

Transcript
June 26, 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

All lines are now bridged.

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

Great. Thank you. Good afternoon, everyone and welcome to the TEFCA task force meeting. Today, we're going to have continued discussion on recommendations. So, let's get started and I'll officially begin by taking roll. John Kansky.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Here.

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

Arien Malec.

Arien Malec - Change Healthcare - Co-Chair

I'm here

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

Carolyn Petersen.

Carolyn Petersen - Individual - Member

I'm here.

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

Aaron Miri. Sheryl Turney. Sasha TerMaat. Steve Ready. Cynthia Fisher. Anil Jain.

Anil Jain - IBM Watson Health - Member

I'm here.

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

Denise Webb.

<u>Denise Webb - Individual - Member</u>

Here.

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

David McCallie.

David McCallie, Jr. - Individual - Public Member

Here.

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

Mark Savage.

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

Good morning. Here.

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

Good morning or afternoon. Noam Arzt.

Noam Arzt - HLN Consulting, LLC - Public Member

I'm here.

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

Thank you. Grace Terrell. Laura Conn.

Laura Conn - Centers for Disease Control and Prevention - Member

Here.

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

Great, thanks. Arien.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

All right. So, we are going to pick up where we left off. We have incorporated the discussion that we had on the previous task force into the revised recommendations. But we're going to do our usual approach of going breadth first and then, doing a cycle back. So, let's go to the next issue.

Noam Arzt - HLN Consulting, LLC - Public Member

Excuse me, Arien. I thought we had decided to start with sort of where we ended last time.

Arien Malec - Change Healthcare - Co-Chair

That's exactly what I'm saying is we're picking up where we left off and going to the next substantive issue that requires –

Noam Arzt - HLN Consulting, LLC - Public Member

Well, no. I thought we said we'd just cycle back to the issue that we ended with because it was a fairly monumental recommendation to sort of talk the QTF. I just want to make sure we really did say that.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. To examine the rewording, that's right, Noam. So, we combined in the rewording the former Recommendation 4 and Recommendation 5 into a single recommendation. That recommendation says that TEFCA should outline functional requirements sufficient to meet the policy goals in the TEFCA and avoid wherever possible identifying specific technical solutions. QHIN functional requirements should be put front and center to communicate the what and leave room for flexibility innovation on the how because the RC and initial QHINs are presumed to have familiar exchange standards and approaches.

We recommend the ONC remove the QTF and clearly document functional requirements in perhaps a QHIN functional framework, a QFF given that the QTF has been published. All right. This sentence should be removed.

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

Sorry, Arien. This is was where I think both you and John had made some edits and so I was just kind of trying to combine what you both were saying. So, we can – before the sentence.

Arien Malec - Change Healthcare - Co-Chair

Yeah. And I was reacting, Zoe, to something you may need to explain, which is that we can't unknow the QTF. Maybe I misunderstood but it's out there.

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

That's exactly right. So, on the debrief, I was sort of saying to John that there is not going to be a release between the TEFCA Draft 2 and the next is the common agreement Draft 1, which at that point, the whole purpose about what is the QTF Draft 1 is going to be completely different. The RCE will **[audio interference]** the stakeholder convening in order to get their import and updating it. And so, I was just sort of questioning the value in saying if we just completely got rid of the QTF as opposed to just recognizing this is out there. Do you have public comment on it? Do we want to really throw away all of that public comment or let the RCE take that and do with it what they will?

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. I kind of feel like our recommendations are our recommendations. I don't think there's anything wrong with providing the comments on the QTF to the RCE. I think that's a valuable exercise. But I'd say we either recommending removing the QTF from the TEFCA final version or we don't. And then, Zoe, you and I had a valuable back and forth email exchange that I want to surface to the group, which is on this point of the QFF. Obviously, that joke kind of got put in through me, through my sense of humor. But the question was don't the MRTCs already outline the functional requirements.

And part of the feedback was they do but I think the entire task force had a collective a-ha when we walked through the MRTCs that were applicable to functional requirements for the QHIN and flat out didn't understand them. And Zoe's feedback was that there have been additional comments that have been received that portray a similar lack of understanding. And so, the recommendation here is really to pull out the functional requirements in their own section. They could be a section of the MRTCs and then, also kind of in the explanatory pros discuss the functional requirements so that people understand that those are the functional requirements. David, I see you've got your hand up.

<u>David McCallie, Jr. - Individual - Public Member</u>

Yeah. I think the point just should be clarified that our recommendation, whether you drop the QTF or not is that we consider the QTF is a list of potentially relevant standards but is otherwise not necessarily binding. I think the concern we have is that the QTF might be taken to be too prescriptive. It's certainly a useful set of standards that are relevant to discussions going forward. But it just needs to be really clear that it's not a binding set. I think maybe that would be the sense that we're trying to shoot for. And then, I have a second thought and this maybe comes back up when we get back to the can QHINs support only a subset of the permitted purposes.

And I think the missing term here in the document that would help clarify some of this is some kind of a notion of a use case where a use case is a set of particular functional requirements and a particular technical embodiment that exists under the framework of the permitted purposes but which may be very narrow and focused for some particular goal. And the technical implementation is use case specific. You could imagine, for example, use cases that are completely based on Fyre APIs consistent with the emerging NPRM and other use cases that leverage the standards that are in the current QTF. And what we need is a way to structure the flexibility for the RCE to determine the use cases, pick the appropriate technical standards to meet a specific use case, specific set of functional requirements.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

So, is that a recommendation or is that more of an RCE – do we believe that ONC hasn't given RCEs appropriate flexibility or do we need to discuss this when we talk about the notion of modular QHINs?

David McCallie, Jr. - Individual - Public Member

I'm happy to bring it back up in the modular conversation. But I think the modular approach needs to be able to allow for much more variety than the current QTF feels like it does.

Arien Malec - Change Healthcare - Co-Chair

Okay. Let me test some language out and then, I'll go to John. I would recommend moving the third sentence starting with because the RCE – sorry. The fourth sentence. Given the QTF has been published, I would recommend something to the nature of given that the QTF was published in TEFCA 2, we recommend the RCE be provided the comments and feedback that have been provided in the comment period. And we also recommend that it be very clear that the RCE is free to choose any technical enablement or enablements of the functional

requirements. Would that address the issue on the table?

John Kansky - Indiana Health Information Exchange - Co-Chair

Arien, this is John. I think it does. And I also think that, as the author of this sentence that we're wrestling with here, I think the last chunk of my sentence tries to say exactly what you just said. I think it's helpful to insert that they should have the comments and benefit from them but the last part of the sentence that's already in there says that potential QHINs – it should be clear that the QTF was created as initial guidance for the RCE who has the authority to work out flexible and evolving technical approaches. I think we're trying to choose words that say the same thing.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah, okay. So, we can wordsmith and massage this. Does anybody else have any comments on this topic?

Noam Arzt - HLN Consulting, LLC - Public Member

The only other comment I would make is if you look at the opening page of the QTF itself, it sort of says that. We maybe have – in our fervor to understand the details, many of us may have overlooked that but it sort of says that.

David McCallie, Jr. - Individual - Public Member

I agree, Noam. It does say that but then it gets weirdly granular in ways that make you feel like they didn't mean it. So, we're just asking for clarity.

Noam Arzt - HLN Consulting, LLC - Public Member

That's right.

John Kansky - Indiana Health Information Exchange - Co-Chair

So, no harm in reinforcing what it says then.

Noam Arzt - HLN Consulting, LLC - Public Member

Fair enough because that was always my reaction to it, too. But it's not that ONC didn't put that thought out there in writing in the overview of that section itself.

Arien Malec - Change Healthcare - Co-Chair

Yeah. Got it. So, I think we've got general agreement on the approach. And at this point, I would recommend that we go to our next substantive issue unless there is somebody else who wants to get their hand in. John, if you could lower your hand. Perfect. Let's keep going. So, we want to go to the next major dispute. So, now we talk about specialized QHINs. Okay.

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

We wanted the RLS Recommendation 6 of the targeted query. Where is that –

<u> Arien Malec - Change Healthcare - Co-Chair</u>

I didn't feel like that was a controversy. Whereas I feel like the modular QHIN is a more substantive and potentially more controversial recommendation. Just to update the group for those who didn't attend the HITAC call, the HITAC reacted very favorably to the notion of a modular QHIN. The specific examples that were used were the public health QHIN that primarily does message delivery relative to surveillance. And then, the notion of a patient or an individual access QHIN that really specializes in the particulars of onboarding individuals and supporting individuals to exercise their individual access rights.

John Kansky - Indiana Health Information Exchange - Co-Chair

Arien, I'm having an Arnold Horshack moment over here if anybody gets that reference.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

I do not.

David McCallie, Jr. - Individual - Public Member

I do.

John Kansky - Indiana Health Information Exchange - Co-Chair

It means I'm going oh, oh, oh, I really want to say something. So, during that HITAC and after, I had a bit of a cheese moving epiphany that I wanted to try on the committee and see if anybody else bit on this and if not, I'll shut up at least for two minutes. So, my thought, and I tried to capture it a little more carefully in the comments there in the document, is here's the punchline. Are we really talking about specialized participants? In my view, and I think I'm beginning to develop some intuition for, and I don't want to put the words in the mouth of the ONC, but I've inferred that ONC believes there should be a small number of QHINs and that QHINs are giant TEFCA transactors. That's their purpose in life.

And so, QHINs that can't transact all of the exchange purposes and modalities, they're not QHINs because that's what QHINs do. And so, the question is why couldn't the same vision for specialization that we thought would be desirable be implemented by participants that specialize in public health messaging or individual access services that choose the TEFCA transactor, AKA QHIN, of their choice. How does that in any way detract from what was expressed as a preference? If that scratches the itch, it does, however, imply that we would need to recommend to ONC that they consider allowing participants that don't do all of the exchange purposes.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. Let me defend and then, we'll go to David. I think that definitely aligns with how ONC was thinking about it. Let me defend the notion of a specialized QHIN as opposed to a specialized participant. So, let's say I see a business — Noam sees a business opportunity recognizing that state by state variation in disease surveillance activities for public health is kind of a mess. And understanding that every meaningful user promoting interoperability user needs to do public health reporting sees an opportunity to just go wire up all of the public health agencies and expose a QHIN interface to that activity and says, hey, guys, if you need to

get to public health, you talk to me. That to me feels like a QHIN interface as opposed to a participant interface.

Otherwise, Noam would have to contract with a QHIN solely for the purposes of being the default end point for public health syndromic surveillance transactions. So, having defended maybe two perspectives on the table, let's go through the number of hands raised starting with David and then, Sheryl and then, Mark.

David McCallie, Jr. - Individual - Public Member

Yeah, thanks. So, I think there is a hierarchy of needs, if you would, that starts with policy goals. Why does TEFCA exist in the first place? A set of permitted purposes that are clarification of the legal constraints of what you can and can't do, which we know is basically HIPAA plus a few things that we may have added on supra above and beyond. And then, there's a set of use cases that involve an actual set of requirements and a technical implementation that QHINs and participants will agree to support. I think you could imagine that a QHIN may be required to support some minimum use cases that everyone must support and then, have a series of optional choices that the QHIN can elect to support or not as long as they fall within the policy goals that are broadly structured upfront.

So, for example, one of those policy goals is reciprocity. We strongly believe I think all of us, that you shouldn't be allowed to be a data hoarder, just a vacuum cleaner that sucks up stuff. But then, we quickly got into the use case specifics that public health might, in fact, be in capable of participating in a fully reciprocal way. And so, you can carve out a specific use case that says within the constraints of the broad policy goals, we understand the special needs of public health will create that as a use case. And then, I think the QHIN should have the choice of saying yes, and we'll support that on behalf of anyone in pubic health who wants to use us as their gateway onto the network. But another QHIN may say we're specializing in EHR based record sharing and that's not a valuable proposition for us.

We're happy to let another QHIN take care of that. So, I think it makes sense in the context of carved out specific use cases. We talked about the health record bank, the notion that an individual consumer could use IAS to authorize the creation of a record and then, authorize that assembled record to be shared back to other providers, even though that's not technically the broadcast use case that is the core framework of the TEF. So, that's a specialized QHIN that benefits patients that meet policy goals and could be authorized in a specialized way. So, I do think we should have module approaches but I think modules around use cases not modules around permitted purposes. The permitted purposes are too broad.

John Kansky - Indiana Health Information Exchange - Co-Chair

Why is it necessary that that specialization be at the QHIN level is my question? I'm still not getting that.

David McCallie, Jr. - Individual - Public Member

Well, because the QHINs are the ones that have to meet contractual terms with respect to each other. The participants don't want to do that with every other participant. They proxy that up to their QHIN. So, I don't know what it would mean for a participant. Certainly,

participants don't have to do everything. No one has suggested otherwise. If you're an EHR, you don't do public health. You don't have public health data. You're not a public health agency. So, by definition, the participants are already specialized. But the QHINs they work with could do subsets based on use cases as long as they meet the high level policy goals and fall within the legally permitted purposes.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

To put it another way, if I'm satisfying all of the TEFCA requirements for public health use cases, do I think need to also contract with a general purpose QHIN in order to publish a QHIN interface that allows everybody to report through me? Or can I just take that work on but only take on the work that I need?

David McCallie, Jr. - Individual - Public Member

Are you speaking as a QHIN in that case, Arien or -

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. So, I'm speaking as this presumed entity that decides to wire up all of the states and then, wants to make that wiring available for everybody because it's a more efficient way of getting public health reporting. And we're really discussing the difference between I can just publish a QHIN interface for that use case or I have to contract with a general purpose QHIN and do some revenue share with them relative to those QHIN use cases. Okay. Sheryl has her hand up.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

Yeah. I think that as was previously stated, participants within this structure don't have to be performing every single act that's going to be allowed in the structure. And the QHIN framework is going to be expensive to administer anyway. And then, by talking about having specialized ones then, it means potentially having to focus on how those should operate differently. I don't see the value add in that, quite honestly. To the extent that the participants only are required to perform to the extent that they're capable, I don't understand really why we need a specialized QHIN.

And if we're stripping out the technical component here, which we said we want to separate then, the functional aspect should be that it should support all of the various different types of requirements that are out there and not everyone is going to participate in every single thing, which we've already decided is the way that it's going to work. So, I agree with what John stated in the beginning. And, Arien, what you tried to describe, I couldn't picture. So, maybe I'm missing the visual. But I just don't see that that would be, the way I see it, in my head to have a specialized QHIN, I don't see how that is even going to be viable from a sustainability perspective.

Arien Malec - Change Healthcare - Co-Chair

So, I definitely appreciate that perspective. Let me try one more attempt at this, which is the question of is direct trust – direct trust is a HIN or an HIE, I'm not quite sure which. And with respect to message delivery, would direct trust be a participant? They're not really a

participant because they're not doing any of the actual technical work. They're not going to be the RCE. So, what's the role that, for example, a direct trust has with respect to providing a policy framework for direct based messaging? Or is that just completely independent of the QHIN? Or does that violate the single on ramp principle?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

What may be a participant though? Why couldn't direct trust that network be a participant under this QHIN?

Arien Malec - Change Healthcare - Co-Chair

Because they're not responding to any queries. They are analogous to an RCE. But with respect to those specific use cases and going back to David's notion, those specific use cases that are associated with, for example, continuity of care, transitions of care that are relevant for the direct use case. Noam, I see you've got your hand raised.

Noam Arzt - HLN Consulting, LLC - Public Member

Yes. Two things. As to answer your last question, as I understand the direct trust, they're neither an HIE nor a HIN nor a QHIN. They are orthogonal to this. They're a trust concept. They aren't the HIP. They don't actually –

<u>Arien Malec - Change Healthcare - Co-Chair</u>

They do meet the definition of a HIN in the Cures NPRM at least in the NPRM.

Noam Arzt - HLN Consulting, LLC - Public Member

But they're not a HIP, right? They don't actually transport or convey messages, do they?

<u> Arien Malec - Change Healthcare - Co-Chair</u>

No, they don't. And as I said, I think they're more analogous to the RCE with respect to those activities than they are to any HIN.

Noam Arzt - HLN Consulting, LLC - Public Member

That's right. So, as you were talking through that direct trust thing, it sounded like you were talking yourself out of it actually the more you talked. It sounded like it wasn't an example of a specialized QHIN.

Arien Malec - Change Healthcare - Co-Chair

It's, basically, a parallel RCE and a parallel network of non QHIN QHINs.

Noam Arzt - HLN Consulting, LLC - Public Member

It's not a parallel RCE because there is only one RCE. It is an RCE-esque type organization. But it is simply something else. On the more central question, I tend to agree with Sheryl. I'm not buying the specialized QHIN. If the idea is to set up a QHIN fabric then, they should all be performing at least whatever the minimum set of required transactions are. So, I would opt for a 7A. The clarification I've been looking for but haven't seen in writing is sort of the

comment that someone started with that ONC envisions a relatively small number of QHINs. I keep hearing that in sort of oral discussion but I never see that vision articulated in writing. And I think it would be terribly helpful for folks looking at this to understand that that really is the vision and some sense of what a small number means.

Arien Malec - Change Healthcare - Co-Chair

Super useful. So, I will relent unless there is something who feels equally strongly just in the interest of consensus on this topic. But I do see many hands raised. So, we got Denise, David, Mark. John, are you putting your hand down?

John Kansky - Indiana Health Information Exchange - Co-Chair

Just to make the observation that if we opted for 7A, it's essentially no recommendation at all but let's hear from the other commenters.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. We certainly should note that we discussed it in detail and then, also note the discussion of specialized participants, which I do think is a new recommendation. All right. Denise then, David then, Mark.

Denise Webb - Individual - Member

I just wanted to say that I align more with John and Sheryl's thinking on this. I could see an HIN being specialized to handle public health transactions that could come across from another QHIN into that HIN's QHIN down to them to do something with it. I don't know. I just don't see a QHIN. I think they need to be more general purpose, the QHINs.

Arien Malec - Change Healthcare - Co-Chair

I am hearing this loud and clear. David.

David McCallie, Jr. - Individual - Public Member

Well, you can hear it loud and clear but I'm a strong decenter.

Arien Malec - Change Healthcare - Co-Chair

You and me.

David McCallie, Jr. - Individual - Public Member

I think it will cripple the appeal of becoming a QHIN. It will diminish the likelihood of any success for TEF by making it much too hard and too expensive to participate. It will constrain everyone to the lowest common denominator network services. And in the long run, potentially make TEF irrelevant. So, I feel strongly about it. I think we have to respect the group process but I think this is one where a dissenting opinion is maybe warranted to be just —

Arien Malec - Change Healthcare - Co-Chair

There was a strong minority or a strong but small minority that felt very strongly about the alternate –

Denise Webb - Individual - Member

Arien, I think some of us could be persuaded in a different direction. I think as Sheryl had said, it's hard to envision. If we could see a picture, I do better with pictures than things because maybe I'm just not seeing what you're saying. And if I saw it, I might be able to analyze it and contemplate a different thought.

Arien Malec - Change Healthcare - Co-Chair

Sure. I could do a diagram and describe the public health use case at least as I see it.

<u>David McCallie, Jr. - Individual - Public Member</u>

And the health record bank use case as well. I think leveraging the IAS permitted purpose, it's not the same as an electronic health record. It would have different functional capabilities and usefulness and requirements and cost structures and expecting every QHIN to become good at being a health record bank is just not going to happen. So, that means we won't have such things because the QHINs won't all be able to do it.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

All right. Mark. We're getting bigger. Mark, Laura, Carolyn, and Noam again.

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

So, I just want to throw this out as more of a conceptual question, not an opinion. But I am drawn more to Recommendation 7A as it says to serve all of the defined exchange modalities and purposes. That is my instinctive response. But my question is if this were modular, is there a possibility that none of the QHINs serve a particular modality or purpose? Conceptually, what is the structure to make sure that, collectively, all of the defined exchange modalities and purposes remain served? For purposes of where we're heading, that may not need answering but that's in my mind.

Arien Malec - Change Healthcare - Co-Chair

Yeah. It's a good point, which is if I'm a participant, do I need to make sure that I'm in a position of having to contract with multiple QHINs in order to address all of the exchange modalities. Let's go to Laura.

Laura Conn - Centers for Disease Control and Prevention - Member

Good afternoon. I just wanted to echo Denise's suggestion around a visual and also volunteer, Arien, to help you with that for the public health piece. I think you're onto something. I'm having a hard time constructing if it's at the HIN level or the QHIN or the participant member. And I think if we lay it down, the need is there. It's just a matter of trying to figure out where the appropriate level is for that kind of functionality to live. So, I'm happy to help with that.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Cool. I appreciate it. Carolyn.

Carolyn Petersen - Individual - Member

Hi, there. Yeah. I think this is complicated and I have kind of feelings going in both directions at once. But I think I'm coming down on the side of having the specialized QHINs because it's probably the best opportunity for engagement with structures like patient powered research networks and other things such that scientists and patient informaticians are doing. It seems that would be, given all of the other challenges that exist if we go in a system without the specialized ones that might not wind up with any place at all because everybody is already so burdened with trying to deal with all of the rest of it that they won't touch anything that's even marginally different or new or not system centric.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yes. Noam.

Noam Arzt - HLN Consulting, LLC - Public Member

Yeah, just real quick since the public health example invoked my name in the midst of it. The more I'm listening to the conversation, the more I'm actually still leaning towards 7A. If you think of the QHIN fabric as, essentially, a multilane highway, a particular use case, to use that language, only needs to travel in one of those lanes if each lane is a modality or different ways to look at it. While a public health example or use case might be national, it's not clear to me that it has to be its own QHIN. It should use the QHIN fabric, in other words, one lane of that if that's all it needs, to be able to implement its use case. That's the whole point of this I thought. So, I don't see what we gain by having a specialized QHIN.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. So, using the QHIN fabric means having to contract with a QHIN merely for the purpose of exposing and message delivery interface for public health.

Noam Arzt - HLN Consulting, LLC - Public Member

That's right. That's the way infrastructure gets built. The whole idea is that everyone isn't stringing their own wires.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

John, unless your hand is raised again, I'm going to propose the following. I will create the mythical diagram with Laura's assistance, maybe David's assistance as well. I think we're settling towards a recommendation to stand with the current draft with some strong minority perspectives in the other direction.

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Yeah, I'm fine to go on. My hand was raised because I couldn't resist adding that something that's outside the scope of the task force but I think is relevant to this question is what will QHINs do to sustain themselves besides transactions on which they cannot profit. And I think it gets back to the question David posed in the very first call, which is what's the incentive to be a QHIN. And so, I think if you allow QHINs to pick and choose, there are two problems. One is that the issue that was raised is if there is only one QHIN in the country that's serving one of the necessary exchange purposes then, anybody that wants to do that exchange purpose has

to contract with that QHIN and the specialized.

And the second problem, the one that's scarier to me is that it's going to distort the economics of how QHINs figure out how to sustain themselves because they'll be QHINs that will choose to do the things that support their business model and not to do anything that just adds cost.

Arien Malec - Change Healthcare - Co-Chair

Okay. I think we've got at least a path forward and the sense of the group is 7A with a minority recommendation for 7B. And some folks are declining themselves as persuadable via diagrams. Let's go to the fun IAS discussion.

Mark Savage - UCSF Center for Digital Health Innovation - Public Member Arien.

Arien Malec - Change Healthcare - Co-Chair

Yeah.

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

Just an agenda point for wherever you want to track it, in reading the draft letter sent out, noted 2B on electronic health information and thought maybe there was more left to discuss on that than I saw in the wording. So, whenever you want to put it in just —

<u> Arien Malec - Change Healthcare - Co-Chair</u>

As I said, I'd like to go through the document first and then, make sure that we circle back and get any clarification or additional discussion of the revisions. Okay. Let's go back to IAS. And the issue on the table is captured in an Alternative Recommendations 8A and 8B. So, 8A says IAS should address shared care planning and patient reported data, including PGHD and patient reported outcomes, remote monitoring, PMI, as well as the right for correction. And 8B says while we support the expansion of IAS, we should start the TEFCA IAS use cases with the use cases that have the broadest area of support and then, work to expand additional use cases, including amendments, shared care planning, data donation for research.

So, maybe this split here is maybe hey, if we don't capture this territory now, we never will versus let's not drive towards a set of activities that we just don't know how to do at scale. Instead, let's scale the activities that we do relative to the right to access and then, work to expand over time. And with that, I will open it up for the inevitable set of hands being raised. And there goes David.

David McCallie, Jr. - Individual - Public Member

Yeah. I would use this as an example of how I'm going to meld this topic and the previous question because I think they're quite related. The ability to expand into some of these much more demanding and potentially valuable to patients and to providers use cases like shared care planning is one of the reasons why I think the network should be structured to allow for emergent abilities to join the network without requiring those emergent capabilities to have to do everything else that the network is already good at in order to join the network. So, I

fully support the goals of 7B or 8B, whatever it is here. But I think the way you do that is to make it easy for emergent players who are addressing and solving those goals to join the network as a participant, as a QHIN without necessarily burdening them with the need to do everything else.

That's kind of how you get there, I think. That's where innovation can enter at the edges. Now, everyone has to meet minimums. I'm not suggesting that you can get away for free. Everybody has to meet a minimum. But if you want to put together an entity that can manage the complexity of a complex shared smart app care plan, those things are beginning to emerge in the world. Make it easy for them to join the network without saying you also have to be a QHIN in every other way.

Arien Malec - Change Healthcare - Co-Chair

So, a vote for 8B. I don't see any other -

David McCallie, Jr. - Individual - Public Member

For healthcare in a sense, yeah. I'm saying it doesn't matter what the vote is. I'm happy with capturing both — I'm not voting for one or the other. But I'm saying if you want to achieve 8B, allowing QHINs to be specialized may be fast track way to get there, faster track way to get there.

Arien Malec - Change Healthcare - Co-Chair

It's 8A you mean.

<u>David McCallie, Jr. - Individual - Public Member</u>

Yeah, sorry.

Arien Malec - Change Healthcare - Co-Chair

Nobody else has their hand raised.

Noam Arzt - HLN Consulting, LLC - Public Member

Just note there are some opinions recorded in the comments there on the right.

Arien Malec - Change Healthcare - Co-Chair

Understood.

Noam Arzt - HLN Consulting, LLC - Public Member

Some of us [inaudible] [00:43:37] already. That's all.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Understood.

Carolyn Petersen - Individual - Member

Yeah. Just to clarify that my opinion was for 8A.

Arien Malec - Change Healthcare - Co-Chair

Okay. So, this may be one where maybe we could take a formal vote. But I do believe there is a majority for 8B but a strong perspective on 8A. And that should be the way that we address this. If people feel like there's a hidden groundswell for – just to be clear, my vote would be for 8B. And, again, not to undermine or not support all of the additional use cases but I'm an incrementalist and a pragmatist by nature. Mark, I know you have your hand raised.

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

Are you calling on me?

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Yeah.

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

Could you sketch a little bit — I sort of think I've heard a split rather than majority, strong minority. I'm not in the school to think that that may really matter. It seems to me like we just ought to put these both out there as sort of reflective of the two strong positions from the group. If indeed it is a majority then, it's fair to state that, too. I just didn't quite have that sense from the call.

Arien Malec - Change Healthcare - Co-Chair

Yeah. I think of — and maybe I'm wrong and maybe I'm just exposing my bias but when I eventually count the declared votes, I get a higher number for 8B. And I'm making the perhaps false assumption on small numbers that there's a majority opinion for 8B. Again, you're right in that it's so evenly split that it's probably not appropriate to declare a majority/minority. And we should just put both opinions out there. I'm okay with that. Denise.

Denise Webb - Individual - Member

Yes. I believe in an earlier version of this, and I don't see my comment in there, but I didn't quite understand why these two recommendations couldn't be combined and worded in a way that we could all get on board because while I'm an incrementalist as well, I also like to push the envelope at the same time. And so, I think I was preferring 8A with some nuances of B being included in the wording of A is what I believe my original opinion was.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

And I would completely support that. Maybe I'd ask Mark to say why he – I don't see Mark as supporting that. So, just to be firmly word, 8A would say you cannot get started with IAS until you handle access, records correction, data donation, and PGHT. So, you will not get started until you handle all four of those use cases. And 8B says we believe the end goal should be all four of those use cases but we support getting started with access while we work out the approaches for record correction, data donation, and PGHD. And Mark, I'm going to ask you to see if you agree with that perspective or do you agree more with Denise's let's declare our goal and then, acknowledge that there's an incremental approach to get there.

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

I think probably announce the goal, the functional expectation there will be some working out of how you get there. I think it really matters between 8A and 8B how you're announcing what the functional expectation is. So, 8B says limited IAS is okay. And I think in practice, what we've seen is that everything else will be on the slow road going forward.

Arien Malec - Change Healthcare - Co-Chair

Just to be really clear -

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

And 8A is not the slow road.

Arien Malec - Change Healthcare - Co-Chair

So, you would support, basically, we do not get started with IAS until we can also support the other three requirements.

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

No, I haven't actually said that on this — I haven't tried to define a marker on here. The conversation for me has been that as defined, it's way too small. I do think these are three basic use cases that ought to be in place pretty quickly. I haven't said it here but I've said it in a discussion about APIs, for example, that I think we are all on sort of a one or two year on ramp with the ONC and CMS rules that's probably going to play out here on this particular recommendation as well. And I see that more on the implementation side, not on the goal side. I'm not sure I articulated that very clearly.

Arien Malec - Change Healthcare - Co-Chair

So, again, I'm trying to poke a little bit because -

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

You're trying to switch it to the cup half empty versus full.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

No, I'm not, actually. So, I think we either as a task force align around a single recommendation that says we believe that TEFCA should address all of the described use cases and suggest starting with those use cases, including IAS that are the most mature. Or we say, basically, don't get started until we can address all of the use cases. And to me, it is that clear. That to me is the key discussion. And maybe we didn't put enough language in 8B. And I think that's Denise's suggestion is can we find a good compromise position where we say we believe very strongly that TEFCA should address all of these uses cases. At the same time, we support getting started.

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

I'll just add as a practical matter, how we define this is the motivator for what people design

to. And I think that what people can get started with will be shaped by what ONC says the expectation is. And I think that's really important.

David McCallie, Jr. - Individual - Public Member

But just to the contrary side, remember that TEFCA is voluntary. Most of these use cases are being addressed in local areas with a variety of tools. Most of the patient generated data is coming in through interfaces to vendors' products from the major device manufacturers' companies today. It works. They have little reason to change. If you saddle TEFCA with the requirement that it somehow has to handle all of those things before it can get started, it puts a further barrier on adopting this voluntary framework in the first place. People are solving these problems today. They're going to have little incentive to change if TEFCA doesn't force them to change.

That doesn't require that they participate in these things. So, we put a lot of energy into bootstrapping, to creating incentives. I think these are laudable goals. But if they become nonstarters then, you may get a non-starting TEFCA, particularly if you require every QHIN to do every use case.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Again, I think this is getting framed around do we do the more expansive use cases or we don't. And I'm trying to be very precise in framing do we hold until we can do all four or do we allow getting started with access while we work on the other three. And I do think there is alignment around setting a high bar in terms of goal and tasking ONC and the RCE and the QHINs to urgently address these other use cases with potentially some additional requirements in a TEFCA 4. So, can we get agreement on that or can we not get agreement on that?

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

Can you restate agreement on what?

Arien Malec - Change Healthcare - Co-Chair

Yeah. So, an amended 8B would say the task force recommends that ONC define the individual engagement goals for the TEFCA to include, among others, access, record correction, and amendments, data donation, and PGHD PROs. And we acknowledge that the system is more ready for individual access. We believe it's appropriate to get started with individual access and that ONC and the RCE need to establish some level of urgency around expanding the use cases. That would be a revised 8B. And the 8A would, basically, say we believe we should define QHIN requirements to be all four of those and the implication being if you can't address all four of them, you aren't a QHIN.

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

Personally, I continue to like 8A because it says that it's beyond the two defined purposes in the current draft of the IAS. It gives a particular example of the HIPAA right. And I haven't really poked at this but there are words under the additional use cases, it says may include. May wouldn't be my choice of words but I haven't really looked at that. And I think that gives you the implementation flexibility that maybe gives the implementation flexibility that you're

looking for.

Arien Malec - Change Healthcare - Co-Chair

Okay. Why don't I – it sounds like we're closer than maybe we think we are. And this may just be a discussion of perspective or emphasis. Why don't I take a crack at a potential consensus recommendation and see if we can get consensus opinion out of the task force? Because it sounds to me like, Mark, you don't – when push comes to shove, you would agree that expanded access to individual access is a good thing. Your concern is that we will lose the momentum on the other use cases.

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

At the least. We're also doing these other things more to some degree already, too. So, it's not like it can't be done. There are some more things that can be done.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

You have a couple of other hands raised.

Arien Malec - Change Healthcare - Co-Chair

Okay. Noam and Carolyn.

Noam Arzt - HLN Consulting, LLC - Public Member

Yeah, just real quick. I continue to support 8B under the notion of floor versus ceiling. I think TEFCA ought to define a reasonable floor and not imply at all that that's the feeling. And it feels like 8A is trying to raise that floor just a bit too much.

Arien Malec - Change Healthcare - Co-Chair

Thank you. And Carolyn.

Carolyn Petersen - Individual - Member

Just thinking back to the language that you shared a couple of minutes ago, Arien, you mentioned ONC should establish some level of urgency. Well, some level of urgency is meaningless. It could be two years. It could be five years. It could be ten years. It could be whenever the market gets ready. I think we need to be more specific than that if we're going to try to get support for the people who are on the side of 8A at this point.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Okay. Again, we'll put together a draft and see if we can get to some level of agreement or not. Okay. Let us move on to our next topic. This is just an editing issue. Let's go on to the not at all controversial at all discussion relative to public health response. And I think we generally have task force agreement on the surveillance use cases not requiring any kind of query based response. And then, the dispute at issue is whether there is an exception for public health use cases that are TEFCA mediated that are patient centered and where there is strong utility in providing query based access.

The specific example being the immunization registry. I know Noam will speak for himself but one of the positions on the table is this is valuable data that improves care, care coordination, and individual involvement in their own care. All of us can remember if we have kids just the pain of keeping your immunizations up to date. And then, the contrary position is this amounts to an unfunded mandate on public health agencies where we have information blocking requirements on providers. And so, requiring access of providers is appropriate. But requiring access on organizations that to date haven't had to do this and aren't funded to do this means that we're actually undermining pubic health participation in the TEFCA. So, with that as the two opposed positions, I will open it up for discussion. And hearing no discussion – okay, Laura, you're on.

Laura Conn - Centers for Disease Control and Prevention - Member

I'll start. I guess what I heard before from other discussions was when applicable law and other things were layered on top of these requirements then, it doesn't become an unfunded – well, I guess it still could be an unfunded mandate for those that don't have applicable law but it protects those that do have applicable law from not being considered information blocking.

Arien Malec - Change Healthcare - Co-Chair

Right. Just to be clear, information does not apply to public health agencies. It's not one of the published actors that information blocking would apply to.

Noam Arzt - HLN Consulting, LLC - Public Member

That's not true, Arien. I don't know why you say that. The proposed rule didn't exclude public health and the definitions of health information exchange certainly could include public health. So, I'm not sure why you're saying that.

Arien Malec - Change Healthcare - Co-Chair

Thank you. That is an absolutely fair point. So, public health as a participant is not a covered entity relative – I'm sorry, I shouldn't use that word. A public health agency as an end point is not a provider under the definition of provider. And so, therefore, it is not subject to information blocking requirements. But to the extent that public health engages in health information exchange or runs and operates the health information network could be subject to information blocking under those requirements. Thank you for that clarification.

John Kansky - Indiana Health Information Exchange - Co-Chair

And this is John. I can't resist saying knowing that the ONC is listening is that's a great example of a flashback to information blocking work group discussions.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

Yeah. Okay. So, David.

David McCallie, Jr. - Individual - Public Member

Yeah. I just want to point out that it's somewhat inconsistent to demand that QHINs do certain things regardless of the complexity and cost but then turn around and say public health is poorly funded so they don't have to do certain things. I think that if you allow for that kind of

flexibility, it's got to be deferred to something like the RCE and stakeholders and flexibility to make decisions that they think are consistent with the broad policy goals rather than hard coding into the structure of TEFCA these special carve outs who just happen to have a strong voice on a committee. It's inconsistent.

Arien Malec - Change Healthcare - Co-Chair

And to use, I think, a John Kansky analogy, FQHCs are very clearly providers and very clearly subject to information blocking requirements and also tend not to be well funded as well. So, this is not the first unwell funded mandate that we have. John, you had your hand raised or was that a —

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Sorry, I'll take it down. It was leftover.

David McCallie, Jr. - Individual - Public Member

Arien, let me make one other qualifying point just because I fully support the notion that public health should have this carve out for that very reason. I'm just saying we need to be consistent. If you're going to allow a decision like that to be made for purposes of bootstrapping the network then, you need to support that elsewhere as well.

<u>Arien Malec - Change Healthcare - Co-Chair</u>

So, here is what I would then propose. I would propose that we keep the recommendation with respect to syndromic surveillance use cases, not publish a recommendation with respect to immunization registries and then, put that in the discussion topics in the some task force members supported X, some task force members supported Y perspective and not make a formal recommendation around it. Noam.

Noam Arzt - HLN Consulting, LLC - Public Member

There may be another way to sidestep this. I'm still a little fuzzy on this notion of establishing a direct relationship. Do I have that term right? I don't have the document in front of me.

Arien Malec - Change Healthcare - Co-Chair

You do. There is a clarification that we're seeking from ONC with respect to the term direct relationship because ONC, I think, uses the term inconsistently in the MRTCs. And so, I think the exception that you're looking for or the sidestep that you're looking for actually wasn't intended by ONC.

Noam Arzt - HLN Consulting, LLC - Public Member

Okay. I was assuming that a direct relationship only exists if both parties in the relationship agree to it.

Arien Malec - Change Healthcare - Co-Chair

Yeah. I do not believe that was ONC's intent and that ONC's intent was really about the direct relationship between the participant member and individual with respect to QHIN based

exchange or mediated exchange. That is the requester as opposed to the responder.

[Crosstalk]

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Noam's assertion that both parties would know there was a relationship isn't mutually exclusive with what you said, Arien.

Arien Malec - Change Healthcare - Co-Chair

Yeah.

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Sorry, not trying to take us down a rabbit hole.

Arien Malec - Change Healthcare - Co-Chair

No, that's okay. I am going to refrain from offering opinion and just go back to this proffer on the table to request a clear carve out for public health, particularly for surveillance cases where, by definition, we're looking for mostly anonymized and aggregated data and not creating an individual centric record. And then, note in the discussion that the task force had a good conversation around immunization registries that they were not able to resolve.

Noam Arzt - HLN Consulting, LLC - Public Member

Well, the first part of it, Arien, is sort of **[inaudible] [01:07:48]**. If the data that you're talking about isn't even something that's returnable to a patient because you don't know which patient it is, why bother making a recommendation around it if I understood what you're saying properly.

Arien Malec - Change Healthcare - Co-Chair

Well, I could, and I don't know all of the details of that public health record, but I could have a patient identifier in a syndromic surveillance report. I could have, for example, medication claims data supplied to CDC for broadscale flu surveillance. There might be a possibility that they could go retrieve the actual patient but that would be a silly case to do.

Noam Arzt - HLN Consulting, LLC - Public Member

Right. But the more dangerous cases say electronic lab reporting where public health agency gets an electronic lab report that is patient specific, patient identified though usually horribly identified.

<u> Arien Malec - Change Healthcare - Co-Chair</u>

Exactly, right. Theoretically, the public health agency could respond but, practically, it's a dumb idea. And I think we all agree on that.

Noam Arzt - HLN Consulting, LLC - Public Member

That's right. So, this is setting us up for a public health agency not to be able to refuse that

dumb idea.

Arien Malec - Change Healthcare - Co-Chair

Right. And so, I think we agree on the recommendation.

<u>David McCallie, Jr. - Individual - Public Member</u>

So, I'm confused. Do we agree on if a public health entity has clinically relevant information about a patient that is allowed for disclosure under the law such as an immunization record? Are we saying, ideally, that should be served up over TEFCA but because public health is poor, we won't require it of them, even though we'll let them query for it?

Arien Malec - Change Healthcare - Co-Chair

No. David, the proposal on the table is to make a specific recommendation with respect to surveillance cases where public health may get EHI but should not respond –

David McCallie, Jr. - Individual - Public Member

I'll take that one.

Arien Malec - Change Healthcare - Co-Chair

Right. And then, I think we're saying with respect to the abhorrent use case of immunization registries to not have a recommendation but clearly articulate in the findings and discussions that we had a vigorous discussion on this point.

David McCallie, Jr. - Individual - Public Member

But I thought Noam's original point, and I don't want to put words in your mouth, Noam, but before we got into the sidetrack of surveillance data, which I think is a sidetrack, the concern was even though it would be nice to have reciprocal bidirectional public health immunization registry participation in the QHIN, it's so costly it would be prohibitive. And, therefore, we should not require it. Wasn't that the original point and we all were trying to decide whether we would say too bad, you've got to pull yourself up and support bidirectional QHIN or we'd say we think you should carve out a special exemption for public health because of how important it is and because of the funding challenges?

Arien Malec - Change Healthcare - Co-Chair

No, David. So, the original discussion was absent any public health carve out, any public health agency that received EHI would be required to respond if they were a participant or participant member. And so, the discussion started with well, that seems like a bad idea. And then, the specific case of an immunization registry came out where it kind of does make sense to respond that then, spurred the particular discussion.

David McCallie, Jr. - Individual - Public Member

Well, this is why we need use cases because each immunization record is very different from surveillance. It's very different from reportable diseases. It's very different from a whole bunch of other things. And you can't just put a blanket statement of you're in or you're out.

Arien Malec - Change Healthcare - Co-Chair

And that's what I think we're recommending is we are focusing our recommendation on the surveillance use cases where a public health agency may receive EHI and may be a participant or participant member but, nonetheless, should not be expected to respond. Not being silent on the immunization discussion in the recommendation section and instead deferring to our comments to give ONC the flavor of discussion.

Noam Arzt - HLN Consulting, LLC - Public Member

If I would just make one other quick point. I simply don't accept the public health FQHC parallel. For better or worse, an FQHC can choose to be an FQHC or close up shop and close its doors. A public health agency cannot simply choose to close its doors. So, to me, there is a difference.

John Kansky - Indiana Health Information Exchange - Co-Chair

Can't a public health agency choose not to participate in TEFCA?

David McCallie, Jr. - Individual - Public Member

Right.

Noam Arzt - HLN Consulting, LLC - Public Member

It can choose not to participate in TEFCA. I'm sure it can.

<u>David McCallie, Jr. - Individual - Public Member</u>

Arien, I want to maybe make an analogous thing about the EHI –

Arien Malec - Change Healthcare - Co-Chair

I, unfortunately, need to drop and reconnect via mobile and transfer moderating duties over to John.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

I'm here.

Arien Malec - Change Healthcare - Co-Chair

All right. Thank you. I'm going to drop and then, you can bring this to close and then, I'll join via phone and I'll be so satisfied that you did a much better job than I did.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

I hardly think so.

Arien Malec - Change Healthcare - Co-Chair

Thank you.

John Kansky - Indiana Health Information Exchange - Co-Chair

Noting that we're four minutes from public comment, David, did you have a parting shot on that one?

David McCallie, Jr. - Individual - Public Member

Well, yeah. The fact that we were willing to make a specific recommendation around public health EHI and carve out a subset of the data that's not required to be covered. Shouldn't that logic apply to all of the other use cases? Because there are a lot of EHI in the various proposed participants that goes way beyond what people are exchanging today because EHI is cast so broadly, which is —

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah. I don't disagree with you. Part of me wants to say that if we had a lot more different perspectives and 40 more calls on this task force, we could identify a lot of these cases that are very practical because many constituencies are going to face due or undue burdens if they choose to participate in TEFCA. Noam and his depth of knowledge in public health has kind of spurred a big part of this discussion. So, sorry, too many words. The way I feel as an HIE being faced with the decision to figure out how and where to jump in TEFCA and having to figure out how to do a bunch of new exchange purposes and modalities versus if I worked at a hospital or an FQHC or a public health agency, I'm trying to agree with you. I think there are many, many examples like this. We just happened to have called this one out.

David McCallie, Jr. - Individual - Public Member

And I will say that the recommendation we discussed a couple of days ago or meetings ago about focusing on USCDI as a definition of what should be exchanged rather than the definition of EHI is valuable in this context. Because if you can get an agreement on a standardized set of data that everyone understands its relevance to care and define that as what you must exchange if you're participating if you have it then, you don't have to go through in the reverse direction of carving out things that you don't have to exchange. So, let's define what you should exchange, do it in terms of USCDI and then, don't worry about carving out every weird edge case of data that shouldn't be exchanged or needn't be exchanged.

John Kansky - Indiana Health Information Exchange - Co-Chair

Right. And this is one of the conundrums that I'm getting into personally. Maybe some of you feel it as well is that some of my opinions about Recommendation A, B, or C change if I know that Recommendation F, G, or H are accepted. So, you make a good point.

<u>David McCallie, Jr. - Individual - Public Member</u>

Yeah.

John Kansky - Indiana Health Information Exchange - Co-Chair

What do you guys think about going to public comment a minute early before diving into the next thing?

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

You're the chair. Call it.

John Kansky - Indiana Health Information Exchange - Co-Chair

Well, yeah, I am. Let's go to public comment, please.

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

Okay. Operator, can you open the line for public comments?

Operator

If you would like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

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

Did we have anybody dial in?

Operator

Not at this time.

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

Thank you. John.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thanks. If we could go back to meaningful choice and I believe Recommendation 11. Okay. So, this one, if you can get the whole thing on the screen, is that possible? Maybe just the recommendation. Okay. There you go. Thank you. It's small now. So, the question is I don't think it's an issue from our recommendation from the task force perspective. But ONC has posed the question of how is this different than what's already proposed. And then, noting that Noam has a comment as well. So, let me give my take on this and then, call for any comments from the task force.

I think all we're trying to say here is we're recommending that when meaningful choice is offered as an individual right, if I'm not misusing the word right, that it's offered in this way that's consistent with these recommendations from the HIT Privacy Committee 2010, which are kind of best practice recommendations in terms of how one offers meaningful choice to individuals or things like meaningful choice to individuals. So, in ONC's question of how is this different than what's already proposed, I guess, I don't feel strongly that it is different. It's also not harmful to make this recommendation. And I, personally, am not in a position to critique where the six bullets are – let me try that sentence over again.

I would defend our recommendation as saying I'm not sure it's different ONC but since your

description of how meaningful choice would be offered didn't include these six bullets specifically, we're just suggesting you take those into account on meaningful choice. And I successfully provoke the raised hands. Yes, ma'am.

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

If it's okay for me to interject, what I'm trying to push you on a little bit here is to just point you to the definition of meaningful choice, which the first thing it says is made with advanced knowledge, which I think is the first bullet. Second, it says not used as a condition for receiving medical treatment or discriminatory, which I think is the second bullet. And third is revocable on a prospective basis, which I think is the sixth bullet, actually. So, I just wanted to make sure you were —

John Kansky - Indiana Health Information Exchange - Co-Chair

No, I appreciate that. Thank you. Mark, you have your hand up.

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

In the interest of time, I'll say the short thing. I think the definition in TEFCA of meaningful choice is sort of black and white, binary. Whereas the bullets describe a sort of sliding scale that the more complicated things are, the more the opportunity for discussion. And that was the core of the discussion by the Tiger team back in 2010 is to recognize it. It has to be appropriate to the issue. And I think that's what comes out in the bullets from the Tiger team's report. And I do think it's important.

John Kansky - Indiana Health Information Exchange - Co-Chair

And, Mark, is that specifically called out in Bullet 4?

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

I'm having difficult reading on my screen. Let me move over to the letter. Yes, in part.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

So, what you're suggesting is that with Zoe's clarification, what our recommendation is really something along the lines of hey, ONC, great job on incorporating Bullets 1, 2, and 6. We suggest you consider especially 4 as well.

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

Let me just –

John Kansky - Indiana Health Information Exchange - Co-Chair

I'm not sure that's what you said but I'm trying to get closer.

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

There may be ways to highlight among these six bullets some that are more significant than others. I can try to help on doing –

John Kansky - Indiana Health Information Exchange - Co-Chair

Yeah. I was going to say we would need to impose on you or others to provide that nuance.

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

I will commence trying to do so.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thanks. And so, if we could capture that in the notes, we can consider the nuance that Mark comes back with. But until further notice, the recommendation kind of stands until we have a different version. Okay. Can we move – is there anything else? I have David McCallie, sorry. David, you have your hand raised.

David McCallie, Jr. - Individual - Public Member

Oh, it was from earlier. I think the language is basically we endorse TEFCA's definition of meaningful choice and would suggest in addition, consider the points that we felt might have been left out. So, it's not looking at it as a change as much as it is an enhancement.

John Kansky - Indiana Health Information Exchange - Co-Chair

Yes, thank you.

David McCallie, Jr. - Individual - Public Member

My real concern is coming later. So, I thought we were going to talk about the other stuff so I'll wait and see. You go next and come back.

John Kansky - Indiana Health Information Exchange - Co-Chair

If you mean Alternative Recommendation 12A and B, that's where I was going next. Is that okay?

<u>David McCallie, Jr. - Individual - Public Member</u>

Yeah.

<u> John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Okay. So, let me catch up my brain here. Alternative 12A, whenever it says alternative, I think that means we have an either/or proposition to settle on. And 12A says that ONC and the MRTCs should not allow for – oh, yeah. This is the right to be forgotten versus as a practical matter, it's okay to permit use and disclosure of previously exchanged EHI. So, we either have to pick one or the other or we have to settle whether we are split or whether there is a strong minority view. Now that I have that in my head clearly, let me make sure that I bring everybody else along. Recommendation 12A says no, it's not okay for previously disclosed EHI to be used and disclosed, which is what the draft says.

I'm sorry, the draft says that is okay. And then, 12B says permitting the use and disclosure of individuals previously exchanged EHI is okay and practical in light of how hard it would be to

try and implement it alternatively. And so, 12B, I believe, is consistent with the current draft. And 12A recommends a change. I will call attention to a question that I had and noted in the comments when I was thinking about this. And this is a question to the ONC. Is TEF 2 clear on whether the uses of previously disclosed EHI are limited to exchange purposes or is any use permitted under 2.2.2 okay? That was something I was not clear on and apologies if I should know that by now.

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

No, John, it's a really good nuance that you pointed out.

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Please, thank you.

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

The language does say that it may be continued to be used or disclosed for an exchange purpose. So, it does not say for purposes under the framework agreements, which would maybe be that broader permitted future use.

<u>John Kansky - Indiana Health Information Exchange - Co-Chair</u>

Our favorite example might be research that if under 2.2.2 you were able to use the EHI for research and the person exercises their meaningful choice then, that's now taken off the table. I'm not sure why that would be the intent. So, if I was making a Kansky recommendation, I would say wow, that makes it extra confusing. If we're going to not recommend a change saying no, you can't use it, I would say don't change the things that you can use and disclose it for from anything under 2.2.2 to only permitted exchange purposes. Okay. I have successfully provoked some hands. David and then, Mark.

<u>David McCallie, Jr. - Individual - Public Member</u>

Yeah. I think the practical limit here is that QHINs — well, TEF is about actively exchanging data. And we all agree that a consumer, a patient, should be given a choice as to whether they want their data to be actively exchanged over the TEF. It seems very difficult to see how you can go beyond that. And it makes sense that you can stop the exchange. But if legal exchange has occurred in the past with your permission and downstream recipients have obtained data through the TEF legally and with your permission, the TEF has no authority over what happens after that. It's only about exchange. It's not about what people do afterwards or what they do before. So, I don't see that there's a practical way to have 12B, I guess. And I don't think there's a legal way in the way the law is written in a voluntary network.

John Kansky - Indiana Health Information Exchange - Co-Chair

Thank you. With my chair hat off, I think I agree with your comment. I accidently have run us up against the bottom of the hour so let's take Mark's comment and then, wrap up.

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

So, I'll limit it to just an observation for future consideration, which is the definition of meaningful choice talks about it being revocable on a prospective basis. And in the Recommendation 12B that doesn't look like revocable on a prospective basis. So, I think we have to figure out – I just want to broaden the consideration to definition of meaningful choice and what that means.

David McCallie, Jr. - Individual - Public Member

And remember that that was a recommendation from the Tiger team. It has no force of regulatory law.

John Kansky - Indiana Health Information Exchange - Co-Chair

I want to make sure I understood that point.

David McCallie, Jr. - Individual - Public Member

It's a policy goal.

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

So, if an individual thinks that they've revoked something on a perspective basis, they don't think that somebody is going to continue to use and disclose.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. I understand what you're saying.

David McCallie, Jr. - Individual - Public Member

And I would counter and say it's perspective with respect to the network that you're choosing to participate in. It's not retrospective with what may have already happened. So, the tension is between it's prospective with respect to what. And I'm saying it's prospective with respect t exchange. Mark is saying it's prospective with respect to downstream use. And it's a hugely important discussion. But if the right to be forgotten is not in scope with TEF, it just seems to me it doesn't have the force of law to make it so.

John Kansky - Indiana Health Information Exchange - Co-Chair

So, in the interest of time, we're going to obviously have to pick back up on this one next time. If perhaps ONC could – I don't know if it's appropriate to suggest that in the comments that we send out with the next draft that we capture if anybody wants to vote on – yeah, I think it might be worth people weighing in to see if we have general support of an A or a B.

Denise Webb - Individual - Member

And John, it would be great if we could get the draft sooner than an hour before the meeting.

John Kansky - Indiana Health Information Exchange - Co-Chair

Yes, I acknowledge that. And we're doing the best we can.

Denise Webb - Individual - Member

I know you are. I'm just saying we're closing in on time, I think, because don't we have to be finished by July 11?

John Kansky - Indiana Health Information Exchange - Co-Chair

Correct. And we have some additional -

Denise Webb - Individual - Member

Yeah. We have a bit of work left to do.

John Kansky - Indiana Health Information Exchange - Co-Chair

And I completely understand and would encourage the task force to stay with us and stay engaged and contribute. We have two calls next week and then, two the week after. And then, we have five more calls. I feel like we should be able to get there but you're making a good point.

Noam Arzt - HLN Consulting, LLC - Public Member

I don't see two the week after.

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

I think we have a few more calls before the final recommendations. We have two next week and then, we have one on the 9th, which would be the final one before we have to present on the 11th. And maybe this is a question that we should pose before we all drop off. If people think that we need more time, we could either try squeezing in more calls or we could potentially extend some of the remaining calls we have.

John Kansky - Indiana Health Information Exchange - Co-Chair

I misspoke. It's three remaining calls, not five.

Noam Arzt - HLN Consulting, LLC - Public Member

Why don't we cross that after maybe the next call?

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

This is Mark. I'm fine with squeezing in more calls beforehand because I will be out of range on July 9th. Not that it's just about me, I like that idea for that reason.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. Lauren, Zoe, anything else before we wrap?

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

Nothing from me.

<u>Zoe Barber - Office of the National Coordinator for Health Information Technology - Staff Lead</u>

I don't have anything.

John Kansky - Indiana Health Information Exchange - Co-Chair

Okay. I apologize for running a little bit long. We will try and turn a draft quickly and get it out for review. Thank you.