Information Blocking (IB) Task Force

Transcript
April 5, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Title
Michael Adcock	Individual	Co-Chair
Andrew Truscott	Accenture	Co-Chair
Cynthia A. Fisher	WaterRev LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil K. Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Steven Lane	Sutter Health	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Sasha TerMaat	Epic	Member
Lauren Thompson	DoD/VA Interagency Program Office	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
Mike Lipinski	Office of the National Coordinator	Staff Lead
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back-up/Support
Morris Landau	Office of the National Coordinator	Back-up/Support
Lauren Wu	Office of the National Coordinator	SME

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

Good morning, Task Force members. We will do our usual role call and then we'll get started. Andy Truscott?

Andrew Truscott – Accenture – Co-Chair

Present.

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

Michael Adcock?

Michael Adcock – Individual – Co-Chair

Here.

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

Steven Lane? 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

Denise Webb?

Denise Webb – Individual – Member

Present.

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

Aaron Miri? Sasha TerMaat? Arien Malec? Valerie Grey?

Valerie Grey – New York eHealth Initiative – Member

Here.

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

Anil Jain?

Anil K. Jain – IBM Watson Health – Member

Here.

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

Cynthia A. Fisher – WaterRev LLC – Member
Present.

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

John Kansky – Indiana Health Information Exchange – Member
Here.

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

Lauren Thompson – DoD/VA Interagency Program Office – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denni McColm? Okay. Andy and Mark, I'll hand it over to you.

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah. I'm working on – the screen is up. Hopefully, you all can see it. But my computer seems to be frozen on this 200%. So, Andy, you want to take it while I try to fix this?

Andrew Truscott – Accenture – Co-Chair
Yeah, thanks. Guys, thanks ever so much for joining us this morning and happy Friday to us all. Mark and I sat down and talked about what we should be looking at today. There were two particular aspects of the electronic health information definition that came out of Work Group 1 which we'd like to discuss with the fuller Task Force. And this is around two data types which we haven't really touched upon before. Mike, can you scroll to the right piece in the screen, please.

Mark Knee – Office of the National Coordinator – Staff Lead
I'm trying. It seems to be frozen so I need to exit out and open it up again. So, I apologize.

Andrew Truscott – Accenture – Co-Chair
Okay. No worries. No worries. Okay. So, guys, I'll outline them. Basically, two types of data which are not called out right now inside the definition of EHI and we wanted to discuss

those as a group and work out whether we think, as a team, that we should be seeking to add those to the definition of EHI.

The first of those is consent and consent status, consent directives, etc. And the second was around access log type information and we can talk about that and how we could define that. But, basically, records of who – either an organization or on an individual level – has accessed patient information and whether that should be included in the definition of EHI as well. And the general principle here is that both of those classes of data are classes that we think should be shared and not subject to blocking and whether we are missing an opportunity here to explicitly include them.

So, Mark has got the screen up now and, Mark, if you can zoom back in to 200% and just scroll to the bottom of this section, please.

Mark Knee – Office of the National Coordinator – Staff Lead
Yeah.

Steven Lane – Sutter Health – Member
Andy? Can I chime in? This is Steven Lane and I apologize for joining in a couple minutes late. So, I think from a clinical perspective that consent is really important clinical information. Well, I don't know about really important. It's important. The fact that consent was obtained, it becomes particularly important – I'm sorry, I'm thinking a little bit in real time. Let me come back to that. Audit trails, I think, should not be included. Let's go there.

Andrew Truscott – Accenture – Co-Chair
Okay. So, we had a long conversation with everyone about this and it's not audit trails. Okay? It's just more who has seen my information. So, it's not what was seen or anything like that. Purely, who has seen it. But we'll come back to that. And John Kansky has his hand raised.

John Kansky – Indiana Health Information Exchange – Member
Just a quick clarification. When we say consent, we mean consent for access or sharing of information, not consent for treatment?

Andrew Truscott – Accenture – Co-Chair
Correct. Or, potentially, it could be consent to treatment as well. It could be any consent status and elsewhere in 21st Century CURES and I would appeal to the sage of sages and oracle of oracles, Mr. Knee, to help us here. There is reference to consent and the principle is that we don't want to be constantly asking patients to give express consent to something when, actually, they've given it already.

Mark Knee – Office of the National Coordinator – Staff Lead
Sorry, are you asking if there is language in CURES or in our proposed rule?

Andrew Truscott – Accenture – Co-Chair

Either/or.

Mark Knee – Office of the National Coordinator – Staff Lead

Well, we talk about consent in the proposed rule in the context of the privacy exception to the information blocking provision. I can't really speak to whether – I'll look it up. I don't know that there's a conversation about consent specifically in CURES and information blocking. But it's a big piece of legislation, I'm sure it's somewhere in there. But I'll look to see about whether it's in info blocking in CURES.

Andrew Truscott – Accenture – Co-Chair

Okay, cool. So, I think that the general point that certainly has come up in discussion is once the patient's given consent, we want that consent to be freely available to those who are providing care so that it's well understood. Steven, have you had time to think through your clinical contextualization?

Steven Lane – Sutter Health – Member

Yeah, thanks. I just don't know how valuable that information is to downstream users. I mean, if you're talking about sharing data back to the patient, the patient should know whether or not they gave consent. I mean, they may be interested in knowing whether or not that was captured and documented, especially if they have a complaint, like you shared with somebody for whom I did not provide consent. But I think as I thought about that some more, whether you're talking about consent to data sharing, whether you're talking about consent for care, it's really most relevant to the organization that obtains the consent. It's like it's a real-time transaction. And whether you're talking about providers sharing with payers or with patients or with subsequent caregivers, it doesn't seem all that relevant. I have a hard time imagining making the argument that it should be part of USCDI, for example.

Andrew Truscott – Accenture – Co-Chair

Okay. Has anybody else got a comment to make on this?

John Kansky – Indiana Health Information Exchange – Member

Andy, it's John Kansky. I may be thinking about this too narrowly, but we can't assume, for example, if a provider requests consent for sharing that patient's data from their organization, that that consent would necessarily apply elsewhere. Right? So, I'm just trying to think through what we're sharing here and what we're accomplishing. Because I can see circumstances where, obviously, a patient would consent to the sharing of their data at Provider A, Provider B, Provider C, but then not consent at Provider D.

Arien Malec – Change Healthcare – Member

So, hold on. As far as I understand the rules, the information blocking exception rules, what they require is that if consent is required, that there be reasonable methods for collecting and offering the consent. You can't say consent is required but then put process boundaries or not tell anybody that consent is required. This is the notion of meaningful consent as articulated by the old, in the past but still great, privacy and security tiger team of the policy

committee.

Andrew Truscott – Accenture – Co-Chair
Were you on that great committee?

Arien Malec – Change Healthcare – Member
I was not on that great committee but I know many people and I admire all of their work. Devin McGraw was probably the most illustrious member of that committee. And the basic requirement here is that if I decide to offer to require affirmative consent, or if I'm in a state that requires affirmative consent, I can't just do that, not tell anybody, and then not share information. I've got to let people know in the appropriate flow of care and care delivery, make sure I've got an appropriate way of collecting that consent, so that I'm able to fairly express the wishes of the patient. That's my understanding of the intent of that language.

Andrew Truscott – Accenture – Co-Chair
And so the issue now, Arien, when you say affirmative consent, you mean an affirmation of consent or dissent?

Arien Malec – Change Healthcare – Member
Yes. This is the so-called, really misleading often, opt-out. But if I'm in a state that requires affirmative consent to share information electronically from, for example, an HIE, which is where some of the mechanics get in here, then I can't just rest on the fact that I'm in a state that requires affirmative consent, the patient hasn't required consent, so I'm not going to share information. I've got to provide appropriate methods in the context of care to explain and collect that consent information.

Andrew Truscott – Accenture – Co-Chair
And would it be reasonable for us to suggest if a patient has consented for information sharing to those individuals who are providing them care, that they don't need to express that consent again at any other point unless they change their mind? And then they have an opportunity to.

Arien Malec – Change Healthcare – Member
Okay. I get the point. Or unless it is explicitly required by state and federal law. But, in general, if the point is the patient should be able to offer the broadest form of consent legally allowed, I think that's completely appropriate. You're trying to avoid the situation where I've got to go collect my consent from Point A, Point B, Point C, Point D, and each of the actors in Point A, Point B, Point C, Point D can rest on the fact that they haven't collected my consent at my facility, which is a real thing. I completely agree with that point.

Cynthia A. Fisher – WaterRev LLC – Member
Could I just ask, from a patient's point of view, isn't this whole point of information blocking to open the pipe so the patient can get care anywhere and have access to their records?

Andrew Truscott – Accenture – Co-Chair

Yes.

Cynthia A. Fisher – WaterRev LLC – Member

So, why don't we just open the pipe and allow the patient to say if they don't want to share it. But why opt out versus opt in? That it's automatic that this data is shared. Because we live in a big country. People go to Alaska on vacation.

Arien Malec – Change Healthcare – Member

You should talk to the states, unfortunately. This is not a federal or HIPAA issue. This is a state-by-state, additional privacy law issue and we're just trying to make sure that in those states that require affirmative consent, that the method for obtaining them actually addresses the concerns that you're raising.

Andrew Truscott – Accenture – Co-Chair

See, I wasn't even going that far. Go on, Cynthia.

Cynthia A. Fisher – WaterRev LLC – Member

I was just going to say that monopolies keep protectionism from regulatory state laws too. So, the question at hand is to say why can't it be an option that this whole process is to open the pipe and that pipe addresses that consent universally state-by-state.

Andrew Truscott – Accenture – Co-Chair

That's what we're getting into, Cynthia. That's what we're getting into. Because if we say that your consent directive counts as EHI and therefore cannot be blocked, then when I go and seek care, my consent should be available. Now, it might be that in a particular state there is also a requirement to gain that affirmative consent again and then that's a state issue. But at least we've encountered this information position that says that information is available. State, you have that available, you can soften your position.

Cynthia A. Fisher – WaterRev LLC – Member

Yes. Or programmatically, it's that HIN or whatever, it's like the patient's default is open pipe. The patient gets to choose here.

Andrew Truscott – Accenture – Co-Chair

The patient choice is made. Go ahead, yeah.

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

We have a few members in the queue with their hands up. John, Steven.

Andrew Truscott – Accenture – Co-Chair

Sorry. My screen's gone blank. Sorry. Sorry, members. We've got four. John Kansky, you're first.

John Kansky – Indiana Health Information Exchange – Member

No worries. So, again, I might be thinking simplistically. The last five minutes of conversation really helps and it makes perfect sense, but if we stick consent in the definition of EHI, then as an implementation matter, the entire country just starts figuring out how to stick consent in everything that they share all the time so that they're not in violation. That seems way less nuanced than what you guys were discussing.

Andrew Truscott – Accenture – Co-Chair

You're right. I think we're discussion some of the outcomes and the functional processes around it but you're absolutely right. Steve?

Steven Lane – Sutter Health – Member

Yeah. I think John said it very well. I think that including consent in the EHI that is shared may or may not be useful right away. It may become more useful over time but it doesn't seem like there's any harm in including it, other than it creates a burden on the EHR and other vendors to capture it and make it transportable. But, again, I do want to echo the earlier point that was made that, oftentimes, patients change providers and they change their perspective with regard to release of their information. Patients will – not regularly, but I hear about it a lot in my privacy role – they change providers specifically so that they can get a fresh start, whether that's for better or for worse, and they don't want their data shared. I like the idea that we will be consent in and only opt out by exception but that's not what we're being asked about. We're being asked simply to say should the consent data be part of the EHI that's shared. And I think the harm is low, the cost is real, the benefit is small, which is why we're still talking about it.

Andrew Truscott – Accenture – Co-Chair

Okay. That's a good point. And I think all of us who have worked in the privacy world appreciate that it can very often be a small group of individuals who have a very loud voice with their very real concerns about their privacy. I would draw members' attention just to Pages 402-405 in the Word version that actually has a discussion around the privacy exception that Arien was touching upon earlier. This is different than the definition we have right now, which isn't discussed or considered by OSC yet, but we are discussing it now. Steven, can you lower your hand and we'll move to Anil?

Anil K. Jain – IBM Watson Health – Member

Yeah, thank you, Andy. I think the important thing is that there can be clinical implications of consenting to information sharing and it definitely should be part of the EHI. The fact that a patient has decided to share their information or not share their information could have a downstream impact on their care. It could have a downstream impact on payment. And if I understand the way that EHI is phrased right now, it's any information that could be used for past, present, or future care decisions. So, I think it's pretty compelling that it should be part of it. We should be very careful about some of the comments made. The fact that we're exchanging that data should not be representing the current state of that patient's desire to share data with someone but it's just historical information that would be critical to reconstruct when a bad care decision has happened or when a payment needs to be made for a certain set of care. So, I think, in my opinion, at least, it's pretty clear cut that it should

be part of EHI.

Andrew Truscott – Accenture – Co-Chair
Thanks, Anil. That's helpful. Valerie?

Valerie Grey – New York eHealth Initiative – Member
Yeah. I was just going to echo that I believe that it should be part of EHI as well. I happen to be in a state that has some pretty strict consent rules and privacy rules and I think the ability to actually be able to do what we need to do requires having consents available so that we can figure out how to exchange with the different states.

Andrew Truscott – Accenture – Co-Chair
Thanks, Valerie. That is helpful.

Denise Webb – Individual – Member
Andy, this is Denise. I can't raise my hand because I'm in transit.

Andrew Truscott – Accenture – Co-Chair
That's okay. Go on, Denise.

Denise Webb – Individual – Member
Well, I just wanted to say that I agree as well that the EHI should include the consent information.

Andrew Truscott – Accenture – Co-Chair
Okay. Thank you. And, guys, I know that we all have concerns around unintended consequences and how this could be implemented. And, John, you outlined those excellently. And, John, you've got your hand raised again. Go on.

John Kansky – Indiana Health Information Exchange – Member
Sorry, really quick. I'm not trying to be clever. This may be a rhetorical question. So, if there is a state that is opt-out and the patient opts out of a specific provider – in other words, expresses to that provider that I do not consent to my data being shared – then that provider gets a query after the information blocking regulations are in place, are they required to not respond or are they required to respond that the patient has prohibited the sharing of their data, which seems to, in some cases, be something the patient wouldn't want disclosed?

Andrew Truscott – Accenture – Co-Chair
Well, I think my instinct on that one is that's a local policy decision that's probably based on local and state regulations, etc. Because that's the same way as if the patient's expressed the consent decision right in front of you, you've just relied on the fact that you've had it shared with you. I'd like others to comment though.

Arien Malec – Change Healthcare – Member

I don't know if that was an invitation for people to comment but I raise my hand.

Andrew Truscott – Accenture – Co-Chair

No, Arien, you can comment. Just chip in.

Arien Malec – Change Healthcare – Member

Okay. So, yeah, I completely agree. I think what we're really talking about is extra HIPAA obligations and how to efficiently extra HIPAA obligations. I think we need to be careful not to design additional privacy law at a federal law outside of HIPAA because I don't think: a) that's our mandate and b) it's a good idea. But in areas where states – and there are some states – there's one state, in particular, that has the requirement that you mentioned. I'd not that it's really hard to comply with because it's, in fact, very hard to tell the patient that their information is not flowing because they didn't express consent because you can't tell the provider that they didn't express consent. So, you end up in very strange and unintended situations. I think what we should be trying to design for is, in those states where there are extra HIPAA obligations, that we don't allow those extra HIPAA obligations to provide an excuse not to share.

Andrew Truscott – Accenture – Co-Chair

Okay. So, I think what we want to achieve in this definition is simply saying that consent directives/information/decisions are EHI and therefore should not be blocked from being shared.

Steven Lane – Sutter Health – Member

Sorry, Andy, I've got my hand up. Can I jump in?

Andrew Truscott – Accenture – Co-Chair

Please, yeah.

Steven Lane – Sutter Health – Member

I think one thing that I appreciate from this discussion is that consent is not just a data field. That consent data is complex. When was it provided, what were the specifics of either consenting to or stating you don't want data shared, that there's a fair bit there to consent. And I don't know that we have standards for how to express that consent. So, if we make it part of EHI, it seems to me it's largely going to be a free text, unstructured field until such time that we have standards. Unless they exist out there and I just don't know about them. But I think it's a big, complex area. So, if we include it in the EHI, it may be worse asking for some clarification about just what that would include specifically.

Andrew Truscott – Accenture – Co-Chair

That's a good point. We do have standards for expressing consent electronically right now. In modern centers as well as older ones. And these are deployed in many EMR systems. I wouldn't mind if Sasha wants to comment as well around this. But, __, you've got your hand raised.

Valerie Grey – New York eHealth Initiative – Member

Yeah, I was just going to say do we want to consider including consent in the USCDI Version 1, if that's what we want to ensure happens, and then put the standards around it?

Andrew Truscott – Accenture – Co-Chair

Given that they exist, I wouldn't have any issues with that at all.

Cynthia A. Fisher – WaterRev LLC – Member

This is Cynthia. I can't raise my hand. We're in transit also. How do we best approach this in light of preventing information blocking where HIPAA has been so misused in the past as an information blocking tool? So, how can we all think of it as the best way to allow for this sharing?

Andrew Truscott – Accenture – Co-Chair

That's a good point. If I have a think about that, can we just let Sasha, who has had her hand patiently raised ever since I said, "Sasha, what's your comment?" Sasha, can you just chip in?

Sasha TerMaat – Epic – Member

Thanks, Andy. So, I did raise my hand. I think I like the idea, if we are determining that consent is important, of putting a level of definition around it. That might be accompanied by including it in USCDI. I know we had a little bit of back and forth earlier in the conversation about consent for what, but the types of consent that were mentioned – whether it's for treatment at a particular facility, consent for a particular procedure and the risks associated with that surgery or type of testing, consents for things like genetic testing and the knowledge that might come along with it, consents for interoperability based on different policies or uses that might be part of a particular network – all of those are quite different in terms of scope and how they might be expressed as far as information. And then also the policies that I think John mentioned around when that should be shared, when should the denial of consent mean that, in fact, the whole notion that consent was asked for should not be shared. And so I think that it certainly could be valuable to share that information but some further definitional and perhaps standards work might make the process much more effective. And I think that including it in USCDI as a data class might be one method to facilitate the level of definition and clarity around all of those pieces so that it could be shared effectively.

Andrew Truscott – Accenture – Co-Chair

Thanks, Sasha. And this has bubbled up from the work group. It was a very brief conversation. It was wholly focused up on consent to information sharing and nothing else, if that's helpful for your consideration.

Sasha TerMaat – Epic – Member

I thought there was a mention earlier that it could include consent to treat or any kind of consent.

Andrew Truscott – Accenture – Co-Chair

That was a question that was asked from the Task Force. That wasn't how it was originally framed in our work group. However, it's a worthy conversation to have notwithstanding that.

Sasha TerMaat – Epic – Member

Certainly, clarity would be important so that it could be defined and communicated appropriately.

Andrew Truscott – Accenture – Co-Chair

Correct.

Steven Lane – Sutter Health – Member

Also, someone mentioned inclusion in USCDI Version 1. I think that's a pipe dream. I mean, it would be included in USCDI Version 5 at best. But putting it out on the table, I agree with Sasha, it would be valuable.

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

This is Aaron. I have my hand raised. Can I quickly mention something?

Andrew Truscott – Accenture – Co-Chair

Well, you can jump in in front of Sheryl, but yes. Go on then.

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

Real quick. So, I know I mentioned this at the last HITAC meeting but I just, even in this provision as it just relates to consent for sharing information, if we leave it right there – which I agree with Sasha's comments, you do need to define in some way or another. But for us to be cognizant that there are a lot of us that are also providers that also have to comply with FERPA because we have an academic component to what we're doing. And FERPA rules for sharing information, student information which could contain health records, like immunizations and shot records, things like that, is a very different level of standard to consent. And so just whatever we agree on here about consent of sharing information, just leave it broad enough that I can comply under FERPA as well as HIPAA.

Andrew Truscott – Accenture – Co-Chair

Okay. So, Aaron, I'm not quite following on what your request is. That's my ignorance, not your explanation.

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

Yeah. So, it's kind of in support of needing to define what consent actually means and being specific, but not being so granular on it that it eliminates my ability to comply under FERPA. That's all.

Andrew Truscott – Accenture – Co-Chair

Okay. Okay. That's helpful. Thank you. Sheryl, you have been waiting patiently with your hand raised.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Good discussion so far. I do agree that consent is important. And, actually, I had asked in the USCDI discussion because some of our folks at Anthem that were working on the FHIR 4 certifications have identified that there needs to be some place where we're communicating when consent is declined, because that's one of the requirements, and yet it's not a data element that we have defined anywhere. So, I was asking that group where would that be held? Is that going to be a USCDI requirement? Is it in the technical information guide? I don't know enough about the technical, but we would need something to, I believe, communicate consent and when consent is denied. Because it's going to be a requirement under FHIR 4 that's required by CMS.

Andrew Truscott – Accenture – Co-Chair

Thank you, Sheryl. So, I heard an interesting discussion earlier about – picking up on what you just said – when consent is denied. And we need to recognize that consent changes over time. And it's interesting to me that this work is going on. So, why would we not try and give it some teeth? Because it seems like there was a true consensus on the call that consent for information sharing is something that we think should be routinely shared and should not be blocked so that information can be shared, subject to local policies and procedures. That seems to be the sentiment that's on the call. Maybe I'm over-reading that, in which case, correct me.

Arien Malec – Change Healthcare – Member

Yeah, I think we got into a lot of very detailed mechanics that, as Steven mentioned, will take many years to sort through. I think we're on safe ground by saying that one of the ways that entities either intentionally or intentionally block information flowing is through means of requiring consent and then not giving appropriate mechanisms for collecting and sharing the consent. And I think that we're saying that, in order for information to flow maximally, we need to make sure that there's an affirmative obligation, if consent is required, to collect that consent or failure to provide consent, and there's an affirmative obligation to share that as broadly as is desired by the patient to allow the data to flow to all the places the patient wishes the data to flow.

Andrew Truscott – Accenture – Co-Chair

Okay. And, therefore, should we add it into a definition of EHI to facilitate that sharing?

Steven Lane – Sutter Health – Member

Can I add one little wrinkle to this? My hand is up.

Andrew Truscott – Accenture – Co-Chair

Little wrinkles, we can cope with. It's the big ones that are sort of bothering right now.

Steven Lane – Sutter Health – Member

Yeah. This is a little one but I think significant. What if the consent, the content of the consent, is that the patient doesn't want the provider or actor to share their information? Would it be required that the actor share if the patient restricted the sharing of their information?

Andrew Truscott – Accenture – Co-Chair

No. Wouldn't it be that the directive would say that the EHI is not going to be shared because that's the consent directive with the patient? Therefore, it would not be shared.

Arien Malec – Change Healthcare – Member

Yes. As a personal observation, or an observation back in the days when I used to do a bunch of this work, we ended up providing mechanisms that would say "some information has been blocked at the request of the patient" and needed to be very vague about that in order to not inadvertently disclose information the patient didn't want to be shared. So, I don't want you to know that I'm seeing Provider Type X. You don't want to say "patient blocked information from X Psychiatric Practice." You want to say there is some information the patient has expressed interest in not sharing.

Steven Lane – Sutter Health – Member

Right. But the question is if the patient seeks care – I go to get my breast reduction surgery and I just don't want the entire fact of that interaction shared, then does that breast reduction surgeon have to share that data is being withheld or would that just all be withheld? I think that's the wrinkle. And we can't solve it here but it's an important question.

Arien Malec – Change Healthcare – Member

Yeah. And as I was saying, as a practical method, the way that we handled that was to say "there is some information the patient didn't want to be shared but not disclose that the patient didn't want the breast reduction clinic or the psychiatric clinic or the what-have-you clinic – that information wouldn't show up. I don't think there's good standards in this area, good policy in this area, so the next step that I think Andy is looking for becomes hard because I think we have policy goals but I'm not sure that we have clear enablements of those policy goals.

Andrew Truscott – Accenture – Co-Chair

I think that's fair. Sheryl's got her hand raised. Before we move to you, Sheryl, I just to point out that other countries have already been through this and based policy recommendations or decisions. I've looked both Australia and the UK, who have actually been through this pretty exhaustively and gone through virtually every single clinical connotation you can think of with different data sites, etc. We are talking about a very course-grain consent to information sharing. However, all we're talking about right now is a focus upon whether consent information should be considered electronic health information and, therefore, not routinely blocked. That's all we're talking about at this point. Sheryl, you had your hand raised.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Sorry, my question was actually asked and discussed by the last person but I do see the dilemma because we have many instances where they might not want behavioral health information or even any of those physicians to respond to a query. So, how would that be handled? And if there's a model that exists somewhere else, maybe as part of the discussion point, we can point to that. But I'm not clear on how that would internally work.

Andrew Truscott – Accenture – Co-Chair

Okay. We can definitely do that, I think. John Kansky, your hand is raised.

John Kansky – Indiana Health Information Exchange – Member

I'm trying to be responsive to your question, Andy. I don't know if this is helpful. If we don't expressly put it in a definition, consent is still applied, right? I mean, consent is whether the information is shared or not. So I may be thinking simplistically again but my hypothesis is that we can leave it out and the consent will be applied to the sharing, or lack thereof, of that data.

Andrew Truscott – Accenture – Co-Chair

Yeah. All we are doing at this point is discussing whether we should include information pertaining to a patient's consent decision as EHI so it is shared. This is nothing about how to comply. This in no way overwrites whether you are giving consent or not because that is your consent decision.

John Kansky – Indiana Health Information Exchange – Member

I get it. So, I guess that I'm offering that perhaps it's less confusing to leave consent out of the definition – it doesn't change whether that consent will be applied or not – because I think we've demonstrated in the last 20 minutes that it brings in a lot of confusion and I'm not sure what we give up by leaving it out of the definition.

Andrew Truscott – Accenture – Co-Chair

I've heard several people say that including consent directives as EHI is a good idea. Okay? So, it would be useful to have that discussion. I think the point Cynthia was making some time back was that we're trying to move the ball forward and make sure the information is not blocked and cannot be blocked because someone relies upon a lack of consent, a lack of expressed and specific consent for a patient to share information. And, therefore, including consent directives as EHI so they are routinely shared would support that. If a consent is not given or is not available, then that doesn't change the providers need to gain consent or their policies on how to process consent. It just means that the information about what the current consent decision is needs to be obtained straight from the patient as opposed to be exchanged electronically. I think that's all we're talking about here. Yeah, Aaron's typing away feverishly into the box. And I agree with you, Aaron. As a personal statement here, being overly granular in the consent definition, I think, might be tricky. But the standards exist for exchanging consent directives right now. The FHIR has this stuff sitting in it. So, I like what someone said earlier about saying USCDI, we want you to go through this and look at how to include it, if the Task Force agrees that we should recommend to HITAC that consent should be included as EHI so it is not blocked. I'll stop at that point. Has anyone else got any

commentary on this? Because I might actually just quickly go through the Task Force and get a vote on this because I'm not sure exactly where we're standing because I'm hearing two distinctly different points of view.

John Kansky – Indiana Health Information Exchange – Member

Can I ask a general question? This is maybe my ignorance or something. We may need to research and understand is any of this going to be prohibitive for research? So, for human subject research and those sorts of things. Because as you may be aware, or maybe not be aware, under IRB rulings, there are some provisions given under HIPAA for that. So, I'm just questioning just to make sure we don't step on anything else, would this prohibit or inhibit anything under research?

Andrew Truscott – Accenture – Co-Chair

My perception is I don't believe it would. I don't believe it would prohibit or inhibit anything, full stop. It's purely about whether the information around the directive given by a patient is shared or not routinely within EHI.

John Kansky – Indiana Health Information Exchange – Member

Got it.

Andrew Truscott – Accenture – Co-Chair

And if a patient says outright, "I absolutely dissent for my information being used for research," then it would be routinely shared that that consent for that research has been denied. If a patient consents, it will be routinely shared that it is consented. I'm going to go back and ask for a vote. Lauren, can we quickly run through all the members and get an aye, a nay, or an abstain? And the question I'm asking is whether the Task Force believes we should include consent directives in the definition of electronic health information?

Arien Malec – Change Healthcare – Member

I don't think it's a well-framed question, if that's okay.

Andrew Truscott – Accenture – Co-Chair

It's a what? Sorry?

Arien Malec – Change Healthcare – Member

I'm not sure that it's a well-framed question.

Andrew Truscott – Accenture – Co-Chair

That's entirely possible. You can have another stab at it and see if I accept it.

Arien Malec – Change Healthcare – Member

Well, that's why I was trying to frame up a perspective that we believe that in areas that are extra HIPAA, that affirmative requirements to collect consent are required and that that consent information should be shared as broadly as necessary in order to express the wishes

of the patient. And that it would be desirable to share that information via USCDI. And I think to Steven Lane's comments, this is a high priority standards activity to make sure that we have adequate standards to be able to do so.

Andrew Truscott – Accenture – Co-Chair

Okay. Honestly, I think you're right but I think that's a level of specificity and granularity which goes beyond what we're seeking to do at this juncture.

Arien Malec – Change Healthcare – Member

Okay. That's fair. My concern is that we're asking for something and then we're asking for something that we don't know how to do.

Andrew Truscott – Accenture – Co-Chair

Well, I wouldn't agree that we don't know how to do it. And, actually, what we're doing is we're making a recommendation to OSC that they look at including this inside the definition. I know where you're coming from, Arien, with the state-by-state dichotomies around how this could be handled but I am mindful of Cynthia's view as well and others that if a patient has made a consent directive, then we shouldn't be blocking that directive from being shared.

Arien Malec – Change Healthcare – Member

I completely agree with that perspective. We just need to be modest as, in some cases, the way that we might share that directive is nonstandard.

Andrew Truscott – Accenture – Co-Chair

Okay.

Mark Knee – Office of the National Coordinator – Staff Lead

So, I think Arien is saying it may be difficult to share and convey that consent due to the variability of it.

Arien Malec – Change Healthcare – Member

Right. But that the bare information of it, which might be – so, yeah. That's exactly the complexity. I am completely in favor of sharing that information as broadly as is reasonable but also mindful that we don't have a standard and computable way of doing so. And so we may need to fall back on paper, electronic notes, or the like.

Andrew Truscott – Accenture – Co-Chair

Or it might be unfeasible.

Arien Malec – Change Healthcare – Member

Or it might be unfeasible. That's totally fair. Yeah.

Andrew Truscott – Accenture – Co-Chair

Okay. Anil?

Anil K. Jain – IBM Watson Health – Member

Yeah. I'm just trying to bring this all together. Because I think we, collectively, probably all agree that this information needs to be shared but are a little concerned that the standards may not be there yet to do it in a meaningful way or to do it in a way that's not going to do undue burden. What if we simply say that our Task Force believes that this information should be shared but should not be enforced until the USCDI has the appropriate standards to allow for the appropriate standard way of sharing and that they ought to do that by a certain timeframe or something of that sort? So that's not a copout but since the general feeling is that we all agree, we just don't know exactly what the burden would be. The other comment would be that there are potential unintended consequences but I don't think those potential consequences of sharing something like the fact that I did not agree to share my records from my behavioral health clinic or whatever it might be, that already happens today. And having the patient in charge of that, I think, is much more meaningful than having what I think happens today, which is you make an inquiry and they say, yes, they're a patient but you don't have any idea of anything and you can't even go back to the patient and ask them. At least in this way, you can say to the patient, "We did find that you had seen this provider. Do you want or do you agree to have that information shared?" So then the patient is put back in charge of what information needs to be exchanged. Otherwise, I think we'll end up with lots of fragmented situations where, if the consent information or the fact that even a record existed isn't shared, then we might be back to the same place.

Andrew Truscott – Accenture – Co-Chair

Thanks, Anil. Those are very thoughtful comments and I think they chime in with what Sasha has just contributed as well. Are we trying to indicate the priority of this or the readiness for inclusion? I submit I quite like the approach of saying this should be included, here's the timeframe for doing it while USCDI addresses how that will be included. I think that's a useful approach. At this juncture, could we just cut to public comment, please?

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

Sure thing, Andy. Operator, can we open the line?

Operator

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

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

And any comments in the queue?

Operator

Not at this time.

Andrew Truscott – Accenture – Co-Chair

I would actively encourage members of the public who are listening to this discussion for their point of view because that would be obviously influential and important to us on the Task Force to take that into account. This is a clear additional class of information we are considering and to know or have some input from the outside world would be very, very useful beyond our own professional and personal experiences. Has any other member of the Task Force got a comment to make at this point?

Steven Lane – Sutter Health – Member

I like the way Anil phrased this, that we encourage its inclusion but look forward to it having clearly defined standards through the USCDI process before it is absolutely required.

Arien Malec – Change Healthcare – Member

And I would say, from a healthcare provider perspective, adding consent as a requirement in the way we're talking about it absolutely helps also raise the level of education and working with patients to have them understand what they are consenting to. I'm aware of too many places that don't do a good job of that and just breeze through it as, "Here, just sign this document and you're good to go," versus actually helping the patient to understand what they're consenting to and what they're not, which helps everything, from security to privacy to everything. So, I think it's a win for a number of reasons, beyond it's the right thing to do.

Andrew Truscott – Accenture – Co-Chair

Thank you, sir. Any public comments?

Cynthia A. Fisher – WaterRev LLC – Member

This is Cynthia.

Andrew Truscott – Accenture – Co-Chair

Go on, Cynthia, quickly.

Cynthia A. Fisher – WaterRev LLC – Member

I think it's also ensuring that the patient has access to this information and control of their complete information. Because as a patient moves through the system, we want to make sure that, regardless, the patient automatically gets real-time population of their health information. So, I guess the thing, as we look at considering this, is that we just don't want to go back to more opportunities for blocking however this consent is appropriated. And I think the other challenge is also we want to make sure there isn't a delay of game because the standards are going to take 3-6 years to try to find a standard. In the rest of our life, even through Find My Friends or Life360, you can time in and time out consent. There are all sorts of ways to know each other's locations. There are so many real-world apps today that make it very easy at the mobile point for control of the consumer. So, I'd just add that to the equation to say that I just hope that we look at making sure that both the physician and the consumer and the provider and the patients have readily available access to have the best

point-of-care information for diagnosis and modality of therapy.

Andrew Truscott – Accenture – Co-Chair

Thank you, Cynthia. I really appreciate those comments. Operator, do we have any public comments on the line with my plea for input?

Operator

There are no comments at this time.

Andrew Truscott – Accenture – Co-Chair

Okay. Guys, I'm trying to get public comment. Has anyone got any closing comments as we head towards the end of our time together this morning?

Arien Malec – Change Healthcare – Member

No, I think this is a good talk. I really do. I think it's a really good debate.

Andrew Truscott – Accenture – Co-Chair

It is definitely that. Well, we won't get to the second topic. We will have to do that when we're back together again.

Steven Lane – Sutter Health – Member

And, Andy, I'll just chime in that my piece of the Workgroup 2 output should be delivered before the clock strikes midnight tonight.

Andrew Truscott – Accenture – Co-Chair

You mean close of day? That's fine. That's 3:00 a.m. for us normal people. Okay. Thank you very much. I really appreciate it. And, actually, Task Force members, I know everybody has been hard at work drafting out their interpretations of the workgroup deliberations and I also fully appreciate that every single member is following the consensus of the group, not necessarily our personal beliefs. So, that's really good too. Okay. So, I think where we've landed on this topic is that, as a consensus – and we are going to quickly go around, everybody, just to make sure that I'm on the right message here – we will draft out some wording as a recommendation for inclusion which specifies consent directives or consent information would be part of EHI and give it a time scale for adoption with a preamble around USCDI ensuring that the standards are in place to support that. I think that's where we landed. Arien, I appreciate it might not be worded as eloquently as you could but, for the time being, that's my 180 characters on it. I know. So, Lauren, can you quickly run through the Task Force members and just get whether that's what people want to do or not? And just get a tally.

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

Sure. We can just run down the list here. We'll start from the bottom up. Denni? Is she on the call? I don't think she's on. Lauren Thompson?

Lauren Thompson – DoD/VA Interagency Program Office – Member
Yes, I concur with that.

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

John Kansky – Indiana Health Information Exchange – Member
I'm going to abstain based on some of the concerns and confusion that I mentioned earlier.

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

Cynthia A. Fisher – WaterRev LLC – Member
I, too, am going to abstain. I'm not sure this is in EHI or not in EHI, Andy, just for clarification.

Andrew Truscott – Accenture – Co-Chair
It is not in the EHI right now in the current definition. Please go on with the vote.

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

Anil K. Jain – IBM Watson Health – Member
I concur.

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

Valerie Grey – New York eHealth Initiative – Member
I think I'm going to abstain, mostly because I need to think through it a little bit more.

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

Arien Malec – Change Healthcare – Member
It should be in EHI and it's hard.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin –

Member
That was concur, right, Arien?

Arien Malec – Change Healthcare – Member
Concur with reservations.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Member
This is Aaron. I agree and I also concur with Arien that this is very difficult but well, well worth it. So, I'm in.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks, Arien. Sasha?

Sasha TerMaat – Epic – Member
I abstain.

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

Denise Webb – Individual – Member
I concur. And I just want to reiterate that we definitely need to be clear about what consent data information we're speaking about in our recommendations.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks, Denise. Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
I concur and agree that same qualification. We need to be clear about what consent we're talking about. And then if we have any suggestions related to the technical implementation, I think we should include those as well.

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

Steven Lane – Sutter Health – Member
I concur and join in the reservations.

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

Designated Federal Officer
And Michael?

Michael Adcock – Individual – Co-Chair
I concur.

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

Andrew Truscott – Accenture – Co-Chair
I abstain.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay.

Andrew Truscott – Accenture – Co-Chair
So, I think we had no nays and about 50/50 between abstentions and concurs, albeit with reservations. Is that right, Lauren?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yes, that's right. I was just doing the tally. That is correct, yes.

Cynthia A. Fisher – WaterRev LLC – Member
Andy, it would be helpful for those of us that are in transit just to write out what the specifics were so we can see it and read it for those of us who abstained. Thank you.

Andrew Truscott – Accenture – Co-Chair
This won't be our last conversation on the subject. It's okay. Yeah, what I'll do is I'll do some drafting around it, seeking to capture what I think I heard, I'll pass it around to the full group for people to do feedback into it as well, and we'll take it from there. I think that's probably going to be the easiest way forward. Okay, on that note, I shall adjourn the meeting until the next time.

Sasha TerMaat – Epic – Member
Thank you, Andy.

Arien Malec – Change Healthcare – Member
Good job, Andy. Thank you.

Andrew Truscott – Accenture – Co-Chair

Thank you, everyone. Thank you for taking the time.

Steven Lane – Sutter Health – Member
Thank you.

Andrew Truscott – Accenture – Co-Chair
Bye-bye.

Cynthia A. Fisher – WaterRev LLC – Member
Thank you. Bye.