – sociogenomics – that would be the intersection of social determinants of health and genomic data in healthcare and research – and standardization of provider notes to enable use and sharing while considering liability implications. Next slide, please.

The Annual Report workgroup is particularly interested in a couple of things. First, describing HITAC concerns about recent areas of ONC activity. For example, information blocking in the TEFCA. We think the Annual Report is a really good place to circle back and include any other things that came out in the discussion that was not easily accommodated in the transmission letters or in other ways we work with ONC. Also, considering the next steps for the measurement mentioned in the recommendations from the HITAC Annual Report for fiscal year '18. A number of individuals, including people on the workgroup, have been really concerned about looking at metrics and finding some ways to measure progress. We think this is of particular importance in our fiscal year '19 report. We have a couple of discussion questions that we would like to bring to HITAC today. First, are there any questions or comments about the draft outline and these topics that we have identified so far? What topics should be added to or removed from the list of potential topics for the upcoming report? Next slide, please.

With that, I would like to open the discussion and bring in Aaron, as well. Robert, would you mind? I guess I could see hands, if there were any. Okay. We will start with Arien.

Arien Malec – Change Healthcare - Member

Thank you for that and for the update. Am I to understand in the first section where you are talking about priority topics and you talk about privacy not related to HEPA, with part of that scope B potential recommendations for Congress to establish a more uniform privacy law that stitches together across HIPAA and FTC regulations and create a broader privacy framework for patient data?

Carolyn Petersen – Individual – Co-Chair

We haven't actually come up with specifics around that topic. We certainly could.

Arien Malec – Change Healthcare - Member
That could be included in one of the topics. Thank you.

Carolyn Petersen – Individual – Co-Chair
Yes. I did not catch all that as you were saying it, but I'm making a note to double back in the meeting notes afterward and take that out and put it on our list when it's in writing.

Arien Malec – Change Healthcare - Member
Okay. That was a topic that was also identified by the national coordinators in their letter to Don. We have sort of a patchwork of privacy regulation. In some cases, we cover things under HIPAA and in some cases, we covered things under FTC and in other cases, we cover things under the research common rule. That is currently an area with a gap.

Carolyn Petersen – Individual – Co-Chair
Okay. That sounds great. We will capture that off of the transcript and be sure to get that on the list. Perhaps we can circle back with you for further discussions as we go forward.

Arien Malec – Change Healthcare - Member
Thank you.

Donald Rucker - Office of the National Coordinator for Health Information Technology – National Coordinator
It is Don, Arien. As a heads up, there is a lot of Congressional interest in this, as well. We are getting requests for technical assistance. We are looking at some language. I would say all of that is early, but there is a lot of interest in that.

Arien Malec – Change Healthcare - Member
That is good news.

Carolyn Petersen – Individual – Co-Chair
Do we have any additional questions or comments from others?

Robert Wah – Individual – Co-Chair
Carolyn, this is Robert.

Carolyn Petersen – Individual – Co-Chair
Yes?

Robert Wah – Individual – Co-Chair
I would also say to the committee that I think the planning of our Annual Report is a good time to also think about those things we want to take on this year as a committee. We have had, I think, one or two sessions talking about the things we wanted to take on as a committee that is maybe outside of the Cures Act that set this committee up. I think this is also an opportunity to think, as a group, about areas of work that we are seeing from our different perspectives and areas of responsibility that impact the intersection of healthcare and technology. I hope folks will think about looking at the Annual Report from that lens as we put together the plan for the next year.

Carolyn Petersen – Individual – Co-Chair
Are there other questions or comments from the full HITAC? Aaron, do you have any comments to share or other thoughts about suggestions for discussions and the topics?

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
No. I appreciate it. I just thought that I would echo that it would be appreciated for the committees to consider and think about over the course of the year. We know last year we were a little bit rushed because that was our first year. This year we have the full year. There are other items, just like Arien mentioned, of the privacy and security mishmash between state and federal. Just think about those and please send them our way.

Robert Wah – Individual – Co-Chair
Denise, you have your hand up?

Denise Webb – Individual – Member
Yes, thank you. As I look at the list of potential topics, it is a pretty expansive list. I guess, what I am trying to understand and what I would like clarification on is: what does that imply for the committee? Are those all topics we are going to work on and then report on, or are we just reporting the current state of those topics? It seems like a pretty expansive list. I am just trying to get my head around that.

Carolyn Petersen – Individual – Co-Chair
Yes. Part of our charge is to do a landscape and gap analysis. Those are things we are required to do as part of the Cures Act. We are coming up with this list of topics for which we will do the landscape and gap analysis. From that, HITAC can choose to take on other particular activities, or it can simply comment upon those areas in ways that the group agrees upon. At this point, we are still kind of determining what should be involved in those analyses and what we should include. There is no specific requirement that we take action on any of the items. That is up to us to decide what we want to do going forward.

Denise Webb – Individual – Member
That helps a lot, Carolyn. I think even, still, doing a landscape assessment and a gap analysis is not a small matter on some of those topics. I am just thinking about resources and time to do that.

Carolyn Petersen – Individual – Co-Chair
Yes. ONC does have contract resources, individuals who work with our ONC report partners, who can do some of that research for us and bring it forward to the workgroup so that we can assess and determine what is appropriate to include in terms of the right level of detail in the right direction that is relevant to our work. Yes, it is true, if the four of us were trying to do this ourselves that would be quite a challenge. Fortunately, we have partners.

Denise Webb – Individual – Member
Or even more than the four of you. It is a pretty substantial amount of work.

Carolyn Petersen – Individual – Co-Chair
It is a pretty constant per hands of the report we put together. We feel that is appropriate. Given the depth and breadth of the expertise of HITAC, that is the right way to go.

Denise Webb – Individual – Member
Thank you for the clarification.

Carolyn Petersen – Individual – Co-Chair
Yes.

Robert Wah – Individual – Co-Chair
This is Robert again.

Carolyn Petersen – Individual – Co-Chair
Go ahead.

Robert Wah – Individual – Co-Chair
It occurred to me also that one point we might to make is about the work that we are trying to do with the NCVHS, particularly the part about prior authorization improvements. I don't know if you want to get that specific or just use the broader heading of coordinating and working with the NCVHS as well.

Carolyn Petersen – Individual – Co-Chair
We will include that in the progress report section. Certainly, there may be topics that spring from that work that we can add to the list of other topics and things that should be included in the landscape and gap analysis. I am making a note of that on my list and we will add that to our spreadsheet. Thank you.

Robert Wah – Individual – Co-Chair
Hopefully, I don't know when we will do it, there very well may be more meetings. I know less is working on his prior authorization idea. That might be something to flag in there.

Carolyn Petersen – Individual – Co-Chair
Okay. Thank you.

Steven Lane – Sutter Health - Member
With Steve Lane.

Robert Wah – Individual – Co-Chair
I am sorry. Yes, Steve.

Carolyn Petersen – Individual – Co-Chair
I don't see any other hands. This is your last chance to make a comment or ask a question. Seeing and hearing none, I will say thank you for the discussion and the additional items for us to add to our list for the Annual Report. I will hand the microphone back over to Robert for the next agenda item.

Robert Wah – Individual – Co-Chair
Thank you, Carolyn. Thanks to both of you for your work on this last year and this year, you and Aaron, to put together this report process. Again, for the committee, as you think of things that you would like to suggest to the Annual Report group for them to look at, please send them in. This is our opportunity to think about our work going forward for the next year, but also to reflect back on the issues you are seeing from your areas that you work in. It is a lot of work to do this report, but I think it is an important contribution to document where we are going and what we are going to do. Thank you, Carolyn and Aaron, for that. With that, we are going to turn it over to John and Arien to start to discuss our Trusted Exchange Framework draft recommendations. I will turn it over to John and Arien.

John Kansky – Indiana Health Information Exchange – Member
Thank you.

Arien Malec – Change Healthcare – Member
Good morning.

John Kansky – Indiana Health Information Exchange – Member
Good morning, everybody. First, I will start off by acknowledging, happy birthday to my co-chair, Arien Malec.

Arien Malec – Change Healthcare - Member
Thank you.

Robert Wah – Individual – Co-Chair
Shall we sing?

John Kansky – Indiana Health Information Exchange – Member
That is a great way to spend your birthday working. Thanks to the task force for their work. I will say so far because what we have today is draft recommendations so far. We have more water to carry. The ONC team has been great in helping us get this far. If we could go to the chart slide, please, or the member slide? Thank you.

This is our team, including the task force and the ONC members. They have been great so far. There are a lot of diverse opinions and professionally delivered input, as usual. The next slide, please.

Our charge, the detailed charge for the task force, was originally articulated as the bottom four bullets. With support from the ONC team, we have included some overarching recommendations related to the value proposition of TEFCA and the alignment with information blocking and applicable law. The rest of the detailed charge was to provide some feedback on the definition structure applications for the QHIN process, including eligibility and application. The exchange purposes and modalities including the seven exchange purposes and three modalities proposed in the MRTCs, as well as reciprocity and permit for future uses. Both the privacy and security requirements are included in TEFCA. Next slide, please. Next slide.

First, I wanted to stress that these slides correspond with the draft transmittal letter that you also have. The recommendations are addressed. There is noted, in some places, where we have the additional discussion we need to have. I look forward to your input today. Specifically, there will be additional recommendations that will be forthcoming. The ones we have today cover the first three bullets of the charge and the beginning of privacy covering meaningful choice. Those recommendations will be forthcoming for the remainder of the charge.

Recommendation number one. It is largely aimed at considerations of adoption of TEFCA and the need to incentivize adoption. This started with an acknowledgment that the broad policy aim of TEFCA is and should be better treatment, quality of care, and the more efficient healthcare system. For TEFCA to achieve or advance those specific policy aims, it will need to do that while complementing and coexisting with existing frameworks and also being sufficiently and appropriately adopted. In the transmittal letter, there are some additional details that we mentioned but largely, the complementing and coexisting with the existing HINs in frameworks is consistent with the 21st-century Cures Act but takes advantage of the significant progress the industry has made, especially in recent years.

In the second bullet, we are trying not to say, “It has to be adopted so figure it out.” We have tried to offer some suggested tactics that can be used to incentivize, including some things that resemble carrots and some things that resemble sticks.

Recommendation number two is focused on aligning the TEFCA. Specifically, most of our discussion has been around information blocking, including that the definitions that are applied for actors in EHI, for example, will be applied across both rules and encouraging ONC to consider the definitions that will be relevant across the TEFCA framework and across the information blocking regulation when they are applied in both context that they make sense.

The next two bullets, regarding good-faith participation but not a safe harbor, are a pair in that good-faith participation in TEFCA doesn't guarantee that an organization is not information blocking, but in terms of network exchange purposes, uses and modalities that are part of TEFCA, participating in TEFCA and not information blocking should be consistent.

The next bullet, again, I think, underscores that the task force, participation in TEFCA should not be a safe harbor from information blocking in that the TEFCA and the information blocking regulation did not have the same purpose.

Arien Malec – Change Healthcare – Member
I want to do some color commentary there. Your TEFCA is not co-extensive with all the activities that are associated with information blocking. TEFCA doesn't cover API-based access. It doesn't cover local access to health information networks. By definition, participation in the TEFCA cannot address all of the information blocking requirements. I think our point here is that to the extent that an organization is participating in good faith in TEFCA and making information more broadly available across networks, at least for those portions of information blocking, good-faith participation should be a key consideration and relative to information blocking, so that there is an incentive that participation in TEFCA is the easiest, safest, fastest path to address information blocking requirements that are broader and cross-network in nature.

John Kansky – Indiana Health Information Exchange – Member
Thank you. The second to last bullet is expressing the opinion that TEFCA should not be a condition of certification, nor should the information blocking requirement require TEFCA press participation. The last bullet is just acknowledging the careful balance necessary. With that -- Yes, please?

Robert Wah – Individual – Co-Chair
This is Robert. It occurs to me that this is not our first chance as a committee, but with the new set of recommendations, I think there is a lot of first-time exposure here. These slides have a lot of information on them. I am thinking maybe we will just take a pause after each slide because of all the information that is displayed there and ask for comments from the committee. I am sorry if I am slowing down your rhythm here, but I think this will be easier than trying to scroll back to the slide after you have gone through several.

John Kansky – Indiana Health Information Exchange – Member
No, I think that feels right to me too.

Robert Wah – Individual – Co-Chair
I look at this slide and I see a lot of information and I want to make sure people have a chance to digest it and comment on it while it is still up for display. Maybe we can take a pause after each slide. I like the way you are presenting, that is great, but allow comments about the slide that is currently presented. I

want to make sure we have a good opportunity to have a full discussion on this. I see Christina has her hand up.

Christina Caraballo – Audacious Inquiry – Member
Thank you, Robert. Thank you both for putting this together. This is great. Arien, happy birthday. I do have a concern with the recommendation with the participation and TEFCA not being a condition of certification or a requirement of information blocking. I understand there needs to be a balance and we need to apply that with the existing framework, but I see this as a major problem. I do think the whole point of establishing the framework is to make it required that folks participate.

When I think, excuse me, of the conditions of certifications, it doesn't necessarily mean that a vendor, in my opinion, necessarily has to participate in the TEFCA, but I think there should be a path in certification. In order to be a certified product, you need to have clear paths for your client to be able to easily connect to a QHIN of their choice. That functionality needs to be in place as part of the certification. For the information blocking piece, I think that it should be a requirement for everybody that is a participant within TEFCA to kind of check the box of the information blocking by being a participant in the TEFCA or else, I just don't think people will participate. I think it is really important that it is a requirement.

Arien Malec – Change Healthcare – Member
First of all, thank you for those comments. I will take them in order. For the first one, it is a really important comment and we should take it back to the task force. As the so-called QTF, the QHIN Technical Framework gets established, there may be pathways to certification there. It is important to know that the TEFCA does not mandate or defined the EHR to HIN side of the connection. It may well be some missing standard in certification there. It might be appropriate for the task force to consider a comment or recommendation that adds the QHIN Technical Framework is fleshed out and real-world tested and there is an opportunity for certification.

On the second point, I think we are saying the same thing. Maybe we just need to say a stronger version of the same thing. There was a technical point. TEFCA is a sub-regulatory framework. It is not a rule. It's not a **[inaudible] [00:36:47]**. I don't think there is a technical way by which ONC could mandate participation in the TEFCA. I think we are saying the same thing you are. There is a whole set of obligations that providers and health information networks and health information exchanges have to offer up data for permitted purposes. That data requirement is not local and it is not network bound. I only have to offer up information in my network. I have to offer up information to any request for a legitimate permitted purpose.

Our intent here is to say the TEFCA should be the natural, obvious, simple, easiest way to address those requirements. We might've got a little lost in the drafting language. We were trying to make sure it really is what it is intended to be, which is the volunteering participation. You can't have too many carrots if you are a voluntary participation framework. You can have too many sticks if you are a voluntary participation framework. Clearly, I think we are saying the same thing. The carrot here should be, this is the natural, easiest, and fastest way to address those portions of information blocking that require across the network exchange.

John Kansky – Indiana Health Information Exchange – Member
Great comment, thank you.

Robert Wah – Individual – Co-Chair
Other comments? Go ahead. Sorry John, go ahead.

John Kansky – Indiana Health Information Exchange – Member
I cannot see the hands. I will depend on you.

Robert Wah – Individual – Co-Chair
Okay. Other comments about these first two recommendations from the task force? I see no hands. John, you may proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. We are on moving on to recommendation 3A and 3B, please. Thank you. This is the section of our charge where we are focused on how TEFCA looks and works in the context of applicable law. The largest consideration the task force is discussing is the need for clarity between the TEFCA exchange framework and the HIPAA regulation. 3A and 3B are a pair. 3A says basically, whenever possible, align the TEFCA privacy and security obligations with the HIPAA privacy and security obligations. While there is an understanding there are new exchange purposes in TEFCA that go beyond HIPPA PPO and the EHI expands the relevant health data beyond protected health information, that to the extent possible, the obligations should be aligned. 3B suggests that to minimize confusion or misinterpretation, that TEFCA should, wherever it is specifically different, in terms of the privacy and security requirements of TEFCA are specifically different than HIPPA, they should be called out clearly. Where they are the same, they should be called out clearly, just to make the regulation easy to understand and implement – make the framework to implement in the context of its HIPPA regulations. Pausing for hands.

Robert Wah – Individual – Co-Chair
Comments from the committee on these two recommendations, 3A and 3B? Questions or comments? Seeing none, John, you may proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Recommendation 4, please. There is an understanding that health information that works in health information exchanges will need to amend the terms and conditions of their participation agreements in order to be able to sign the ultimate comment agreement and participate in the QHIN exchange network. Furthermore, those requirements and the implications of those changes will need to flow down an impact participant and participant member agreements, as well. Minimizing the need to do that and minimizing the extent of those changes is desirable. We are trying to suggest – the last phrase in that leading paragraph means we are trying to offer some ideas and possible tactics about how to minimize that disruption. These require a little bit of explanation.

The first suggestion is that allowing the RCE, with respect to QHINs, and QHINs with respect to participants, some latitude to agree to bootstrap periods. Basically, that is the ability to say, "Okay, your RCE can say you are a QHIN," acknowledging that we have agreed you have time to amend your contracts and give the RAC some latitude to say what needs to be amended and in what timeframe is reasonable while still allowing that organization to be a QHIN in good standing. Slightly trickier is allowing QHINs to do something similar with respect to participants. Obviously, the RCE would need to have some role in that and suggesting that the cohort, the RCE may be able to utilize with respect to QHINs, the cohort tactic that is discussed to do that.

The second potential tactic is to allow this evaluation and approve process between the RCE and the QHIN and the QHIN and participants. The idea here is that the RCE can look at a current participation agreement of a QHIN candidate and suggest places where those two organizations can agree to places where amendments to their participation agreements were necessary and places where they weren't. Again, a similar process could be between the QHINs and the participants with the RCEs having clear governance over that process. We tried to be clear. The idea is to minimize, to leave as much of the existing participation agreements that have been successful in HIEs and HINs in building networks, leaving as much as those terms and conditions can be undisturbed.

Finally, the third potential tactic, which is a bit of an homage to HIPAA security, is to determine whether certain terms of TESCA could be required and others as addressable, meaning, "You have to do these," and, "You really should give these serious consideration." With that, I will pause for comments or questions.

Robert Wah – Individual – Co-Chair
Thank you. Questions, comments or recommendation 4 before you on the slide? Again, seeing no hands up, we can proceed, John.

John Kansky – Indiana Health Information Exchange – Member
Okay. Thank you. We're looking at the move to recommendations. Pause there for a second. Acknowledging that we are moving on to recommendations related to the QTF, including the exchange purposes and the exchange modalities. There was plenty of discussion here. Let's move on to the next slide, please. Recommendation 5 is encouraging, in general, encouraging ONC to specify – to frame tests in terms of policy and functional requirements, and to defer technology solution specifics to the RCE. There is some perception of the need to be careful in the alignment of the QTF which is in the MRTCs. Arien, do you want to weigh in and add color on this one at all?

Arien Malec – Change Healthcare – Member
Yes, the draft ETS names a number of standards. Each come with their own functional requirements. In some cases, in the TEFCA 2, there are diagrams that describe some of the interactions of the standards in ways that go above and beyond and don't necessarily map cleanly to the MRTC defined functional requirements. I think the task force had some difficulty understanding what the functional requirements were. The intent of this recommendation is to make sure the technical specifications address the functional requirements and that we don't have the needs of the technical specification accidentally becoming functional requirements or described as functional requirements in TEFCA 2 or the final version of TEFCA.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Recommendation 6 is acknowledging that we believe there is a specific gap between the requirements of the information blocking regulation and the TEFCA, what is described in TEFCA, and encouraging ONC to address the gap. What we are specifically calling out is that information blocking requires the exchange of all EHI, whereas TEFCA calls on participants and participant members to exchange at a minimum EHI, which is in USCDI. That creates a higher expectation to avoid information blocking than is implied in TEFCA. That gap may be manageable, acknowledging that additional responsibility for TEFCA participants. If you want to exchange more information in a situation where you are not under an information blocking exception, you would need to do that, but better would be to close the gap or address the gap in whatever way ONC feels would be appropriate. I will acknowledge

the task force needs some more discussion on this because the two obvious choices are either, say that in TEFCA you have to exchange all EHI or, say in information blocking, at a minimum, exchange EHI and USCDI to avoid information blocking. With that, I will pause for comments.

Robert Wah – Individual – Co-Chair
Thank you, John. Comments, questions or recommendations on recommendation 6 as you see on the slide?

Donald Rucker - Office of the National Coordinator for Health Information Technology – National Coordinator
This is Don Rucker. On recommendation 5, it would be helpful to have some of the specific instances. We don't need that now, but just as an email to Laura or something like that. That would be helpful.

Arien Malec – Change Healthcare – Member
Zoe has been staying super close to all of this. I think we can enumerate some of the examples.

Robert Wah – Individual – Co-Chair
Okay. Are there questions or comments about recommendations 5 and 6? Okay. You may proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. We're moving on to recommendations 7 and 8. Recommendation 7 is the cousin of recommendation 5. We discussed that there may be some opportunity to combine these or tease out the nuance between them. This speaks to, in general, minimizing the QTF and allowing giving the RCE the latitude to manage what will be evolving technical approaches. Similar but different than recommendation 5.

In recommendation 8, there are some additional explanations in the draft transmittal letter. We recommend that ONC avoid the use of the terms targeted query, broadcast query or RLS and instead, describe things in terms of functional description. This stems largely from a discovery that when you say broadcast query to industry people, they assume that means a transaction that goes everywhere across the entire network of participants, participant members across all the QHINs and returns and would be unscalable. That is not what TEFCA intends via broadcast query. Avoiding the use of that term and describing things in terms of the functional expectation would be clearer. Again, I will pause for comments or questions.

Robert Wah – Individual – Co-Chair
Thank you. Comments or questions about recommendations 7 and 8? John, as an OB/GYN, we consider ourselves as masters of all abbreviations. You've got quite a few in here. Maybe RLS could be expanded on?

John Kansky – Indiana Health Information Exchange – Member
Absolutely. I will just explain. I'm sorry, I skipped some steps. Record locator service, the assumption – when we talk through what a broadcast query means in the context of TEFCA 2, the assumption was that the QHINs – anyone who can jump in and correct me who was on the ONC area, if I get this wrong – but the assumption is when a, air quoted, "TESCA broadcast query" is initiated, the QHIN or the participant layer below the QHINs are employing a record locator service, such that even if you don't know where you are querying for information, your QHIN or the participants under the QHIN would

know where that information was and not need to spray a query across the entire network to find it. That was a little hard to tease out.

Arien Malec – Change Healthcare – Member
That is right. The MRTCs do not define a record locator service as being required. There are multiple ways for a QHIN to address its functional requirements, but part of the functional requirements of a QHIN when it receives a query is to figure out what participant members and what data and locations are applicable in the context of that query. That applies either with record locator service or document repository or some other technical or some internal spray on behalf of the QHIN in order to address that functional requirement. Again, we just want to make sure that we are not confusing people. We are using industry terms that mean one thing that in the context of functional requirements mean something else.

Robert Wah – Individual – Co-Chair
Okay. Thank you. Questions, comments about recommendations 7 and 8 you see displayed now? Okay. John, proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Yes, I am glad that is in red font. This is another pair. It requires more discussion but any feedback is appreciated. One possibility is that as stated – I'm sorry. These are specific to modalities, the three modalities and the seven exchange purposes. As currently stated in this second draft of TEFCA, QHINs are required to serve all defined exchange modalities and purposes. It is possible that is exactly right. An alternative is that the ONC and RC use should support what we are calling specialized QHINs to serve a subset of exchange purposes and/or modalities. The idea of there being – again, you want a well-designed, well-functioning network that is adopted by the industry and there is sort of an open question as to whether it would make sense for there to be QHINs that can specialize in a modality or a subset of exchange purposes. I will pause for comment.

Arien Malec – Change Healthcare – Member
Just as a color commentary example, a specialized QHIN might be, for example, public health enabling QHIN that primarily deals with in, I forget the term, it is used in TEFCA, the primary deal that pushes transactions to public health agencies for surveillance activities. As it stands, that public health input would have to address all of the other exchange modalities and purposes of use. The question the task force is currently working through, if there is a strong perspective on the committee, that would be useful. Would it make sense to have a special purpose public health QHIN that would only need to address particular exchange modalities and requirements, again, against the notion that is expressed in the TEFCA of a single on-ramp that addresses all of the requirements?

Robert Wah – Individual – Co-Chair
Thank you. Okay. Questions or comments about recommendations 9A and 9B? It looks like Christina, your hand is up.

Christina Caraballo – Audacious Inquiry – Member
Thank you. I do think that we should consider some specialized QHINs. I like the idea of looking at it from a public health standpoint. I would also recommend considering a patient-focused or driven QHIN where the individual can request all of their PHI with their clinic or provider organizations. I think this

will also tie into some of your recommendations we will discuss in the next slide on addressing individual access service.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Okay. I didn't see the order when it came up, but I will take them first. Les, do you have your hand up?

Leslie Lenert - Medical University of South Carolina – Member
I wanted to second the idea that specialized QHINs for public health operations may be a good idea. There are some prototypes that Georgia Tech is working on with us at MUSC on how to ensure patient confidentiality and appropriate queries for case investigations. I am not sure that the idea here is that you should take one of the national organizations and reserve them for public health, but perhaps there is a way to add to the organizations that are part of connecting at this level with a focus on public health and operations. I think that of patient-centered query would not be a bad idea, either.

Robert Wah – Individual – Co-Chair
Thank you. Steven, you had your hand up?

Steven Lane – Sutter Health – Member
Yes. I also wanted to chime in support of the idea of allowing flexibility for QHINs. I think if we are going to have an ecosystem that is innovative and evolves in new directions and functionalities, we need to allow new entrants to come in and serve specialized markets and requiring each QHINs to be all things to all people I think will stifle innovation.

Robert Wah – Individual – Co-Chair
Okay. John, I did not give you a chance to respond to the last two comments. Do you have any before we go on to the next person?

John Kansky – Indiana Health Information Exchange – Member
Actually, yes, thank you. I have a question I would like to see if there is a reaction to. If it might be a good idea to have a QHIN specializing in patient interval access services, would it also be potentially okay for there to be a QHIN that did not offer individual access services because they were specializing in other things? I guess, perhaps, that question is already been answered. If there is a public health-focused QHIN, I guess I am just trying to say, to confirm the opinions of the committee, there is enthusiasm for considering these specialties, is it going to be okay to have any QHINs that don't handle individual access services?

Robert Wah – Individual – Co-Chair
Okay. It looks like some people are raising their hands. Steven, did you want to respond directly to that?

Steven Lane – Sutter Health – Member
Yes. I think you identify a key challenge, John, which is we want to be sure that all of the exchange purposes are addressed and that all of the modalities are available and that all the stakeholders have their needs met. It seems that requiring every QHIN to do everything is a rather blunt instrument but similarly if we simile allows QHINs to come forward and do what they want, we may not reach all of the goals. We have to reach some way that we check all the boxes, but then also support specialized services and innovation. I am just thinking out loud here, but I am wondering if this could come in phases or if there could be multiple paths. There could be some general purpose QHINs. Some come to

mind that has been doing a lot of these things are ready and could relatively easily expand to do them all. There could be a separate track for specialized QHINs. We don't want to leave anyone out in the cold. We went to meet all of the policy objectives. I am musing about how we will balance those two goals.

Donald Rucker - Office of the National Coordinator for Health Information Technology – National Coordinator
It is from Don. One way of looking at the QHINs is that they are supporting the query part of this. The HINs would be where the various specializations would come in. Some of the things that have just been mentioned – because the HINs would allow that variety, different paths, one-offs, entrepreneurial activities and public health activities. I think when you think of this as a network, don't forget, the HINs are still all there. That part is designed to give maximum bandwidth to the currently installed base of HIEs, just to spell that out for consideration.

John Kansky – Indiana Health Information Exchange – Member
I appreciate that. Speaking personally, hence my question, I'm trying to develop my instincts. On the one hand, a QHIN seems like if you are not stepping up to enable what is described in code TEFCA 2, all the modalities and all the exchange purposes, then you're not stepping up to be a QHIN. That way of thinking suggests that the participants could indeed be specialized and operate through a generalized QHIN that handles whatever they need and that anybody on the network could take advantage of a specialized participant. The alternative is what we have captured in 3B, which is that it may make sense, but then that process has to be managed. I assume the RNC with the ONC with the slippery slope of pick and choose QHINs versus taking advantage of specializations. There you have it.

Robert Wah – Individual – Co-Chair
Okay. I also see Steve from ONC, and I guess the only Steve in the ONC is Steve Posnack, maybe, and Carolyn. Steve, did you have a comment specifically about this or was there something new?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology
Yes. This is Steve from ONC. I think I am the only Steve here now, but I would have to check around, at least with the appropriate spelling of Steve, which is with a V, for the record. I think it is a really important and great discussion you all had about tradeoffs. My other namesake, Steven Lane, took a lot of the points that I was going to mention earlier when I raised my hand. The trade-off you guys are discussing in practice is attractive to think about specialization.

Getting back to the goal I think David raised, as well, about what the purpose is of the statute, as well as what the Trust Exchange Framework Common Agreement are set out to do, are important to keep in mind. One of the goals about having stakeholders feel they easily connect, the point Don just made about specialization at the HIN level. It is certainly worth additional discussion among the task force and the many opportunities to identify if there are specific exchange purposes for which specialization would be recommended and then everything else would be in the general bucket, so to speak. There are a variety of different options you could proceed with, but this is a really important, I would say, policy trade-off, as Steven Lane mentioned, to make sure that everything we all envisioned collectively would be supported ultimately in the formal execution of the work.

Elise Anthony – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Policy
Yes. This is Elise, also from ONC. Just **[inaudible] [01:07:31]** on what Steve said, it is important having this background as the RCE begins to do their work, will also help inform their activities. To the extent there are some considerations about specialization aware that might be critical, or even where having a diversified QHIN would also be helpful, being able to share that information with the RCE to move toward a full common agreement, I think, is also valuable.

Robert Wah – Individual – Co-Chair
Carolyn, you have your hand up as well?

Carolyn Petersen – Individual – Co-Chair
I have a comment and a question. First the comment. Going back to the notion of specialty, just thinking out loud, if we have the specialty public health QHINs, for example, I would think that if I am getting some sort of healthcare service from my local public health group, whether that is immunizations for my kids or family planning services for myself or other kinds of services, that information is something I should be able to request and receive as I would from any other kind of QHIN. The fact they are a specialty group or a public health QHIN should not preclude my ability to get that medical information about myself like any other organization. To get to the question, Les had mentioned we might also look at patients under QHINs. I wonder if he could talk more about what he envisions that involves. I think most patients and consumer advocacy groups would expect that every QHIN would be patient-centered to the degree that patients could get whatever information they need and that that should be baked in. I would like to hear more details, please. Thank you.

Arien Malec – Change Healthcare – Member
Carolyn, this is Arien, not Les. We have discussed this with the task force and their solution is that there should be organizations that would specialize in connecting patients. In so doing would primarily be concerned with QHIN to QHIN inquiries for patient access purposes. That is opposed to being in general-purpose QHINs. I think you are right, the obligation of a QHIN, with one exception, that we have noted relative to public health for surveillance purposes, there is an obligation to always respond for patient access queries. The question really is, is there a rule for an organization to be specialized in assisting patients on the patient side of this with getting access to their own information and depositing it in the place of their choosing?

Carolyn Petersen – Individual – Co-Chair
Thank you, Arien.

Robert Wah – Individual – Co-Chair
Christina, you have your hand up?

Christina Caraballo – Audacious Inquiry – Member
Yes. I just wanted to think about this a little bit more with the patient-centered QHIN. It is something I have been thinking about for a while. I do think it is really important. I understand there are challenges, but as we have a growing amount of these cases where direct access for consumers to come in and act as their health information becomes greater, I think it is something we should really consider. Right now, it is dependent on current ecosystems in organizations for patients to go to individual places to access their health information. That is really not conducive to a patient gathering all of their health

information. I think there are a growing number of use cases. **[inaudible] [01:11:44]** your individual access slide, you bring up the need for broader functionality for individuals to access their information.

For example, you put on here the Precision Medicine Initiative. For the Precision Medicine Initiative, I as a patient go out and collect all of my health information and contribute it to the All of Us research program. It is still on me to go out and gather all of that data. That is one example. Another one that recently came across my inbox was a survey that the Social Security Administration put out. It was a consumer conducted exchange feasibility study. They were looking to see if they could explore integrating consumer-directed exchange for disability applicants. Currently, it is my understanding they have an applicant applying for disability benefits. They sign an authorization form and then a caseworker goes out to all of the providers of that applicant and tries to get the data that is needed. It's a long process that is very costly, but if we had a place where the patient could easily come in and access all of their information and then hand it to a case worker such as a disability claims specialist, I think that's just a lot more of a streamlined process and something that we really need to start thinking about. Those are just two use cases. I could come up with a whole, not more.

I think if we have this place that we can access consumer data more broadly, we're also gonna see innovative apps come in. I know that the National Association for Trusted Exchange, or NATE, tried to do this a couple of years ago to make the blue button functionality work. When I was working as an app developer, I was really excited about this concept and joined for this reason, so that I could access data across the **[inaudible] [01:14:12]** zone and provide it to patients and do really cool things with it. I think we are a little ahead of the market. I think if we can get the TEFCA to work, there is still a need. I would like to discuss it more and get other people's thoughts.

John Kansky – Indiana Health Information Exchange – Member

This is John. I would reflect back. This is speaking for what is in my own head and not that of the task force. Christina, that was super helpful. My question that I am trying to develop my own TEFCA intuition is, in the context of the specific recommendation, the best use of that end to have a QHIN that's really good at that and doesn't have to do other stuff and therefore, it becomes known to individuals that that is the place to establish their direct relationship? Or on the contrary, we want to individual access services, whatever those ended up being, to be embraced and adopted across TEFCA? We are expecting, as drafted, all participants, all QHINs, all participant members to be capable of responding to IAS queries. I am inferring that the hope of the ONC would be that individual access services offering those services would be embraced at many points across the TEFCA network at the participant member level, at the participant level, and at the QHIN level because individuals can declare their direct relationship at any level in TEFCA. Does establishing a patient-specialized QHIN make that better or are you just discouraging or giving that QHIN a competitive advantage against others in the network who were eager to offer IAS services? That is a rhetorical question, but I am happy if anybody wants to respond to it.

Leslie Lenert - Medical University of South Carolina – Member

I would like to respond. There might be some patient – This is Les. There might be some services for that kind of a network where the there was a focus on this notion of patient center data exchange where the data was first downloaded to the patient's smartphone and then uploaded to the target agency. With that, you would need to maintain the provenance of the data as it was being assembled and have a secondary record of where the sources came from. It might be accessible so that activities focused on patient-centered exchange might have this enhanced provenance type of infrastructure that would

better support this particular activity. I could see a patient QHIN would be focused on providing this enhanced provenance, along with – it is not so much delivering the data to the patient that is unique. It is allowing the patient to use the data in **[inaudible] [01:17:38]** HIE with provenance that is coupled with it. Again, this is way beyond, but it says, "I am giving you a use case where a patient QHIN would be different than a general QHIN." The different QHINs might just download the data. The patient QHIN might make it possible for them to download it and upload it again.

John Kansky – Indiana Health Information Exchange – Member
Thank you.

Robert Wah – Individual – Co-Chair
Christina, you had your hand up, as well?

Christina Caraballo – Audacious Inquiry – Member
Yes. I don't think it necessarily needs to be one or the other, just going back to John's statement. I do think there needs to be patient-focused QHIN but that doesn't mean that other QHINs cannot provide patient-focused services. I think by offering both, if you have within the individual QHIN functionality that allows access to the information within the individual QHINs, that is a really positive thing. Then, this broader QHIN that stands alone and represents the consumer and consumer safety organizations, I think that also needs to be in place. I think you will see different apps and devices and models show up.

For example, if you have a QHIN focused on a certain type of patient population, that QHIN might do an initiative that offers data and access to information to support its users and participants. Then, you've also got that broad scale, bigger QHIN that represents the patient where the data and information from the individual QHINs could also be accessed by that single access point. If I am being confused, sorry. I think I was getting a little confusing. Let me think about how I was going to say this.

I do think they are, they can be separate. There could be QHINs that represent consumers and QHINs can individually have consumer strategies within their own organizations. I do think that the main QHIN that has access to all the health information where anybody can come in that is not within a specific individual ecosystem is really important.

John Kansky – Indiana Health Information Exchange – Member
Thank you.

Robert Wah – Individual – Co-Chair
Arien? Do you have any comments about anything we discussed here? I wanted to give you a chance.

John Kansky – Indiana Health Information Exchange – Member
[inaudible] [01:20:50]

Robert Wah – Individual – Co-Chair
I was also going to say, there are a couple of comments in the public comment and chat line. I don't know if you can see them.

John Kansky – Indiana Health Information Exchange – Member
Yes. I appreciate the input and the openness to it but the need to manage – There is a lot of variables that go into the consideration of allowing specialization. That is good input. We will discuss it with the task force.

Robert Wah – Individual – Co-Chair
All right. Thank you. Other questions or comments about recommendations 9A or 9B already in Oak Point we have discussed at this stage? All right. Seeing none, John, you can move onto the next one.

John Kansky – Indiana Health Information Exchange – Member
Okay. I apologize that recommendations 10A and 10B is a little bit deceptive in the way that we presented this. This is an either/or. The task force has articulated both these positions and we have more discussion. We value input.

10B is basically saying that individual access services should start as somewhat as described in TEFCA 2 with encouragement that they should be expanded over time. It is a little bit closer to what is drafted in TEFCA 2 now. I am trying to be clear. It is individual access services exchange purposes, that is described is a good starting point but there are more capabilities that individuals will need that should be appropriately worked in via the RCE-ONC relationship.

Recommendation 10A acknowledges there are several use cases aimed at individuals that go beyond what is articulated in the individual exchange access purposes that are described in TEFCA 2, which are pretty much limited to obtaining and accessing a copy of their EHI. We offer, in recommendation 10A, and Christina alluded to one or two of those, additional capabilities that might be considered for expansion of IAS immediately. I am pausing for comments or questions.

Robert Wah – Individual – Co-Chair
Comments or questions about either 10B or 10A, here? Okay. We can come back if we need to. John, proceed.

John Kansky – Indiana Health Information Exchange – Member
Recommendation 11, the next slide, please. Recommendation 11 is around some confusion that we have encountered with the capitalized defined term “Direct Relationship.” Two things in this recommendation. It is to clarify whether all participating entities must respond to requests for individual access services or only those with a direct relationship to the individual? That means that we feel whatever the intent – I believe, I don't know if ONC is willing to clarify that yes, you are right, John or no, that is not right, John. I believe the intent is that an individual who declares a direct relationship, whether it be at the participant member, participant or QHIN member, if they exercise or ask, for example, a copy of their records, that the organization they have a direct relationship with is just there means to access the TEFCA ecosystem and that transaction will go across the ecosystem across all QHINs and down all branches and get an appropriate response to their query. That is versus asking for clarification or for it to be clarified in the actual TEFCA, whether instead is really it is that the individual would be transacting with the organization where they have declared a direct relationship. That is one thing we are asking to clarify. I will pause if anyone from the ONC wants to comment.

Going on, the other is embedded in recommendation 11. There is a request clear finding the meaning of the term “direct relationship.” Does it refer to a declared relationship an individual is declaring with a TEFCA QHIN participant or participant member that offers IAS and says, “Hey, I'm declaring my direct relationship with you? You are where I want to get my individual access services,” or is that Direct Relationship – capital D, capital R – meant to have a broader meaning? We are just asking for that to be clearer.

Recommendation 11a, which I want to acknowledge, requires more discussion. Is there the implication that public health agencies will want to participate in a TEFCA ecosystem? It is considered it might be appropriate to not require all public health agencies to respond to individual access services, except where required by law.

Let me give an example of where this is coming from. If you have any experience with local health departments, the burden that would be created on those local health departments to respond to individual access services with all modalities would be difficult, to say the least. However, if that local health department is a provider and therefore a covered entity as defined by HIPAA, they would be required to respond. We also noted there may be exceptions where a public health agency should be required to respond to individual access services. For example, immunization registries, which are set up as a registry to contain comprehensive information and be able to respond directly to the individual. With that, I will pause for comments or questions or any color commentary on 11 or 11A.

Robert Wah – Individual – Co-Chair
Comments or questions on 11 or 11A? I think John was asking if there were ONC comments as well. Arien, I don't know if you had other comments you wanted to add to John's.

Arien Malec – Change Healthcare – Member
No.

Robert Wah – Individual – Co-Chair
It's somewhat in line with some of the other discussions about public health agencies and specializations as well. Okay. Seeing no questions or comments and no hands raised, we can proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Noting that, as I mentioned at the very beginning, these are partial. We are not all the way through our charge. Where we stand now, we are part of the way to privacy and security remains, so there will be more recommendations coming. The final three recommendations, 12, 13, and 14, are the beginnings of our discussion on privacy, specific to meaningful choice. Next slide, please.

Recommendation 12 is suggesting that ONC should clarify the policy goals around meaningful choice but leave the granular, technical requirements of how it is implemented to the RCE, but also, encouraging that meaningful choice is not just a quote-unquote, "check the box" exercise, and that it provides meaningful information and opportunity for discussion about where an individual's EHI will be used and disclosed. There is a very well-crafted list of suggestions of characteristics that the meaningful choice consent might conform to. I cannot take credit nor can the task force take credit for those. Those from the HIT policy committee privacy and security integrity team and some work they did in 2010. I am pausing for comments, commentary, questions.

Robert Wah – Individual – Co-Chair
Comments or questions on recommendation 12? Okay. I do not see any hands up. I do not hear any comments. John, you can proceed.

John Kansky – Indiana Health Information Exchange – Member
Thank you. Next slide, please. Both of these recommendations require more discussion as noted. Recommendation 13 contemplates whether participants in TEFCA, once an individual exercises their right to meaningful choice, the way that it is drafted – It says that it applies prospectively and that

information exchanged on the individual prior to their exercise a meaningful choice could continue to be used and disclosed for anything that was permitted. The question is should that be the case? In the task force, we talked about the right – the TEFCA 2 as drafted acknowledges the extreme difficulty in implementing a right to be forgotten for information that has been previously disclosed and shared across the network, but there's also an acknowledgment that individuals might have that desire. That is recommendation 13 that is being discussed.

Recommendation 14 is a couple of aspect of what meaningful choice really means in terms of how it should be implemented, would it imply only to individual information as exchanged within TEFCA or is that meaningful choice expected to apply more broadly? My understanding from my ONC education is that TEFCA can, on a meaningful choice exercise, under TEFCA, it can only apply to TEFCA transactions. We have to think about, as a task force and as a committee, what the applications are for the individual who is not probably going to appreciate what information is being exchanged within the TEFCA ecosystem and via other means of that if they exercise their meaningful choice and that limits the use only on TEFCA to find modalities that exchange purposes, that they might find that confusing.

The last bullet under recommendation 14 is noting that meaningful choice – is it a clarification as to whether you are expressing your meaningful choice that you do not want your information to be further used or disclosed to the organization you have a direct relationship with and therefore they will honor that meaningful choice, or is it to be communicated and implemented across all of TEFCA, or is it to be communicated and implemented up at your QHIN branch?

There is some language in the draft that says, hey if you get, if you are a to spend a participant member or QHIN and the individual expresses meaningful choice, you are to communicate that to your QHIN. Where is that right to apply to the direct relationship, to the QHIN branch or is it medicated or up and down throughout the entire TEFCA system? We are asking for some clarification in that regard. Again, I am pausing for comments or questions.

Robert Wah – Individual – Co-Chair
Thank you, John. I would also say that on our agenda, we were scheduled to go until 12:30 PM Eastern time. That's 9:30 AM Pacific time. We had a public comment period scheduled at 12:15 PM Eastern time. We are obviously running a little bit ahead of schedule. I know you all know how obligated I am to our public comment period we advertise. We will not extend the meeting until 12:15 PM. All of those that are listening on the phone now, you have a public comment you would like to make, I would ask you to start thinking about preparing those comments because I think what we will have to do is open the public comment period at the end of our committee discussions and that might be earlier than 12:15 PM. It's just to give you that notice now. I wanted to say that before we continue our discussion here. With that, I will also solicit comments or questions about recommendations 13 and 14. Terry, I see your hand up.

Terrence O'Malley – Massachusetts General Hospital – Member
Thank you. First of all, this is an incredibly nuanced and thoughtful discussion. Thank you for all the work that went into doing it. My question is not on number 13 and 14. I'm going back to 11 and the direct relationship. It seems to me that comes in the background, there has got to be a model for how the network, the ecosystem is actually set up. I can see two somewhat competing models. One is that the individual, the patient, the center can collect connect directly with everybody, almost indiscriminately, and the other is that the individual connects to the QHIN for which they have a direct relationship and

that entity does the coordinating and poses the privacy barriers and enables exchange. I am torn between those two models and I wonder sort of what is the model in the background? Thank you.

Arien Malec – Change Healthcare – Member
Les, the current TEFCA 2 draft is the latter model, the one where an individual designates the participant or participant organization that is participating with QHIN. That is their direct relationship. They could designate more than one, but at least one, and that organization serves as a proxy relative to all of the concerns you noted.

John Kansky – Indiana Health Information Exchange – Member
Arien, could you expand a little bit on that and how does that impact the privacy controls?

Arien Malec – Change Healthcare – Member
That is exactly part of what we are hoping for ONC to clarify in the final version. The way that I think it is intended to work, and I welcome ONC comments here, is that, let's say I have got a relationship with a phone better or with my local provider and that is the organization that gives me an opportunity to have meaningful choice to help me understand information, how it flows, how it will be used, and other key considerations regarding my participation and gives me the opportunity to make decisions relative to my participation.

And then, the question that we are raising is so then what? Is there a corresponding responsibility to communicate my choices, my elections to other QHINs so that they can use that material or are my elections relative to meaningful choice kept only locally and it is the QHIN that I am connected with that is responsible for managing those elections? That is the key question that we are getting after.

Again, just to be really clear, the assumption in TEFCA 2 is that I, as an individual, have a direct relationship with a QHIN, a participant, or a participant member. I gave two examples of what that might be, my mobile phone provider, my local provider, my local provider. Then all of the meaningful choice and discussion they get done locally. As I said, then we are the reason the question of, "Okay, then what?"

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, hello. This is Zoe from ONC. I just want to make a clarifying point about that chain of communication of where meaningful choice goes. Currently, the way it's drafted, the participating entity that has the direct relationship with the individual who exercises their meaningful choice is responsible for communicating the meaningful choice up the chain to the QHIN that they participant with. Then that QHIN is responsible for then communicating that across all of the other QHINs in the network. That is where it stops. I want to make the differentiation that I think that question we are asking here is doing that meaningful choice – once it goes to all of the QHINs in the network, do all of the other QHINs in the network then have a responsibility to can indicate that meaningful choice all the way down to the participant and participant members within their individual network?

Presumably, the way it is written today, if an individual exercises their meaningful choice in one QHIN, and then they go to a participant or a provider that is participating in another QHIN, that participant member, that provider might not know that the individual has exercised that meaningful choice. They may send it or exchange their information all the way back up and the meaningful choice would not stop

until I got all the way up to the QHIN. I think what we are really asking is the scope of how far and wide the full choice should be communicated across the TEFCA network. Does that make sense?

John Kansky – Indiana Health Information Exchange – Member
Yes.

Robert Wah – Individual – Co-Chair
Thank you. Other comments or questions about 13 and 14 specifically? We are really coming to the point where we are going to take comments about the entire suite of recommendations here from the task force.

I just wanted to comment that this sounds technically challenging. It's distributing the request for information across the network, which may or may not be aware of an individual. It would be almost as if every QHIN would have to know and have a record for every individual in the country.

Robert Wah – Individual – Co-Chair
John, Arien, ONC, comments?

John Kansky – Indiana Health Information Exchange – Member
We just have a lot to think about and more work to do.

Robert Wah – Individual – Co-Chair
Okay. I want to also take, as was mentioned at the opening by Doctor Rucker, one of our members, Doctor Patrick Soon-Shiong, has resigned from the committee. He just dialed in. And I mentioned to him that he would have an opportunity –

Patrick Soon-Shiong – NantHealth
Hello, Robert.

Robert Wah – Individual – Co-Chair
Are you on?

Patrick Soon-Shiong – NantHealth
Yes. I am. Thank you for giving me the time here.

Robert Wah – Individual – Co-Chair
Yes. As I was just mentioning, the committee heard from our national coordinator this morning that you would be leaving the committee. I know you have got – I think you told me your hands are full with running the LA Times and seeking out a cure for cancer. I am sure there's a lot more mind all that, but we certainly appreciate your participation both in person and on the phone. I will give you the floor for a couple of minutes. I appreciate you dialing in this morning.

Patrick Soon-Shiong – NantHealth
First of all, I want to appreciate you and thank you for giving you the time. I just want to say the committee has been amazing and not just with this committee but with administrations past and this administration on trying to solve – what you're doing. You are doing such important work with regard to all the issues of healthcare and interoperability. I wanted to ensure – and thank you, Robert, for literally giving me the time to share not only my thoughts about, share the reasons why, since we took over the

LA Times and the work we have been doing on the **[inaudible] [01:46:38]** vaccine, it was very difficult for me to attend the many meetings. I felt very guilty that I was not contributing as much as I could and I thought this slot could be used better by somebody who had more time. It wasn't that the work that you do is unimportant. It is critically important to the nation.

I want to thank you truly for allowing me to participate as much as I could. I am happy to say that the work we are doing in cancer – Robert, sorry? The work we are doing in cancer is really bearing fruit. We have now, over the course of the last 2 years, received authorization from the FDA on 20 INDs, which I think is a record to test the hypothesis that we can induce what we call immunogenic cell death in patients with cancer.

That is some very exciting data that we're about to announce literally in the next few months both in triple negative breast cancer, bladder cancer, head, and neck cancer. That's not an excuse for why am resigning, but it is quite factually correct. Thank you for sharing that, Robert. The LA Times has been all-consuming as we initiated. Yesterday was my one-year anniversary and it was important for me to give some time to that paper because I think it is an important opportunity for us to have a voice from California. But I also want you to know that I will be thinking of the work you do, and I will be watching the work that you. Thank you again for the opportunity. Robert, thank you for the time to allow me to just say a few words. I am happy to take any questions either you or anybody may have, but I'm sure you've got more things to do.

Robert Wah – Individual – Co-Chair
I just mentioned we are running a little bit ahead of schedule so if we have a little bit of time here. If anybody has any questions or comments for Patrick, this would be appropriate as well now.

Donald Rucker - Office of the National Coordinator for Health Information Technology – National Coordinator
I'm Don Rucker, the National Coordinator. Patrick, I want to thank you for – I know you have been busy, but I want to thank you for, as a citizen, throwing your hat in the ring here and working to address these things. Best wishes for your future endeavors.

Patrick Soon-Shiong – NantHealth
Thank you, Don. I really appreciate it. It does not mean I will not be working with the government agencies in any way I can. I certainly will, but as I said until I can address what I'm doing on the cancer thing, I think I better focus for a while.

Robert Wah – Individual – Co-Chair
Like all members, it is really, I think we are all very grateful for the time, experience, and expertise that you and everybody on the committee have been sharing to improve health and technology. Again, as John said, best of luck in all your endeavors. And we appreciate the opportunity to work with you and we look forward to future opportunities to work with you down the road.

Patrick Soon-Shiong – NantHealth
Thank you so much, Robert.

Robert Wah – Individual – Co-Chair
You can stay as long as you want, and we will return back to our discussion of the TEFCA at this point. But again, thank you

Patrick Soon-Shiong – NantHealth
Okay. Thank you.

Robert Wah – Individual – Co-Chair
So back to the issues that we were discussing, other questions, comments, about the entire suite of recommendations from the TEFCA task force, I will take those for John and Arien at this time. Other closing comments from the task force chairs, John, Arien?

John Kansky – Indiana Health Information Exchange – Member
No. Not me. Thank you. We've got a call tomorrow.

Arien Malec – Change Healthcare - Member
Fantastic discussion.

Robert Wah – Individual – Co-Chair
You guys have done a lot of work. We appreciate that. There are a lot of details here. All right. As I mentioned before, we are running ahead of schedule. We certainly won't extend the meeting waiting for the designated time for public comments. I am going to turn it over to Lauren to set up the public comments.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Robert. And the phone number, operator, with open up the light.

Operator
If you like to make a public comment on it, please present star-one on your telephone keypad. A confirmation tone indicates your line is in the queue and you may press star-two if you would like to remove your comments from the queue. For participants using speaker agreement, it may be necessary to pick up your handset before pressing the star keys.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. While we are giving folks time to dial in, I will just remind everyone that our next committee meeting is scheduled for July 11. We hope to wrap up the rest of the TEFCA recommendations. The next two TEFCA task force calls, there is one scheduled for tomorrow and June 24. So we welcome the public and the other HITAC members to join as you are able. There's also an ISP task force meeting on June 25 and a USPDI task force meeting hundred 28 if you want to share the upcoming meetings for your awareness and all of the meetings I just mentioned can be found on the calendar on the HITAC page at healthit.gov. At this point, I will ask the operator if we have any comments in the queue.

Operator
We have none at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Robert, I will hand it back to you for any closing remarks.

Robert Wah – Individual – Co-Chair
Thank you, Lauren. Certainly, from my point of view, thank you to the committee and thank you to the

task force, both on the Annual Report and the TEFCA comments for all of your hard work in this area. I think we had a good discussion on a number of points today. I am sure the TEFCA task force and the Annual Report task force welcome any additional comments that come to mind after the call. I think we are in a good place on both of those. I asked that the committee said along with comments to them as they occur to you. We have one more meeting to review and finalize our recommendations for the national coordinator in the area of TEFCA. Be ready for that as well. Thank you for allowing me to indulge Patrick Soon-Shiong as he departs the committee as well. With that, I wish you all a good summer. And I look forward to our next call. I will turn it over to Carolyn for her closing comments.

Carolyn Petersen – Individual – Co-Chair
Thank you, Robert. I just want to reiterate Robert's thanks for the good work that we did today and for the work of the TEFCA. And again, I encourage those interested to share feedback and comments with the task force so we can ensure that we provide recommendations that represent the full perspective of the HITAC and I look forward to working with you in the next meeting, next month. Thank you.

Robert Wah – Individual – Co-Chair
With that, Lauren, you adjourn us, I think.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
That is it. Thank you, everyone. We are done for today.

Aaron Miri – The University of Texas at Austin Dell Medical School and UT Health Austin – Member
Thank you.