Trusted Exchange Framework and Common Agreement Task Force

Transcript
May 16, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Role
Arien Malec	**Change Healthcare**	**Co-Chair**
John Kansky	**Indiana Health Information Exchange**	**Co-Chair**
Noam Arzt	HLN Consulting, LLC	Public Member
Laura Conn	Centers for Disease Control and Prevention (CDC)	Member
Cynthia A. Fisher	WaterRev, LLC	Member
Anil K. Jain	IBM Watson Health	Member
David McCallie, Jr.	Individual	Public Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Carolyn Petersen	Individual	Member
Steve L. Ready	Norton Healthcare	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member
Mark Savage	UCSF Center for Digital Health Innovation	Public Member
Sasha TerMaat	Epic	Member
Grace Terrell	Envision Genomics	Public Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Cassandra Hadley	Office of the National Coordinator	HITAC Back Up/Support
Zoe Barber	Office of the National Coordinator	Staff Lead
Kim Tavernia	Office of the National Coordinator	Back Up/Support
Alex Kontur	Office of the National Coordinator	SME
Morris Landau	Office of the National Coordinator	Back-up/Support

Michael Berry	Office of the National Coordinator	SME
Debbie Bucci	Office of the National Coordinator	SME
Kathryn Marchesini	Office of the National Coordinator	Chief Privacy Officer

Operator
Thank you, all lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Welcome, this is now our second meeting under the second draft. We will go ahead and get started, starting with roll call. John Kansky?

John Kansky – Indiana Health Information Exchange – Co-Chair
Here.

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

Arien Malec – Change Healthcare – Co-Chair
Good morning and/or afternoon.

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

Carolyn Petersen – Individual – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Aaron Miri? 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
Sasha TerMaat? Steve Ready? Cynthia Fisher? Anil Jain? Kate Goodrich? Andy Truscott? Denise Webb I believe is going to be absent today. David McCallie?

David McCallie, Jr. – Individual – Public Member
Here.

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

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Good morning, here.

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

Designated Federal Officer
Noam Arzt?

Noam Arzt – HLN Consulting, LLC – Public Member
I'm here. Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And Grace Terrell?

Grace Terrell – Envision Genomics – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, I do believe that's everyone. Arien, I will turn it over to you.

Arien Malec – Change Healthcare – Co-Chair
Awesome. So, we are going to start this conversation first with a brief discussion on the aims and goals of the TEFCA. We are going to time limit the discussion, just to make sure that we don't sidetrack the rest of the agenda, but given that I've raised the subject, and I think other people might, I thought it would be useful to have a conversation about what policy goals we would evaluate to propose to TEFCA against. And I'm going to frame maybe a narrow policy goal, and a broader policy goal, and then open up discussion and additional considerations. So, the legislative mandate for the TEFCA comes from the Cures Act. In particular, Section 4003: Interoperability, subpart B. And subpart B calls for the National Coordinator, in conjunction with this and other relevant agencies within DHHS, for the purpose of ensuring full network to network exchange of health information. Can be public-private and public-public partnerships to build consensus.

And developer-supported trusted exchange framework including a common agreement among health information networks nationally. And then there's a whole bunch of mechanics for that, including common methods, common rules, organizational policies, educating noncompliance, technical assistance, pilot testing. And then, some timeframes associated with all of that. So, there are at least two ways of thinking about our charge as the task force that is tasked with providing recommendations to the advisory committee to provide recommendations to ONC relative to TEFCA 2. The first is very narrow. Which is a factual question, of would the proposed TEFCA 2 address the narrowly adjudicated needs and aims of Congress. That is, in particular, would it ensure "full network to network exchange of health information."

The second frame, which I think we should be evaluating the TEFCA against, but I just want to propose this as a frame, is does the "full network to network exchange of health information" address the broader policy aims and goals of improved care, improved health, and reduced cost. And also, does it address at least certain parts of the information-blocking mandate? And again, just to gloss this, my assumption would have been that participation – and you know, I used earlier today the example of IHIE, where we have the great John Kansky as our co-chair. If I'm a provider in Indiana, I have to stay in IHIE, and IHIE participates with TEFCA and can interoperate with other health information networks.

You know, my presumption is that that hospital or health system or provider organization in Indiana would A) be able to do a better job of care coordination, driving healthcare quality, addressing public health, and reducing costs. And also, would be able to better address the publications under information-blocking. And in particular, that there would be if not a formal safe harbor, at least the moral equivalent of a safe harbor, in that hospital or health system participating in IHIE would be able to say, "Look, I participate in IHIE. IHIE is a TEFCA member in good standing. My data is available for these broad set of purposes, and I do nothing to block that."

So, I'm going to pause there. And now, I just proposed a narrow frame, which is that our job and mission is to address narrowly the words of Congress, and a broader frame, that our mission and purpose is to address the words of Congress in order to address the broader policy goals of improved care, improved health, and reduced cost, and to help address at least portions of the information blocking mandate. I will shut up now and open it up for discussion. Unless, John, you wanted to add any additional commentary?

John Kansky – Indiana Health Information Exchange – Co-Chair
Well, I have my own comments, but let's let the task force speak.

Arien Malec – Change Healthcare – Co-Chair
Cool. Mark?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Yes. Thanks, Arien. So, I would say I don't see them as being distinct frames, narrow and broad. I think in Congress, that both of those provisions and the interoperability section, they defined interoperability more around your broad frame. One of the specific means is the TEFCA. I think the TEFCA serves the broader interest of interoperability, and I think we had to follow the specifics of the section on TEFCA, but we are doing so in service of the definition of interoperability and the other provisions. And actually, I understand why they say narrow and broad, but I see them as parts of the same piece.

Arien Malec – Change Healthcare – Co-Chair
Yes. So, again, I guess the way that I think about that question is we could imagine a TEFCA where John would be able to go check on a participant in TEFCA, I can theoretically exchange data, but the means that we have chosen to address that are fairly narrow, and not that useful, and don't address the broader goals. I think we could say that would not be an adequate TEFCA.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
I would agree with that. Correct.

Arien Malec – Change Healthcare – Co-Chair
David?

David McCallie, Jr. – Individual – Public Member
Yeah, it's a good question, a complicated question. One angle that I think of it in terms of is since, as I understand it, under the narrow definition, TEFCA is voluntary, what would be the incentives for QHINs to go to the trouble of actually becoming QHINs and doing all that work. And what would be an incentive for providers to participate, given that they in many cases already have in place some substantial subset of what's been described in TEFCA. In some cases, quite a complete subset, and in

other cases a partial subset. So, what's the motivation to do it? And that's where I think the broader interpretation in coming back to information blocking, and the prohibitions and the costs of being an information blocker may be relevant to sort of justifying or increasing the demand for participation in what is otherwise a voluntary system. So, I think the broader question is valid. What is the quid pro quo?

Arien Malec – Change Healthcare – Co-Chair
Yes. And that's the question that John's raised as well. John, I don't see anybody else who has their hand raised. Is there anybody else who's not in a position to raise their hand that wants to jump in with discussion? Okay, I hear none. John, I know you've got a perspective?

John Kansky – Indiana Health Information Exchange – Co-Chair
Yeah, thanks. So, I think that I'm glad you raised this. I think that while we can't be members of Congress, this discussion is going to inform my thinking in terms of the recommendations that we ultimately discuss and make. Because I hear an emerging consensus on what you term the broader perspective, which I appreciate. And I think it is in no way inconsistent with the ONC views of what we really want to see. Now, how do we overlay that in terms of recommendations we make that aren't within the scope of our charge? It remains to be seen. And the example that you offer, in terms of should it be a safe harbor? Should it not be a safe harbor? Should it be kinda sorta correlated to being a safe harbor? Etc., etc. Those are tougher questions. But in general, I am glad we started here.

Arien Malec – Change Healthcare – Co-Chair
Yeah, I think we can assert the sense of the task force, and this would be one of our recommendations, is that the intent of the TEFCA is and should be broadly determined towards the broader policy aims of the nation, No. 1. And not just narrowly construed as in the narrow section, but as Mark said, seen in the broader context being included in an overall section titled "Interoperability," and bundled together with other content, including information blocking. So that's kind of No. 1. And I'm hearing a good sense from the workgroup of the task force that we should state that. And maybe the second sense of the task force – and I just want to poll to see if it a sense of the task force – is that we should recommend that participation in a QHIN that is a member in good standing in the TEF, should address at least a portion of the information blocking requirements. Or should be at least presumed to address at least a portion of the information blocking requirements.

And I'm putting qualifiers in there, because there are other requirements, including offering APIs, providing direct patient access, and others that pretty clearly would not be addressed through participation of the TEFCA. I guess the way I'd frame this is that my presumption would be the theoretical provider in Indiana who participate in IHIE would be able to say, "Hey, I participate in IHIE. IHIE participates in the TEFCA. Anybody that wants to get my data for permitted purposes, we have the trusted framework to be able to do that. And so, an information blocking claim that says that I'm getting in the way of that activity doesn't make sense." So, that was a long rambling sentence, but I'm proposing that the task force state that to ONC as a recommendation, that ONC include that as a value proposition for participating with TEFCA. I'm going to pause; I see Mark's got a hand up, David's got his hand up.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member

I think where I am, Arien, definitely an important and valid question we should have on our list of things to do. I would personally like to wait until we can get into the details of the information blocking portion to see whether – for example, we have heard people say, "You participate in the trusted exchange framework, that should be a safe harbor." I'm not sure that that's enough. I'm not sure how I would think about some of the other factual scenarios that the MPRM is raising as information blocking, whether those could also be operating alongside participation in the TEFCA. What do we think there? I'll just say I agree, and I have been thinking about that question myself. And I personally would rather wait before formulating a specific recommendation.

Arien Malec – Change Healthcare – Co-Chair
It's among the recommendations that we might want to consider.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Correct.

Arien Malec – Change Healthcare – Co-Chair
Okay, David?

David McCallie, Jr. – Individual – Public Member
Yeah, I support what you said, Arien. And I think I would express it, maybe, in terms of asking ONC to make a clearer connection between the information blocking rules and that TEFCA , so that areas where they are connected to each other, such as you are in good faith if you are participating in TEFCA and not an information blocker for the purposes of broad sharing of data, and where there is alignment around things like patient preference for privacy, that's defined in both. That is one of the reasons that you are exempted from being an information blocker, and TEFCA has a whole bunch of privacy assertions expressed in it. How do those align with each other? What the connection? If you do it through TEFCA, you have met that requirement in terms of information blocking or vice versa. I would think those are important things to clarify, those connections. And I kind of think of it in terms of incentives.

You know, the information blocking rules, they lay on a new set of obligations for providers, and other HIE/HINs. What's the incentive that TEFCA helps them solve those obligations? Because that'll drive it forward and make it successful.

Arien Malec – Change Healthcare – Co-Chair
Okay.

John Kansky – Indiana Health Information Exchange – Co-Chair
Sorry, this is John. I just wanted to say I think it makes sense for this to be on our list of possible probable recommendations, and we'll let it take shape. And I think it's unlikely that it's going to say, "Participation in TEFCA equals safe harbor," but there is going to be some nuance to that. And I just wanted to add that. Thanks.

Arien Malec – Change Healthcare – Co-Chair
Yes, I agree with that. So, I think we have burned through our 15 minutes having this discussion. If there are other perspectives, please raise them. Hearing none.

David McCallie, Jr. – Individual – Public Member
Arien, it's David. I think there may be some other things that we want to recommend that aren't on our specific list of questions. So, I hope we keep that door open.

Arien Malec – Change Healthcare – Co-Chair
Okay.

David McCallie, Jr. – Individual – Public Member
I would just say, for example, we have current experience with CommonWell, Carequality, eHealth Exchange, and others of attempts at building national exchange networks, and there is a certain set of core problems that have come up that need to be addressed for those existing efforts to be more successful. Some of those, like for example lack of a clear understanding of how a record locator service would work and would be helpful is something I would like to include in our recommendations in the long run. So, just to the fact that I think there are things that we might not be specifically asking about that ought to, if given the opportunity, weigh in on.

Arien Malec – Change Healthcare – Co-Chair
Yep. I definitely agree with that. All right.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Great. Thank you so much. This is Zoe. So, we're going to get started with our proposed topic for today, which is the exchange purposes and modalities, and we are going to start with a very, very quick presentation on the human technical framework by Alex Kontur. So Alex, go ahead when you are ready.

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
Thanks, Zoe. If we could just bring up that slide real quick. Thanks. So, when I say QTF, please know that I mean human technical framework. Not to introduce too many new acronyms, but it will make this a little bit shorter. Just as a very high-level reminder, the QTF represents the technical and functional requirements for exchanging electronic health information among QHINs. I just wanted to address a couple of real high-level points about the QTF, beginning with why did we create it. So, first and foremost, we created the QTF because we wanted to allow the technical standards and functions that are contained within to evolve and change without impacting a QHINs legal obligation. So, in other words, we don't want QHINs to have to go ahead and modify and re-sign all of their legal agreements every time that we see a standard change or a new function added to the QTF.

Another kind of guiding reason that we did this is that we didn't want to put out a new draft of the TEFCA and the MRTCs, without providing some technical direction for people to react to. So, we wanted to do some of the work up front, to put something together that could really help people understand what the technical implications of all of this complex legal language are. And so, that's all to say that this first draft of the QTF is really our best guess at one, what the QTF will actually look like when it's complete, and that includes the approximate detail and focus of the QTF. And that focus – you can go to the next slide – is really on exchange among the QHINs, rather than exchange within QHINs. So, you will see a lot of the technical specifications and functional requirements deal with the inter-QHIN exchange rather than the intra-QHIN exchange. As a general guiding principle – go ahead.

John Kansky – Indiana Health Information Exchange – Co-Chair
Sorry, I should've been on mute. Go ahead.

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
No problem. So, as a general guiding principle at this point at least, QHINs are relatively free and flexible to implement standards, specifications, technical approaches within their networks as they please to meet the needs of their diverse groups of constituents in their business cases. However, we did want to standardize the methods for exchange across QHINs. And the second thing that I wanted to note about the QTF, at least this point, is that it was our best guess what specifications are available today to effectively operationalize the MRTCs as they currently stand. So, that's all to say that we should really be looking at the QTF as a starting point and not a finish line, because from this point forward, really, the RCE is going to be the entity that's primarily responsible for the evolution of these documents.

We know that there is publicly going to be a lot of changes between now and when this network is up and running, and that updates to the MRTCs are probably going to impact the technical direction that's outlined in the QTF. So, what does this all mean for you guys, for the task force at large? Given that we expect TEFCA and the MRTCs to potentially change significantly in the future, and given that we have fairly limited time, we think that it's best for the task force not to get too bogged down in debating specific standards or functions that are included in the QTF. Rather, we are looking for the task force to issue recommendations to ONC that we can pass on to the RCE about principles for the QTF at large, and its scope and shape for the future.

So, just as a few representative examples of the types of things you guys might want to provide recommendations on, whether it's appropriate to split the QTF and its technical standards and functions away from the MRTCs in the first place? Does the overall technical direction that we've outlined in the QTF adequately reflect the obligations of the QHINs that were spelled out in the MRTCs – at least this version of the MRTCs? And then, is the scope that we have identified, which is more focused on the inter- or between QHIN exchange rather than the intra- or within QHIN exchange, is that all appropriate? So, that's pretty much what I wanted to say. I'm happy to answer any questions you guys may have.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Perfect. Thanks, Alex. And I think we do have a question. Mark Savage.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Yes. Thanks, Alex. I just wanted to check, will there be times where the inter-QHIN exchange might have implications or the way that that's structured, the technical framework for it, might have implications for the intra-QHIN exchange? And in the event that there are those possibilities, should we be thinking to try to simplify the two combined, or make sure that the two combined works?

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
I think the short answer to that -- go ahead.

Arien Malec – Change Healthcare – Co-Chair
Okay, so I think the way I'd answer that is that I don't think the QTF should get into the mechanisms of intra-QHIN exchange. At the same time, I think we should evaluate the QTF relative to the functional requirements, and make sure that it's sufficient to address those functional requirements.

And this is again why I was trying to raise some of the broader questions. One of the ways I'd frame that is to say, if I am a provider who is treating a patient who – if I'm in Indiana and I'm treating a patient who has previously been in California, alas, then are the technical means associated with the QTF sufficient to deliver an experience for myself, as a provider, where I can address the quality and care goals that I have?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
So, a factor to be considering as we're looking at the QTF, does it have any adverse effects on the intra-QHIN exchange? I know it's just a factual question, but it's something we will be pausing to ask from time to time to make sure we are getting the QTF correct.

Arien Malec – Change Healthcare – Co-Chair
Yep.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Okay.

Arien Malec – Change Healthcare – Co-Chair
David, I think you've got your hand raised.

David McCallie, Jr. – Individual – Public Member
Yeah. I mean, my reaction, in general, is the QTF should be a set of policy requirements that are directly connected to the technical architecture rather than the specific set of standards. And that the selection of which standards are best to meet those particular policy goals should be left to the RCE and the stakeholders and the early cohorts to figure out. So, I want to understand whether these are binding standards in the QTF as it's written now, or just suggested a starting point for discussion? When it's actually down at the standard level, when it specifies a specific XCPD or XCA or XUA, is that a required standard, or is that a suggestion for the RCE to start there and go where the cohorts agree to go? Does that make sense as a question?

Arien Malec – Change Healthcare – Co-Chair
It does make sense as a question.

David McCallie, Jr. – Individual – Public Member
ONC?

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
Starting point.

David McCallie, Jr. – Individual – Public Member
Starting point, okay.

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
Because that's why we turn it over to the RCE to finalize.

David McCallie, Jr. – Individual – Public Member

Okay, that's good. I am glad to hear that because I think there are places where the existing networks might have some concerns about the particular standards that were put on the table.

Arien Malec – Change Healthcare – Co-Chair
Yeah, I do think it's fair to say it's handed to the RCE as a starting point. There's a presumption that it's a good standard fit for the purposes described and will be the main standard. So, I'm not sure we are completely out saying starting point, because at least it should be a good starting point. Noam, have you got your hand raised?

David McCallie, Jr. – Individual – Public Member
Are you soliciting opinions about the particular standards in that case, then, that are listed here?

Arien Malec – Change Healthcare – Co-Chair
So, I guess the way I would like to frame this is to go at the exchange modalities, that are assumed in TEFCA 2, and then… first of all, I think, is it wise to separate the QTF from the MRTCs? And I generally think the answer is yes, I think it's a good approach, but we should discuss that. Secondly, I think we should evaluate the QTF as a starting point with respect to understanding and agreeing to or amending, or recommending amending, the MRTCs and functional specifications that are assumed in the TEF. Does that make sense?

David McCallie, Jr. – Individual – Public Member
The first part did, I'm not sure I follow with the second part, but I'll just endorse your first notion. I agree that the separation is a good idea. It's a good solid information engineering. Separates the document and technically those are in a different document.

Arien Malec – Change Healthcare – Co-Chair
So, I guess the second point is basically saying you evaluate a standard relative to its utility for a particular purpose, and we should first understand the purpose, and then evaluate the QTF with respect to the applicable D for those purposes. Was that a clearer way of understanding what I was trying to say?

David McCallie, Jr. – Individual – Public Member
Better, yeah. And I mean, I think we need to maybe – I would say we are approaching this in backward order. I think the purpose of exchange is a prior question.

Arien Malec – Change Healthcare – Co-Chair
Exactly.

David McCallie, Jr. – Individual – Public Member
For example, the notion that the TEF should support direct messaging is, I think, a bad assumption. And if you took that off the table, then I wouldn't worry about some of the standards proposed, because they wouldn't be needed.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Hi, this is Zoe. Please feel free to discuss the QTF as it relates to exchange purposes and modalities. In fact, it's the next part of the presentation…

Arien Malec – Change Healthcare – Co-Chair

Yes, we can get into that.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Sorry?

Arien Malec – Change Healthcare – Co-Chair
I do think we should get through this discussion so we can get into the exchange purposes and modalities. If you are trying to keep us on time, I am highly aligned.

David McCallie, Jr. – Individual – Public Member
So, just finishing then, because I do think the modalities are more important to discuss, but just in broad strokes, I think that one of the goals that I understand of the whole approach to creating cohorts, and some of the purposes of what you hope to achieve, what ONC stated to hope to achieve, was a sort of quick emergence of networks that function and have reasonable chances of success. If that's one of the driving goals, then I think the selection of these standards – which, by standards, terms are kind of outmoded standards, and in some cases, even poorly supported with technical frameworks, but nonetheless have been widely deployed and used, most of them. So, starting with them, I think, is in general not a bad idea. With respect to certain of the exchange modalities, which we'll talk about later. I think there are some exceptions buried in there.

But I think if you want rapid uptake of TEF, you will have to use some of the standards that have been – for better or for worse – integrated into most vendor systems. Even though in some cases, there may be better approaches available if you were starting from scratch, but we're not starting from scratch. So, I'm okay with that.

Arien Malec – Change Healthcare – Co-Chair
Noam?

Noam Arzt – HLN Consulting, LLC – Public Member
I know we are tight on time if you want to move on. That's fine.

Arien Malec – Change Healthcare – Co-Chair
Okay. Well, I am sure we will all get a chance to re-adjudicate or relitigate some of these issues, but hopefully, we can understand the exchange modalities first because I think that's going to help the rest of this conversation. So, Zoe, can we get to that portion?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, absolutely. And please feel free to discuss sort of all of this stuff together. I know you guys have all done the reading already for the purposes and modalities. And so, I sort of anticipated that the discussion would be around all of this as a whole. So I'll just really, really quickly go through the next few slides, and then we can get back to the discussion. So, if you go to the next slide. So as you guys are aware, in this draft, we have proposed seven exchange purposes: treatment, benefits determination, quality assessment improvement, business planning and development, public health, utilization review, and individual access services. So, we'd love your recommendations on these definitions, and especially on how we modify the definitions to narrow the payment and healthcare operations and to kind of keep those as their definitions as they are in HIPAA. And then -- go ahead.

Arien Malec – Change Healthcare – Co-Chair

Yeah, I'm sorry. I just wanted to point out to the task force that our previous recommendations were that the exchange purposes were defined too broadly. In particular, it was defined as PPO, plus benefit determination cases, and public health cases. And that we recommended that operations and payment be more narrowly defined. And TEFCA 2 took us up on those recommendations and defined exchange purposes more narrowly. This is really the effect of the narrowing of those broad definitions. I just wanted to connect this to the previous work that we've done.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, exactly.

David McCallie, Jr. – Individual – Public Member
So you are saying, Arien, we can't take it back?

Arien Malec – Change Healthcare – Co-Chair
I am just saying, we got what we asked for, then we got at least directionally what we asked for, then we got to go into detail, exactly.

David McCallie, Jr. – Individual – Public Member
Yes. And I was just kidding. I'm kidding.

Arien Malec – Change Healthcare – Co-Chair
I hear you.

David McCallie, Jr. – Individual – Public Member
I appreciate what happened here. This is good. So Zoe, we interrupted you.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
No problem at all.

Arien Malec – Change Healthcare – Co-Chair
Mark has a question. As well.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
So, it just popped into my head, I haven't had a chance to think this through ahead of time. There's a big discussion about what happens when a patient exercising patient access asks a provider to transmit information to an unaffiliated third-party app, which is a noncovered entity that's outside of HIPAA. These definitions are now, looks like the TTO is around HIPAA only. What happens with noncovered entity apps that are being used, that the patients are using?

Arien Malec – Change Healthcare – Co-Chair
I propose we punt on that question. Generally, that form of access to would be individual access services, and that includes the definition that a copy of their EHI be transmitted to another person or entity designated by the entity or obtain a copy of the EHI. And yeah, I think we previously had comments about the role of intermediaries for the patient in that process. But I propose at this stage, we just understand it and then dive into details if that continues to be a concern.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member

Okay.

Arien Malec – Change Healthcare – Co-Chair
Sheryl, I see you have your hand up.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Yeah, I have a concern, because we had previously put in a comment that treatment is too narrow. From a payor perspective, there's care management and other things, and there does not seem to be in this list any place where medication reconciliation – the work we're doing with CMS right now, and the documents requirement lookup service – none of that stuff would fit in here very well. So, I think we need to look at the purposes and make it clear, there are purposes that should be supported that are not presently in this list.

Arien Malec – Change Healthcare – Co-Chair
So Sheryl, under quality assessment and improvement in these definitions – these sub-definitions, by the way, come directly from HIPAA – it included quality assessment and improvement, so outcomes evaluation, development of clinical guidelines, patient safety activities, population-based activities relating to improving health or reducing healthcare costs, protocol development, case management and care coordination, contacting of healthcare providers and patients with information about treatment alternatives, and related functions that do not include treatment. So, I think that between treatment and quality assessment and improvement, we've got most of the cases that you've outlined, and maybe you could read through the sub-definitions, and then we can pose some hypotheticals to make sure we have a properly addressed those value add cases.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Yeah, I don't agree with the fact that treatment and quality address those. So, we can discuss them later.

Arien Malec – Change Healthcare – Co-Chair
Okay. David?

David McCallie, Jr. – Individual – Public Member
In general, I like the narrowing from TEFCA 1. I would, maybe to take it back on what you said, Arien, say that even though population health queries was removed – which, if I understand it, was the notion that a QHIN could query for large populations all at once – that the ability to support population health goals is not removed. And that would fall under that, as you just said, Arien, in the mix between treatment and quality assessment improvement. So really, it was a removal of a technical requirement, but not saying you can't do population health kinds of activities, using QHIN acquired data. Right? So, you can get the data, you are just getting it a patient at a time, rather than a broadcast to get a whole population.

Arien Malec – Change Healthcare – Co-Chair
Yes. The way to say it I guess is the purpose is there, the standards and exchange modalities may not support all purposes.

David McCallie, Jr. – Individual – Public Member

Right, so there is nothing saying you cannot use QHIN services to do population health management? They just removed a particular technical means to achieve that, which is not yet well supported by anybody.

Arien Malec – Change Healthcare – Co-Chair
Yup. That's right.

David McCallie, Jr. – Individual – Public Member
And then the second point is as always, it's useful to sort of say what's excluded to test your boundaries, and I think the most obvious thing that's excluded here is research. So, I just want to confirm that the notion of acquiring data for research purposes is not a permitted purpose. Not an exchange purpose, I shouldn't use the HIPAA term here, sorry.

Arien Malec – Change Healthcare – Co-Chair
Yeah. That's a good ONC question. And again, I think Sheryl has hypotheticals or some examples that she might want to test against these purposes, just to make sure that we understand that either they are included or they are not, and whether that's problematic. Yep.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member xyz
Arien, on the research question, I cannot remember if it was on this task force or another task force, but the All of Us is a good example to consider the implications, I think. The nationwide initiative.

Arien Malec – Change Healthcare – Co-Chair
Yeah, we discussed the fact that you could get at All of Us data through the individual access channel if you've got a motivated individual, but you might not be able to get that data if you are just going system to system under this rubric.

John Kansky – Indiana Health Information Exchange – Co-Chair
This is John, is there anything more that, whether it be from a task force discussion, that ONC can share? Was there an overt exclusion of research, or I mean, can we recommend putting that in as an exchange purpose? Or what else can you share?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Is that a question for ONC?

Arien Malec – Change Healthcare – Co-Chair
I think it's a question for ONC. So, I think David's assertion this excludes research and John's question about whether that was intentional are definitely questions for ONC.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, I would say I think that is definitely something that would be in scope to make a recommendation on. If that is something you would like us to add.

Arien Malec – Change Healthcare – Co-Chair
Sorry, just to be precise, you agree that these definitions do not include research, right? Except through sort of secondarily through individual access services, where the patient could download their own data and then designate it someplace? And then, we should consider or contemplate whether we should include that research as a permitted purpose. We've got a lot of questions. Mark

and David? And John, I assumed you raise your hand, but take prerogative and jump in whenever you want to, but I assume that was the point you wanted to get in on?

John Kansky – Indiana Health Information Exchange – Co-Chair
No, but I would rather hear from the committee. I'll jump in later, keep going.

Arien Malec – Change Healthcare – Co-Chair
Mark?

David McCallie, Jr. – Individual – Public Member
Must be muted. Mark?

Arien Malec – Change Healthcare – Co-Chair
Go, David, while Mark figures out his mute button.

David McCallie, Jr. – Individual – Public Member
Just to clarify what I meant by research, so if you have acquired the data about a patient through one of these modalities, like treatment or quality improvement, and you have rights to do research on the data that you have acquired through those standard modalities, I'm not suggesting that that is excluded by these proposed exchange purposes. That would be fine. What would be excluded, however, might be something like for example, a researcher saying I need a cohort of 10,000 patients between the age of 50 and 55 with the following diseases. I'm going to use the QHIN to go get those patients.

Arien Malec – Change Healthcare – Co-Chair
Also excluded would be, I am a PI who is evaluating inclusion/exclusion criteria for a patient, and I want to go query the detailed patient information relative to inclusion or exclusion criteria. Or I am a provider who is treating a patient on protocol, and I want to query with respect to determining if there is other medical information that might be indicative of adverse events. Those two things would not be a permitted purpose or exchange purpose under these definitions as well. So, you contemplated a broad go find a specific general cohort. I'm addressing, even on the individual level, those kinds of queries would not be exchange purposes under the TEFCA.

David McCallie, Jr. – Individual – Public Member
Yeah, I certainly agree with your first statement. I threw out a purposely broad, complex, but highly interesting use case. On the other hand, I think that your narrow exclusion might not be accurate. If you get data for treatment, you can get all the data. There is no minimum necessary requirement for treatment.

Arien Malec – Change Healthcare – Co-Chair
Right, if I get data for treatment, and then I use it for inclusion/exclusion criteria, that's a different matter. But if I'm specifically querying for adjudication and inclusion/exclusion criteria relative to appropriating his file, that would be a purpose that is not included.

David McCallie, Jr. – Individual – Public Member
Yep. Because you are not in treatment at that point.

Arien Malec – Change Healthcare – Co-Chair
That's right. Mark, you figured out your –?

David McCallie, Jr. – Individual – Public Member
All data is fair if… it's good data if it's derived from treatment. But if it's not, it has to fall into one of these categories. And research is not one of them.

Arien Malec – Change Healthcare – Co-Chair
Okay, Mark?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Sorry, bad connection. I am thinking that the individual access services' defined purpose might be unintentionally narrow because the opening is to define it around the individual's right of access under HIPAA and obtain a copy. But individuals, especially now, are using information from more than just that access. We've got access and use with things like shared care planning. So, in answer to your question, Arien, I am thinking that that definition needs some work.

Arien Malec – Change Healthcare – Co-Chair
Okay. Zoe, or other folks from ONC, can we take that as a placeholder, that we want to evaluate more and discuss research, and then we also want to discuss individual access, both with respect to the appropriateness of the definition here as well as relook at a recommendations relating to intermediaries or third party operating on the patient's behalf.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, I think that now is the time to do it, actually, if you want to go to slide eight on the screen.

Arien Malec – Change Healthcare – Co-Chair
We are on slide eight of 20 and we have 40 minutes.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, here is all of the individual access pieces and the MRTCs together. So, you have the definition here and the three specific provisions in HIPAA that we referenced. And we have expanded those definitions to apply to all electronic health information and all participating entities, regardless of whether or not they are covered entities or business associates. We also say that, so for the exchange purposes, there is a duty to respond for the six exchange purposes; however, for individual access, if you only provide individual access services then you only have to respond for request for individual access services. So, if you are a third-party app, you don't have to respond to requests for treatment, and quality assessment and improvement, and benefits determination. We also state – go ahead.

Arien Malec – Change Healthcare – Co-Chair
Sorry, I've never understood that point, so I just want to clarify for at least my purposes, and the purpose for the Members. As I read the TEFCA, if I'm a QHIN, I have to satisfy all of the exchange modalities and all of the purposes. I think you are saying there is a special class of QHIN that only participates with respect to individual access, and only to respond with respect to individual access. Am I right in thinking there aren't any other subsets of QHIN activity allowed? I can't be, for example, a QHIN with respect to directed exchange, but not with respect to query-based exchange?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
So, actually, as you said, QHINs have to support all of the exchange purposes. And so, what I'm actually referring to is a subset of participants and participant members. Actually, you'll only find that language in sections 7 and 8. So, I think section 7.12, and 8.12, there is an exclusion for if you are somebody who only provides those types of services, then you only have to respond.

Arien Malec – Change Healthcare – Co-Chair
Respond. So, if I'm a participant, there are some cases where I only have to respond to one type of query, but in other cases, I would respond to all types. And a QHIN in all cases has to support all purposes and all exchange modalities, at least as currently defined?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Correct.

Arien Malec – Change Healthcare – Co-Chair
Got it. David?

David McCallie, Jr. – Individual – Public Member
It's David. Can I dive into that one a little bit better? I had that exact same question, Arien, and I appreciate the clarifications, but I'm a little still confused. Let's say a participant is a PHR offering services to individuals who exercise their right of individual access and pull data down from the network. Does that PHR have an obligation to share that data with the network in reciprocation? Or is it a sink, it only can consume only, and not share?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
If that participant stored data, so they have the data available, and they received a request for individual access services, then they have to respond with the data they have available.

David McCallie, Jr. – Individual – Public Member
What about if they receive an access for treatment purposes?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
If they only ever initiate service… like, if they only provide individual access services, so they never initiate queries for any of the other exchange purposes, then they would not have to respond for any of the other exchange purposes.

David McCallie, Jr. – Individual – Public Member
Okay, they could respond if they wanted to. So, I'm thinking for example, a PHR that wants to offer a health record bank service to its members to say, "You give us the right to go aggregate your data, we will pull it in, we will clean it up, then we will serve it back to the position that you see, if they query us through the QHIN." That would be allowed, just they don't have to do that? Is that correct?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
That's correct, yes.

Arien Malec – Change Healthcare – Co-Chair

Okay.

David McCallie, Jr. – Individual – Public Member
Just on the individual services, just first just tell me. I think that sounds right, Zoe, what you described. I need to think about it some more, but I think that would be a benefit and not get abused. I do want to point out, however, that to distinguish between sort of the emerging notion of consumers with interactive apps that are talking via APIs to specific providers or to PHRs, etc., those the QHIN currently proposed would not support that kind of directed API access. It's a storing forward model. It has to go fetch the data, lump it all it up, send it to me, but it's not an interactive API model. I think that's appropriate, due to technical constraints. But I just think we should point that out, that apps wielded by consumers may still need API access in a much more directed and interactive fashion than is supported by the QHIN framework, and I think that's okay.

Arien Malec – Change Healthcare – Co-Chair
Again, nothing determines what the QHIN offers to the app. But the QHIN itself through the QTF would only build access the document level information and would not have access to API level information.

David McCallie, Jr. – Individual – Public Member
Correct.

Arien Malec – Change Healthcare – Co-Chair
Okay, Noam?

Noam Arzt – HLN Consulting, LLC – Public Member
Yeah, thanks. I wasn't on the last call, but with respect to individual access services, I believe there was a question raised about public health registries who are participants in TEFCA. So, they're not QHINs, they are participants who might be called upon or expected to respond to queries for individual access because, perhaps, they can. Or have an expectation that they should be able to. So, assuming that it's not in violation of the law – which in some jurisdictions it is – I believe that the answer given last time was yeah, a public health registry would be expected to do that. But my read of the reference here on the screen, particularly 45 CFR 164.524a, which is essentially the HIPAA stuff about a patient's right to ask for the information, it's a patient's right to access information of a covered entity. Which for this purpose of the public health registry wouldn't be. So, am I understanding this correctly? That the public health really shouldn't expect to have to be required to respond to an individual access service, if it sort of isn't prepared to either by technical capability, or financial reality?

Arien Malec – Change Healthcare – Co-Chair
Noam, I think you have that exactly. So, you ended with a "shouldn't expect to." I think factually, the way this definition is written because it leverages the HIPAA right to access it only applies to covered entities. And so, factually, you are right that a patient access query to a noncovered entity participant, the noncovered entity participant has no duty to respond because the access that is requested does not fit the individual access requirement. I think that's a factual statement. Yes?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
So actually, no. No. That's exactly the opposite. So, we have expanded the definitions for individual access services. The references to HIPAA have been extended to apply to both all EHIs and to any

participating entity in the TEFCA regardless of whether or not they are covered under your business associate. So, actually, if you look at the second bullet here, "Participating entities must respond to request for queries for IAS whether or not the request was prompted by a covered entity or business associate."

Arien Malec – Change Healthcare – Co-Chair
Okay. That's saying the opposite. So…

David McCallie, Jr. – Individual – Public Member
Yeah.

Arien Malec – Change Healthcare – Co-Chair
Whether or not it was prompted by – but I think what we are saying is the participating entity is not a covered entity, and so --

Noam Arzt – HLN Consulting, LLC – Public Member
Or a business associate.

Arien Malec – Change Healthcare – Co-Chair
Right.

Noam Arzt – HLN Consulting, LLC – Public Member
The public health registry is not a business associate either.

Arien Malec – Change Healthcare – Co-Chair
So, do you understand the distinction we are making here?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I see. Yeah, I see what you're saying.

David McCallie, Jr. – Individual – Public Member
This is David, I think it might be helpful to have a little chart of roles that initiators and responders would be obligated to or required to because it is tricky. When you talk about a covered entity, you have to make the distinction of whether it's the issuing querier or the responding querier.

Arien Malec – Change Healthcare – Co-Chair
And we've got FTC-regulated entities, we've got public health regulated entities, we've got covered entity regulated, HIPAA regulated entities. It would be nice to see a matrix that says who may query and who must respond.

David McCallie, Jr. – Individual – Public Member
Right.

Noam Arzt – HLN Consulting, LLC – Public Member
I'm happy to have an off-line conversation about this. I'm not clear actually that everyone is in agreement with what I said. So, I don't know that we have time to continue this now, but it does need to be resolved with some clarity.

Arien Malec – Change Healthcare – Co-Chair
I completely agree. I would propose this as a question that we address, we make recommendations of as a task force, which is – I think I heard Zoe say maybe unintentionally, but ONC has intended that all participants have to respond to individual access queries, whether or not they are a covered entity. And I think that we should either double down on that recommendation or say where we think that recommendation is a bad idea. And then also just acknowledge that the current definition – maybe we just don't understand it well enough – may not support that requirement. Go ahead, Zoe.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yes, If I could cut in, I am just going back to the actual language in the text, because what's in the slide is paraphrased. So, I don't know if we can get the actual text up on the screen and go to section 7.14, which is on page 57? There is a provision in there, it's 7.14-2. Each participant that receives a request for IAS from an individual with whom it has a direct relationship shall provide the individual with access regardless of whether the participant is a covered entity or business associate.

Arien Malec – Change Healthcare – Co-Chair
There you go.

Noam Arzt – HLN Consulting, LLC – Public Member
Right, but a Public Health Agency is neither a covered entity nor a business associate.

Arien Malec – Change Healthcare – Co-Chair
No, I think that's what this is saying, is that each participant that's queried for individual access will respond as if they are a covered entity.

David McCallie, Jr. – Individual – Public Member
Yep.

Noam Arzt – HLN Consulting, LLC – Public Member
Oh, okay. Okay. All right.

David McCallie, Jr. – Individual – Public Member
I think that a really important point to debate. I mean, if you give public health the exemption, who else gets the exemption? Because there might be other noncovered entity things that want to connect as participants.

Arien Malec – Change Healthcare – Co-Chair
Yep. Thank you, Zoe, for clarifying that. Okay, hold on. I just want to go back to our queue and also get through all the materials. Mark?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
So, I'll just raise that I still have the same question. This discussion has all been around individual access services. Maybe I'm reading this too much like a lawyer, but it starts off saying it's limited to the HIPAA right of access and to obtaining a copy of the individual's EHI. And so, all of this extensive

stuff, noncovered entities, whoever's a participant, is still limited to those two particular rights. I think we would want to take a careful look at that.

Arien Malec – Change Healthcare – Co-Chair
What's an additional right that you think should be contemplated, or would be excluded by those two definitions?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member xyz
Well, I don't know about thinking in terms of it as rights, but use cases, we've talked about patient-generated health data, shared care planning on the fast ecosystem, use case tiger team, where we just design a shared care plan and use case that is not structured around an individual exercising a right of access under particular provision of the CFR.

Arien Malec – Change Healthcare – Co-Chair
I see. So, there are cases that are bilateral that would not be contemplated. This is a read-only, get a copy, not a bilateral interaction. That's the distinction you are trying to make?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
No. I think that's included, but it's also broader than that. You are right, those examples I mentioned, did involve bilateral by the direction of exchange, multidirectional actually.

Arien Malec – Change Healthcare – Co-Chair
Yep. David, I see you still have your hand up?

David McCallie, Jr. – Individual – Public Member
Yeah, it was on an earlier point, but I'll just respond to Mark's question. I think that is where I was trying to touch on earlier, a distinction between an interactive connection and a batch style connection that the QHIN is currently based on. And I think the way I would interpret it is that all of that care planning data, however, it got accumulated by whoever had it, is EHI and therefore would be shareable via the QHIN, because it's EHI. But the QHIN wouldn't be the means by which the app connected to a system to interact around the care plan. Does that make sense?

Arien Malec – Change Healthcare – Co-Chair
Yep. Okay, Noam, quickly, then we go onto the next section so we can get through it.

Noam Arzt – HLN Consulting, LLC – Public Member
Just very, very quickly, the other ambiguity in this section Alex quoted from the actual document on this topic has to do with this notion of direct relationship. So, it's not clear to me that a public health registry has a direct relationship, necessarily, with a citizen. Do you know? How in the world. I'm not all that clear on the definition of a direct relationship. It feels very legalese to me, I am not sure I understand it.

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
Noam, that is exactly what I was trying to raise. If I understand, an individual has to declare a direct relationship, and it's very unlikely they are going to do that with a public health registry. They are going to do that with some vendor or add QHIN. And so, that query would come to the public health registry to the participant or participants member does not have a direct relationship with the individual.

Noam Arzt – HLN Consulting, LLC – Public Member
Maybe.

David McCallie, Jr. – Individual – Public Member
Yeah, I mean, patients don't have direct relationships with HIE's. They are obligated to respond. They have EHI.

Noam Arzt – HLN Consulting, LLC – Public Member
I am just saying, I think within, within TEF 2, direct relationship is a defined term.

Arien Malec – Change Healthcare – Co-Chair
The indirect relationship falls back on the HIPAA definition of direct relationship.

Morris Landau – Office of the National Coordinator for Health Information Technology – SME
Hey, this is Morris. The direct relationship is a relationship between the individual and the QHIN participant or participant member that arises when the QHIN participant or participant member as applicable offers services to the individual in connection with one or more of the framework agreements. And the individual agrees to receive such services.

Arien Malec – Change Healthcare – Co-Chair
Okay, I think Noam is right. I think we're back to the position where a public health agency, an immunization registry would be able to say, "Sorry, I've got an indirect relationship with the patient, so I'm not obligated to respond."

Noam Arzt – HLN Consulting, LLC – Public Member
That's right. Saying, "I don't offer the services, thank you very much."

David McCallie, Jr. – Individual – Public Member
No, no, it's not obligated, I think that this direct relationship is just talking about who gets to talk to QHINs. It's not talking about the QHINs' obligation to respond if they contain EHI. I mean, the EHI may be spread out all over the place that the patient does not have direct relationships with, in the sense of this definition. They're still obligated to respond with that EHI.

Arien Malec – Change Healthcare – Co-Chair
This is a, "an individual user may assert his or her right in individual access services with respect to the participant if it has a direct relationship with the participant. The participant may require such individual use **[inaudible] [01:05:46]** his or her right in digital access to EHI in writing, etc. And again, if the public health agency is a participant, and doesn't have a direct relationship, then I don't think they are obligated to respond. I think we have raised some really interesting topics. I would like to go on to the next slide because we are at 9:20 AM, and we have 20 mins left.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
So also, I think we can continue this discussion on our next call. I was able to put aside some time for us to finish this, and then we can start proviso next time.

Arien Malec – Change Healthcare – Co-Chair

I'd like to go broad first, and not go all the way down to the depths.

David McCallie, Jr. – Individual – Public Member
Agreed. Are we going to do modalities?

Arien Malec – Change Healthcare – Co-Chair
I don't know if we have time, but we need to get through modalities as well. Okay, go ahead, Zoe.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, no, so if you want to just take the slide back to the modalities, you guys can go ahead and keep talking through things. As broadcast query, targeted query, we've added message delivery and remove the top level query.

Arien Malec – Change Healthcare – Co-Chair
Yeah, so, my comment with respect to broadcast query is that – and maybe I could ask ONC to comment, because I didn't see specific treatment of why the specific definition of a record locator service was removed from TEFCA 2. But I do not, and maybe just asking for clarification, I do not see an obligation for a QHIN to provide a record locator service in order to respond to a broadcast query. And maybe I just don't understand a broadcast query in TEFCA 2 well enough to understand this question, but I do not understand what a broadcast query is in this iteration of TEFCA 2, whereas I thought I did with respect to TEFCA 1.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Alex, do you want to weigh in?

Alex Kontur – Office of the National Coordinator for Health Information Technology – SME
I'm not sure how to answer that question, to be honest. I don't have any insights into actual language around record locator services. I do know that there is a specific function in the technical framework dealing with record location. I think as just a guiding principle, we kind of left it open-ended because we didn't want to have too heavy-handed of an approach in determining what architecture or infrastructure QHIN's are required to have.

Arien Malec – Change Healthcare – Co-Chair
Yeah. We'll go through a round of discussion, then maybe go back to this point. Noam, do you still have your hand raised relative to individual access or do you have your hand raised relative to exchange modalities?

Noam Arzt – HLN Consulting, LLC – Public Member
No, I guess I didn't undo it, sorry.

Arien Malec – Change Healthcare – Co-Chair
Okay, David?

David McCallie, Jr. – Individual – Public Member
On modalities, a couple of things. The one that I feel most strong about I will say first, which is the message delivery push model. I feel really strongly that this is a mistake. I think it's unnecessary, and would create far more problems than it would solve. And I'm happy to dive into the details of why I feel that way, but I will just leave it to say I feel really strongly that that would be a mistake. We

already have direct, as an ONC funded and sponsored approach to solve this problem, and that process I think should be finished rather than starting fresh with an even flakier approach. So, that's No. 1, and then No. 2 on a broadcast query, based on what we just heard from ONC, the way I would say that makes sense to me is the distinction of the targeted query, you are going after a known location.

A broadcast query, you are asking for a federated record. You are saying by some means, find me the federated record. And if that is the interpretation of broadcast without specifying how you do that, then I think it makes sense.

Arien Malec – Change Healthcare – Co-Chair
I agree, it was not clear to me that broadcast query was… it was not clear to me, functionally, what was included in the definition of broadcast query. David, can ask relative to your message delivery, comment? I can frame your strong objection in one of three ways. Way one is we just shouldn't include push exchange at all. And I remind everybody, the last time we had this discussion, we were split on this topic, and I don't think we are going to be un-split on this topic next time around. So, we have had this discussion, we have pretty exhaustively enumerated a set of recommendations to ONC, and I don't really want to go back and re-discuss that. Then, there are two subsidiary questions, which is, is it appropriate for a QHIN to have all of the use cases addressed? And is the QTF the right standard with respect to those definitions?

So, David, I could frame your question one of the ways. No. 1 is ONC should just be silent on direct exchange. I don't think that's what you're saying. I think what you're saying is we already have standards and methods for direct exchange. And we shouldn't create new ones or create new obligations in ways that are duplicative of obligations that are already out there.

David McCallie, Jr. – Individual – Public Member
Yeah, just be careful. Don't say directed exchange, because I think that sounds like another modality. Push exchange. Right. Yeah, so I'm saying we already have invested as a community a decade and lots of resources into a push model that is getting rapidly expanding uptake and has been integrated into a very large number of EHRs. The proposal here for push would be a step backward in functionality. The QTF proposes a completely outmoded technical standard that would be difficult to support. And would, I think, just set us backward immensely.

If there was an interest in proposing something new and different in the QHIN, I would say go after secure messaging, like XMPP text messaging. If you really feel like we need something more than what Direct gives us, put a standard on the table that would, in fact, give us more Direct gives us. Don't put a standard on the table that would actually take us backward. I could riff on this all afternoon, I am sorry.

Arien Malec – Change Healthcare – Co-Chair
No, let's, we have heard you. Let's just placeholder that one. I think with respect to broadcast query, I don't see any other definition other than a QHIN's electronic response for an individual EHI in the context of the Common Agreement that requests EHI from all other QHINs to the extent permitted by the Common Agreement and applicable law. So, I do think there's a functional requirement missing, which is the equivalent of a record locator. And maybe we can have that discussion at some point, Noam, I see your hand is raised?

Noam Arzt – HLN Consulting, LLC – Public Member
Yeah, just real quick. As strongly as David feels that the message delivery or push method should not be included, I and my public health colleague believe that some kind of push transaction does need to be included. I agree that the particular transaction and standards defined in the QTF aren't necessarily what public health is looking for. But then, that's a reason to talk about this and get this right, and not a reason to throw the whole thing out. And, Direct in and of itself is not terribly relevant in most, not all, but most public health reporting transactions that are push transactions.

Arien Malec – Change Healthcare – Co-Chair
Yep. And again, I just want to remind this task force that we had the debate about what should or shouldn't be included, and we were split. We are going to continue to be split, so we probably shouldn't re-adjudicate or re-fight that debate. Mark?

Mark Savage – UCSF Center for Digital Health Innovation – Public Member
I lowered my hand, I agree with your original thought, but this is decided. Let's move on. I do support a push.

Arien Malec – Change Healthcare – Co-Chair
All right. So, it's decided. We are going to move on, but we definitely want to evaluate the QTF relative to the policy goals that message delivery is intended for. And I also think we want to have a discussion about whether the definition of broadcast query is sufficient to address the policy goals relative to the task.

David McCallie, Jr. – Individual – Public Member
I would put that functional definition.

Arien Malec – Change Healthcare – Co-Chair
Functional definition, right.

David McCallie, Jr. – Individual – Public Member
And, if necessary, QTF aspects of that to support it.

Arien Malec – Change Healthcare – Co-Chair
Right, because I think that if you look at the QTF right now, it supports the transaction where I say to another QHIN, “Do you have data about this patient, yes or no?” And the QHIN says yes or no. So, it's explicitly a QHIN to QHIN exchange of, “Do you have data about this patient?” And it's the QHIN's obligation to figure out how to respond to that, as opposed to the question of “Where might this patient data be found, and can you get it for me?” Those are slightly different functions.

David McCallie, Jr. – Individual – Public Member
Very different when you throw in the word efficiently.

Arien Malec – Change Healthcare – Co-Chair
Exactly. And this is not a theoretical issue. Brainplay is a functional modality that we should say we should not drive an architecture that supports brainplay. All right, we've got to go to public comment. We haven't gone through all of our information. We got through, I think, barely half of our slides. This is not boding well for our ability to get to this efficiently.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Thanks, Arien. Operator, can we open the line?

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks. And before we go to comment I just wanted to check, did any other members join the call after I took roll?

Anil K. Jain – IBM Watson Health – Member
Yeah, this is Anil Jain. I joined a few minutes after the meeting started.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, thanks. Anyone else?

John Rancourt – Office of the National Coordinator for Health Information Technology - Director, Interoperability Division, Office of Policy
Hi, it's John Rancourt. I joined, but have to jump off very soon.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Any other Members? Okay, operator do we have any comments in the queue?

Operator
No comment at this time.

Arien Malec – Change Healthcare – Co-Chair
Okay, let's go back and try to see if we can get broad before we go deep. But I just want to comment that in this brief discussion, we have addressed some issues relative to individual access and make sure we understand the duty to respond, relative to the obligations in the TEF. I think we've raised issues relating to appropriateness of the applicable standards relative to message delivery. And to make sure, to Noam's point, let's make sure the message delivery is functionally specified in a way that addresses public health concerns, as well as other concerns. And then, I think we have also raised a placeholder discussion for the definition of broadcast query, we gave a couple of perspectives we should address broadcast query functionally with a little more meat, and make sure that we have the functional means, and the technical means, to do so efficiently. All right, let's keep going.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead

Just I think things to note about this one is that, aside from individual access, for other six exchange purposes, if you receive data for one of the exchange purposes, then you can exchange, retain, aggregate using disclosed for any those exchange purposes aside from individual access. If you received data for an IAS, then you can only exchange, retain, aggregate using disclosed for IAS. We also, in section V, we do note that you can also do it as otherwise permitted by applicable law, so if you are covered under the business associate, then you would be permitted to exchange, retain, aggregate, using disclosed for all of PPO. And then also in VI here, we say for any purpose explicitly approved by the individual, only after the individual has received at least a written privacy summary, and the minimum information such purpose.

So, if you go to the next slide. We have the definition of minimum information here. And, the goal is that the individual would receive not just a notice or a summary, but actually something that they could consent to or deny. And that they would have a reasonable understanding of what is going to happen with their data.

Arien Malec – Change Healthcare – Co-Chair
Okay. So, some quick questions for purposes of clarity. There are some exchanges that limit subsequent use of data for only the purposes for which it was requested. And this language basically says if I requested for treatment that somebody queries for quality improvement, that I can't be limited in my ability to reuse the data, No. 1. No. 2 is if you go up one slide, I believe you are limiting it to either be in obligations or permitted purposes, exchange purposes. So, I don't get a free pass to aggregate data, and sell the de-identified data to third parties. I only get such rights as are granted to me under BAA. Am I right on both of those assertions?

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I believe so.

Arien Malec – Change Healthcare – Co-Chair
Okay.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
I have to think about the question a little more, but yes.

Arien Malec – Change Healthcare – Co-Chair
David?

David McCallie, Jr. – Individual – Public Member
Just a clarification on what you said, though it sounded to me like it conflicted to what we had discussed in a previous question. Maybe it comes down to the definition of what is secondary use or future use. But let me just put the PHR question out there again. So, I'm a PHR, I contract with an individual, have a direct relationship with an individual. I have my PHR, who's a participant in a QHIN, fetch my data for individual access services. They aggregate all my data, and clean it up, and normalize it into a very nice medical record. Now, a provider I go see wants to query. Would that PHR be prohibited, because this is now future use of PHI? Or of individually aggregated data? Or would they be allowed to actually share that data? I'm hearing it both ways.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
That's a really interesting point. I think we should explore that point more.

Arien Malec – Change Healthcare – Co-Chair
Okay.

David McCallie, Jr. – Individual – Public Member
I will say, I am in favor of allowing, you know, individuals to control such kinds of things, so maybe the simple answer is if the individual says, "Yes, you may share the data back to the network for treatment purposes, that's why I hired you," then it should be allowed. So, I think it's a good thing, but just unclear in the way the current rules are written.

John Kansky – Indiana Health Information Exchange – Co-Chair
I had a question I wanted to work in on this permitted and future uses issue is with the question of why would one want to be a QHIN sort of floating in the air, I think, is the question as it pertains to QHINs participants and participant members. I just want to make sure I am understanding this correctly, that if you acquire and accumulate data that was not through individual access, but the other exchange purposes, you are able to implement any business model that makes use of that data, if it's not illegal, immoral, or threatening.

David McCallie, Jr. – Individual – Public Member
If it's individual access? Or are you saying in general?

John Kansky – Indiana Health Information Exchange – Co-Chair
No. It's specifically not the data that was accumulated through individual access. I understand that can only be used in individual access. So, whether a QHIN or a participant, you are participating a whole bunch of exchange purposes as through TEFCA, and you've retained data. You could reuse that data if it's not illegal, and not in violation of your contracts, etc. Is that a true statement? Want to see if anybody knows the answer to that question.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
So, this is Sheryl. I know that if you are a covered entity, there are certain uses that you can have if the data is considered to be identified. There is also been a bill that's been raised to allow HIEs and other clearinghouses to use data for other purposes, but that has not moved forward.

John Kansky – Indiana Health Information Exchange – Co-Chair
So, I'm trying to – I think I'm asking an even more basic question. Maybe I missed a really obvious answer. But, let's go back to the research use case that was raised earlier. I think David kind of clarified this in my head, for me. So, I am a QHIN, I accumulate a ton of data through exchange purposes, none of which were AIS. And there is nothing that prevents me from sharing that data for research, and maybe I wrap some services around that and I get paid for those services. There's nothing here that says that's prohibited?

David McCallie, Jr. – Individual – Public Member
But the law prohibits that, legally.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Right. And one of the exchange purposes right now is not research. So, I think we need to **[inaudible][01:26:50]**, because we are at the end of our time. And I would like to weigh in on it.

Arien Malec – Change Healthcare – Co-Chair
think we have basic questions in this area of what is and isn't allowed under this definition. So, as noted, we are at the end of our time. We got through 10 slides out of 20. Although some of this, we actually had 11 slides plus the public comment. We've got about eight more slides to go. Some of the stuff is really meaty stuff indeed, so maybe John, with your permission, we'll continue these discussions in the next task force.

John Kansky – Indiana Health Information Exchange – Co-Chair
This is complicated.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Yeah, and sorry, Arien, those extra slides at the end there, those were just some examples of the modalities and the purposes just so that we have them on hand. So, I think we actually got through – this is content that we want recommendations on for this topic. So I agree, we should continue discussing this on our next call, which isn't until the 23rd.

Arien Malec – Change Healthcare – Co-Chair
Okay.

Zoe Barber – Office of the National Coordinator for Health Information Technology – Staff Lead
Although we do have to do an update on the 22nd to the full committee.

Arien Malec – Change Healthcare – Co-Chair
Yep. Thanks all.