Conditions and Maintenance of Certification Requirements Task Force

Transcript
April 26, 2019
Virtual Meeting

Speakers

Name	Organization	Role
Denise Webb	Individual	Co-Chair
Raj Ratwani	MedStar Health	Co-Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha TerMaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
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Mike Lipinski	Office of the National Coordinator	Staff Lead
Kate Tipping	Office of the National Coordinator	Staff Lead
Christopher Monk	Office of the National Coordinator	SME

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

Good afternoon, everyone. Welcome to the Conditions and Maintenance Certification task force. We have with us Denise Webb, Carolyn Petersen, Ken Kawamoto, Sasha TerMaat, and John Travis. At this point, I will turn it over to Denise to walk us through the discussion of our last few outstanding recommendations. Denise?

Denise Webb – Individual - Co-Chair

All right, good afternoon, everyone. I thought we did really quite well yesterday. We got through and have 31 of 36 recommendations that went through a vote and we had majority consensus. We have five remaining, four that we presented yesterday. That would be Recommendations 8, 12, 13, and 22. We still have to complete our discussion on Recommendation 25 on self-developers.

I think what we'll do is we will dive right in with Recommendation 8. Kate put this all in a Google doc for the four that didn't get approved yesterday, so that we could do some editing and see if we can get these in a shape where they address what the concerns are. It would be nice if we could float the four across the full committee and make sure we covered what they were concerned about before we go to the May 13th meeting. We can see if we can do that.

On Recommendation 8, this is the recommendation we had around real-world testing and testing the use of data. My recollection of yesterday's conversation was that there was a concern. I think Clem did not understand what was intended here in our recommendation around the use of data and what do we mean by "usability testing," and what does that include? Then there was some discussion around the integration of data. I have to say, I am a little concerned about specifically calling out testing integration of data because that isn't, as I believe, in Cures, nor is that word used in what I could find here in the real world testing preamble.

It seemed like it was the second line where we probably could put a little meat around it. I'm in the second paragraph, where we have the TF recommends, "ONC expects that if health IT developers are testing the use of data receipts through the exchange, the health IT vendors should have intended users involved in usability testing." Maybe we could do, "For example, validating the effectiveness and efficiency of viewing, acting on, and reporting on data received along with users' native data." We're not saying how that should be done, or how the vendors should design their product. So that's one idea I'll throw out. Let me open it up for the group.

Sasha TerMaat – Epic – Member

I agree with your assessment, Denise. I think it was primarily not a substantive concern, but confusion about the wording. I'm wondering if we could, maybe, clarify from some of the language that we took from Cures, and then, maybe, reorganize the sentence that way. I was looking for the original language on use just so that we could, perhaps, reference that.

Denise Webb – Individual - Co-Chair

When we first drafted this you mean?

Sasha TerMaat – Epic - Member
No. I think, "testing the use" was the phrase that confused people. Right? Particularly, Clem brought that up. But that actually comes from ONC's language. So I just pasted it into a comment over on the right. They say, "the requirement is that you test the real-world use of the technology." So I think some of it is that we echoed in the recommendation the words that ONC was using, and then Clem said, "I don't really understand what that means." Well, that's why we were asking for clarification because the phrasing that was confusing to him, I think, actually originates from ONC.

Denise Webb – Individual - Co-Chair
Actually, on Page 276, it says, "The Cures Act defines interoperability as health information technology that enables the secure exchange of electronic health information with – " it doesn't say. With other health information technology.

John Travis – Cerner - SME
If you go down a little farther, they list out on Page 278 of the display copy under the third bullet, they actually say, "EHI is received by, and used, in the certified health IT." So it's, kind of, a plain language statement there. So to interpret what do they mean by, "used in."

[Crosstalk]

Sasha TerMaat – Epic - Member
I put that into a comment, too, just for reference.

Denise Webb – Individual - Co-Chair
Yeah, maybe we should parrot the words that are in the preamble and say, "Based on this, we recommend X."

John Travis – Cerner - SME
Yeah, because there is a scoping question that we were trying to get at about what does that exactly mean? Because integration is a tricky word when we also have incorporation, already a certification requirement for exchange of health **[inaudible] [00:06:23]** for the transition of care. If you borrow on incorporation that suggests that you're going through a process of NS – terms that have been used earlier, reconciliation. So it's use-bounded by what it takes to incorporation and reconciliation, as an example.

Denise Webb – Individual - Co-Chair
Yeah, and it was really good to reread this because I was thinking about self-developers because when I look at Page 278, there's only their coordination, clinical quality measures, VDT, public health criteria, API, and transport. If you have modules that are certified for those criteria, then you are subject to real-world testing or those criteria. So, it seems like we've all been deep into the language here and maybe the rest of the committee hasn't. So we've got to put our words in a way that, I guess, they could stand on their own, so that when they read our recommendations they know exactly what we mean.

So what do you think? Who wants to take a stab at this?

Sasha TerMaat – Epic - Member
I'll just, maybe, start by adding some context, so you can tell me if this – well, here I'll even put it in the suggestion mode so it's clear what I'm adding. "ONC indicates…" and then, here, maybe we want to say –

Denise Webb – Individual - Co-Chair
So in your first line that you want to put in there, "ONC indicates that one common component of real-world testing would include testing electronic health information received by and used in the certified health IT."

Sasha TerMaat – Epic - Member
I don't know that they actually say that on 278. They're saying, "Successful real-world testing means that electronic health information is received by and used in the certified health IT." They don't say that has to be tested.

Denise Webb – Individual - Co-Chair
You could say, "ONC states that one component of real-world testing means that electronic health information is received by and used in the certified health IT."

John Travis – Cerner - SME
So your point of clarification is what is that **[inaudible] [00:09:52]**?

[Crosstalk]

John Travis – Cerner - SME
So if you're in the position of the developer proposing a test plan, you're going to have to interpret that because it's going to set a proof point for successful real-world testing. You're either leaving it to the real-world – I'm sorry – the HIT developer to propose an interpretation for the purpose of their own test plan – and given that this is a common requirement that might vary some, depending on what's being tested, which interoperability criteria are being tested.

If that's the case, then that should be clear that the HIT developers are going to bear the need to state what that is for them, or ONC is going to need to give better specific points of guidance about what it means. It's probably going to have to be at least somewhat more finely grained than a common statement because it's going to mean different things for what you're testing. If you are testing transition of care, it might suggest that you're proving that you can reconcile a med list and be duplicated, and all of that goes with incorporation and reconciliation. If it's quality measures, it's that you can have – well, there's import and export and submission, but ultimately, it is a successful submission of a semantically valid data set and an accurate calculation of measure. That's not really using it within the EHR, but that's what you're getting to. Maybe that doesn't apply to quality measures because it's not a receipt.

Denise Webb – Individual - Co-Chair

Right. So I have thought when you look at the list that's here, every one of them except for the first bullet – and this is one thing the CIOs had a real beef with – that all the focus is on export. So the second bullet is export. The third bullet is export. The fourth is export. Public health criteria, application programming interface criteria could be bidirectional, and the last one is transport methods. That's the exchange. That's send and receive.

Sasha TerMaat – Epic - Member
Well, not quite Denise because some of the public health ones are bidirectional and the API criterion for certification is only one way.

[Crosstalk]

Denise Webb – Individual - Co-Chair
Okay. Which ones are bidirectional on public health now?

Sasha TerMaat – Epic - Member
Immunization.

John Travis – Cerner - SME
Immunization, yeah.

Denise Webb – Individual - Co-Chair
Okay. So we could call out the first bullet and then the immunizations and say, "For example, this would apply in testing the use of data and care coordination and in receiving immunization data," for example. Something like that.

I just don't think people realize that this is not as broad as it may seem. It's targeted to very specific criteria here and not everything that is certified.

Sasha TerMaat – Epic - Member
Yeah, we had a different recommendation where we said that if there was no receipt and use, then this was irrelevant. Right? Or is that part of this?

Denise Webb – Individual - Co-Chair
Yeah, it's still in there. When there are no end-users of the health IT product being tested. Or maybe we say, "The Health IT functionality being tested," rather than "product."

Sasha TerMaat – Epic - Member
Well, that's not quite the right answer, though. Right? Because if you think of a public health submission that isn't bidirectional, there are still end-users who document case reports.

Denise Webb – Individual - Co-Chair
Yeah.

John Travis – Cerner - SME

Yeah. Probably the purpose of use. And a friendly amendment to your list, I would argue there is, very much, possibly a use element to view, download and transmit for the view component.

Denise Webb – Individual - Co-Chair
Yeah, there is. I was focused on the providers – I apologize – and what they receive. That was my – I was being myopic there. Sorry.

[Crosstalk]

John Travis – Cerner - SME
Yeah, but I think that's a good scoping statement, that the minimum thing ONC should say – even if obvious – this conversation is highlighted. It's obvious to the people who know it. It's not obvious to the people who do not. And certainly, I think a developer is going to need to know it well enough to say that. I don't think we want the developer stating for themselves – again, I'm back to that points of, don't you really want a fairly consistent set of requirements to guide the development of the test plan?

So if you're ONC, don't you care about what you mean by a term like "use"? That it's not just a noun that somebody is going to interpret for themselves and that you're going to get a wide variety of results? Even if it's for the ONC, ACB, or the ATL to judge the appropriateness of the test plan as it's proposed, they're still going to need to have an understanding of what is the appropriate way to understand the meaning of the word "use." So if you're going to be providing guidance to them on how to interpret that, which I assume you would if you're ONC, why don't you just go ahead and say it in the rule preamble?

Denise Webb – Individual - Co-Chair
Yep. I like the changes. Ken and Carolyn, at least in the first paragraph we've gotten that far, but I think we're going to have to do something with the second paragraph. Ken and Carolyn – thoughts?

Carolyn Petersen – Individual - Member
I'm good with the notion of including the intended users and usability testing there in the second paragraph. And I'm sure that you'd want to say more about it because then it just dilutes that point. And a nice tight, specific sentence like that pretty much benefits from not being diluted.

Denise Webb – Individual - Co-Chair
Yeah. No, we're going to work on changing the second paragraph. I'm just wondering if you're okay with what we've got for the first paragraph, if that helps.

Carolyn Petersen – Individual - Member
Yeah, I think so. I think so.

Denise Webb – Individual - Co-Chair
Ken?

Ken Kawamoto – University of Utah Health - Member

It's okay with me.

Denise Webb – Individual - Co-Chair
Okay. Guys, jump in if you've got thoughts on changing things. Okay, should what should we do to – because the second paragraph here, that was called out. That was a concern of Clem's. Do we want to say more about…

Sasha TerMaat – Epic - Member
I wonder if we want to just use the same clarification I tried above and say – because then it becomes clear that they have proposed that this successful real-world testing has data received and used. So we're saying, when you test receive and use of data, it should have the intended users involved in the usability testing.

Denise Webb – Individual - Co-Chair
Yeah. And I know Kate and Lauren, you were listening to the conversation, as well. If you want to jump in and help us interpret it, maybe what Clem was saying about usability because I only have a few notes. Anybody who knows but he was concerned about with just stating, "usability testing." I know Raj they tried to explain that to him, but I didn't think –

[Crosstalk]

Sasha TerMaat – Epic - Member
We could try to send a clarification to Clem and see if it helps.

Denise Webb – Individual - Co-Chair
Yeah, that's a good idea. Because I think, wasn't there only one other person that chimed in on this? Wasn't it Steve, Steven Lane? I think he said a few things about integration, but I really think we need to stay away from that word. It's not in the rules.

[Crosstalk]

Sasha TerMaat – Epic - Member
Yeah, I worried that word had other meanings, too.

Denise Webb – Individual - Co-Chair
Who is that speaking?

Carolyn Petersen – Individual - Member
This is Carolyn. There was some mention of usability in the Care Continuum Task Force, particularly when we were talking about DS4P and with the opioid thing – that was in the DS4P – and the importance of usability and how physicians want all the information and nothing should be segmented, and a lot of that. I know at that point, Steven Lane did pop in and try to help frame it a little bit.

Denise Webb – Individual - Co-Chair
Yeah. Well, I personally, don't have anything else to add to this. I do wonder if some of the members read the transmittal memo that had the discussions. They may not have. I like the idea of sending it to Clem and asking, and explaining that the Cures Act in the proposed rule, this is what has been specified and we just think there should be more clarity around what they mean by "testing receipt use," what that looks like.

Sasha TerMaat – Epic - Member
Yeah.

Denise Webb – Individual - Co-Chair
So are we good?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I'm okay.

Sasha TerMaat – Epic - Member
Do we need to vote or we're just going to ad hoc consensus?

Denise Webb – Individual - Co-Chair
All in favor?

Carolyn Petersen – Individual - Member
Aye.

Sasha TerMaat – Epic - Member
Aye.

Denise Webb – Individual - Co-Chair
Aye.

Ken Kawamoto – University of Utah Health - Member
Aye.

Denise Webb – Individual - Co-Chair
Anyone opposed? All right. Any abstentions? Okay. I know we have Les missing and Raj, but I'll certainly share this with them.

[Crosstalk]

Denise Webb – Individual - Co-Chair
Sorry, just Kate. On the edits, can we just make sure that we track the changes from the last version to the current, just so that when we present it that's clear for next time?

Kate Tipping – Office of the National Coordinator – Staff Lead
Sure. I'll put it in slide next time. I'll put it in the marked-up version.

Denise Webb – Individual - Co-Chair
Good, that's good. At the high-tech yesterday, I didn't recall, Lauren, was he present?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I do believe so, yes.

Denise Webb – Individual - Co-Chair
Okay, good. All right, I just wanted to make sure he was aware of this.

I don't know what to say about this one because I thought it was pretty clear. So, what Clem was concerned about is why would there be a version of standards available for vendors to use that wouldn't have testing tools already? Is it because he doesn't understand, maybe, the process for certification and how that all works, Sasha and John?

Sasha TerMaat – Epic - Member
My sense was that he was actually concerned about the SVAP proposal, not about our recommendation, or that that's where his misunderstanding's rooted. That was my sense of what he said. I do think there are cases where the timing of a new version of standards will not align with the testing tools and certification, but Clem seemed to be thinking more of conformance tools provided by HL7, which are not the same as testing tools and that might be why he's puzzled.

Denise Webb – Individual - Co-Chair
Oh, did we use the word "conformance"? We used the word "conformance" in there to determine conformance. Maybe we don't need that.

Sasha TerMaat – Epic - Member
We could take that out because it's really just about testing tools which might have broader purposes, too.

Kate Tipping – Office of the National Coordinator – Staff Lead
And I just pulled the language from the preamble, here, that I've highlighted. I don't know whether that will be –

Denise Webb – Individual - Co-Chair
It has "conformity" in there. Oh, boy. "And conformance to a newer version of the standard." That's the developer's product conformance not – right? Well, do we point this out? Maybe we need to point this out and revote on this and put this on a slide.

Sasha TerMaat – Epic - Member
What are you proposing, Denise? Either that the existing wording is clear or that we don't actually even need the recommendation given this clarity in the proposed rule?

Denise Webb – Individual - Co-Chair
Oops, my screen just went blank.

Kate Tipping – Office of the National Coordinator – Staff Lead
Sorry about that was my screen. Sorry about that. Here we go.

Denise Webb – Individual - Co-Chair
Let me read this a minute. "On the other hand…"

Kate Tipping – Office of the National Coordinator – Staff Lead
Sorry, you want me to go back down?

Denise Webb – Individual - Co-Chair
Yeah, would you? Quit moving it. Okay. "I experienced certain lag times in terms – when updated test tools support the **[inaudible] [00:25:17]**." Self-step declaration.

Okay, so let's go back to our recommendations. This does help. Okay. We even say that they factor all claimed versions of standards into their real-world testing. Clem thought that that was onerous, I guess. We should clarify – are to address new versions – yeah, that they have a tested…

John Travis – Cerner - SME
In other places, I think, in this whole section we talk about recommending not to repeat testing for things that are unchanged. I think it depends on whether or not what you're seeking now is only relative to the new version, and that's really where the rub lies here. I don't know if we have a conflict, there **[inaudible] [00:26:50]**.

Denise Webb – Individual - Co-Chair
Maybe we have too much in here and that's what's throwing us off. Maybe we want to state that – and John, some of this came from you, originally, that you were concerned about. "When a version of standards is available under this process but the testing tools used by the ONC needed to certify," are those the tools were talking about? Right?

Sasha TerMaat – Epic - Member
Yep.

John Travis – Cerner - SME

Right. You know what? I think we were on a nut because I've been spending a lot more time on our own comment and a lot on this particular provision. I'm trying to put it together, where our comment now is. So the term that they use of – I'm trying to get back to the exact term, again.

Denise Webb – Individual - Co-Chair
It's an attestation of your conformance. And I know you were concerned about how is the health IT developer and the ONC to judge or determine conformance when there's **[inaudible] [00:28:18]**.

[Crosstalk]

John Travis – Cerner - SME
Yes, exactly. Exactly. Honestly, what I think we took it as was that it was weak, unless – because it could be challenged. It was weak unless it included some element of the HIT developer, whether it's they actually provided with the attestation or they speak to what they did to prove conformance since no tool's available. How is it exactly that they did that? Or there's an opportunity that once tooling is available, they don't have to go back through certification, but maybe there's a provision that says they have a certain amount of time after tooling is available to prove their conformance to substantiate their claim. Because otherwise, it seems like a claim without a proof statement. They're on the hook for proving it, certainly, but as the **[inaudible] [00:29:17]** profits itself.

[Crosstalk]

Denise Webb – Individual - Co-Chair
Well, isn't real-world testing annual, though? You could have your product certified, and you'd have to do your real-world testing because now –

[Crosstalk]

John Travis – Cerner - SME
Yeah, and that may be the proof point. Maybe it's as simple as cross-correlating those two things.

Sasha TerMaat – Epic - Member
I'm wondering, given the language from the preamble and rereading it, how important we think this recommendation is or if we should just cut it?

John Travis – Cerner - SME
It's not a showstopper because you're right, there's going to be **[audio cuts out] [00:29:56]**.

Sasha TerMaat – Epic - Member
We, perhaps, overlooked some of the preamble language. We were worried about a scenario which might happen, but I don't think the significance of it is that important. Since we are now –

John Travis – Cerner - SME

It's not going to happen a lot. The one that stands out for me, historically, where tooling really wasn't available was more because the tooling that was put out – and you probably remember this, Sasha. I think it was in 2014 edition certification where the Cyprus tool was just full of defects and they had to withdraw it, and then they republished it.

Sasha TerMaat – Epic - Member
Yep. And it's still true there's a lag between the publication of a CMSIG and the Cyprus updating to the CMSIG. So there's still windows of time where if you wanted to certify right in that window it could present this situation. But I think that the annual tracks with real-world testing and the self-declaration that ONC has proposed as the option are a reasonable way to address it. So I don't know that the…

John Travis – Cerner - SME
More repeated –

Sasha TerMaat – Epic - Member
Yeah, I don't know that we need 12.

Denise Webb – Individual - Co-Chair
Well, I'd like us to make a motion that we remove 12. Second?

Sasha TerMaat – Epic - Member
I'll second.

Denise Webb – Individual - Co-Chair
Sasha. Okay, any discussion? Carolyn?

Carolyn Petersen – Individual - Member
Go for it.

Denise Webb – Individual - Co-Chair
Ken?

Ken Kawamoto – University of Utah Health - Member
Go for it.

Denise Webb – Individual - Co-Chair
Okay. All in favor of removing recommendation 12?

Carolyn Petersen – Individual - Member
Aye.

John Travis – Cerner - SME
Aye.

Sasha TerMaat – Epic - Member
Aye.

Denise Webb – Individual - Co-Chair
Okay, Kate, what I would like to do on this one is, I would like to say that we went back and revisited the language in the preamble and decided that this recommendation was not necessary and are withdrawing it.

Kate Tipping – Office of the National Coordinator – Staff Lead
Okay.

Denise Webb – Individual - Co-Chair
Okay?

Kate Tipping – Office of the National Coordinator – Staff Lead
Yep.

Denise Webb – Individual - Co-Chair
All right, next. Let's see, they got hooked up on the word, "those who have limited resources," and who is "those?" Are we talking about Health IT developers or the recipients of testing requests?

John Travis – Cerner - SME
Well, in terms of testing…

Denise Webb – Individual - Co-Chair
This one is a sticky one. Go ahead.

John Travis – Cerner - SME
It is. No, I was going to say, maybe, there's clarity needed around "recipient of test request," because it could be somebody you're looking to have participate as another entity. And it could be somebody you're looking to participate as a supporting third-party entity of another kind, like a HIT developer or public health entity, or somebody else other than another provider, or an exchange partner. Broadly speaking, it's probably both exchange partners and it could be HIT developers.

Sasha TerMaat – Epic - Member
Yeah, it could be any of those entities. It could also be providers. I guess if a provider got approached by all of their health IT developers to participate in testing or patients. Right? If several applications that a patient used asked them – probably less likely with the patient case, but certainly, I can picture if you think of a California state immunization registry, which probably many EHRs that are in California if all of them wanted to test their immunization functionality with the California state registry, registries are often strapped to begin with for resources just for their operations, much less additional testing.

Denise Webb – Individual - Co-Chair
I can confirm that that's true because I worked in public health here in Wisconsin, and I've got to tell you that when this whole thing came through and they had to deal with providers registering – remember they had to register? They were just beside themselves because we don't have the resources to support all this. So then you add testing on that and wow. They're living off a piggy bank of pennies.

Sasha TerMaat – Epic - Member
Any entity, I think, might get more test requests than they can accommodate. I don't know if folks remember – John, you might – the HIE, back when in early Stage 2 when there was a pro forma test of interoperability with a system by a different vendor, and then ONC had there HIE testbed. We were a testbed vendor for a while. We would just do interoperability tests with users of other systems. And it took many hours of staff time a week just to help other people test their EHR's interoperability with us.

I think you can volunteer some amount of time to further interoperability testing, but at some point, there will be a limit, whether you're an immunization registry, or another public health entity, or an EHR developer, or a patient, or a provider, or an app. You'll be able to contribute some amount of testing time before you'll say, wow, I don't have any more time. I have to focus on my own business.

So what we were trying to say here is, that will happen. When that happens, the people who have to do real-world testing will be disadvantaged because they have to find someone else to participate, a different state immunization registry, for example, a different provider, a different patient. And then if you were the immunization registry who says, "I just can't," you don't want to be accused of information blocking because you said I could only help one group test this year. I'll help you next year.

[Crosstalk]

Denise Webb – Individual - Co-Chair
Would it be information blocking though? I'm trying to figure out whether it's information blocking or not being DMC for real-world testing.

John Travis – Cerner - SME
Yeah, you wonder if they're not going to evolve. There's, at least it's a precedent for that, with the attestation statements that are already present for provider attestation regarding surveillance – that they have to cooperate if they are approached. It's not hard to fathom them continuing that kind of a concept to support this. It's not surveillance, but it's real-world testing. And Sasha is right. There are criteria in here. I don't know how, for example, you test direct or transport in any real, legitimate way, unless either there's a test harness that has been set up to play that role of neutral convener, or you find somebody who's a willing partner, or some other form of neutral convener. Because otherwise, you're sending it to your own construction of some kind of receiving point, which doesn't really accomplish real-world testing very well.

Sasha TerMaat – Epic - Member
Right. You could make your own harness, or you could, with direct, set up two instances of your own software and send messages to each other, but that doesn't really seem to accomplish the real-world aspect of it. That's very lab-based testing. So it seems like you need other third parties to do this and then there's going to be this challenge of overburdening certain third parties. I don't like the word "third parties," though, maybe that is the best word.

John Travis – Cerner - SME
External entity. You'd have to define it, in any case.

Sasha TerMaat – Epic - Member
I think what we're saying is there are two testing parties. There are the people who are obligated under this condition of certification and maintenance of certification. I think it's maintenance, right?

Denise Webb – Individual - Co-Chair
Yeah.

Sasha TerMaat – Epic - Member
And they are trying to undergo testing as part of their obligation. And then there are all of the testing partners who may or may not have, their own obligations to do testing, but are requested to assist in the testing process as a provider test participant, as a registry recipient, as another EHR that uses direct, as an app.

Denise Webb – Individual - Co-Chair
Yeah, you just came up with a good word. What if we changed "third parties" to "testing partners" over which the health IT developers have no control?

Sasha TerMaat – Epic - Member
Okay.

Denise Webb – Individual - Co-Chair
Okay, now let's read this. "For example, some testing partners," and when you say, "other EHR developers," yeah. And I would add providers, too. Right.

Sasha TerMaat – Epic - Member
Sure.

Denise Webb – Individual - Co-Chair
So you could – yeah. Now we have the word, "in other parties." Well, I think "parties" is fine there. "In other parties real-world testing." "While these testing partners can try to be helpful, they will have limited resources."

Sasha TerMaat – Epic - Member
This was, kind of, a different thought, so I was just separating it. And here we mean –

Denise Webb – Individual - Co-Chair
Do we want to say, "They may have limited resources?" Some might have more. Some might have others up above.

[Crosstalk]

Sasha TerMaat – Epic - Member
Well, everyone has limited resources because unless John's holding out on me, everyone's resources are limited somehow.

John Travis – Cerner - SME
I'm not feeling it.

Denise Webb – Individual - Co-Chair
"Recommends **[inaudible] [00:41:08]** declining to participate in a real-world test is considered…"

[Crosstalk]

John Travis – Cerner - SME
But I think to your point, Sasha, other parties than us are going to feel constrained. I don't know that we want to get too broad here, but how do you entice that participation or to your point, Denise, whether or not information blocking, how do you get the cooperation, never mind the threat of a stick?

[Crosstalk]

Sasha TerMaat – Epic - Member
I think that's in this last thing that I highlighted here.

Denise Webb – Individual - Co-Chair
Yep, and then above, where you have the word "those," they got hung up on that. "Can be provided for those who have limited resources." Change that to "testing partners."

Okay. What's everybody think about this? Because the big thing was they got hung up on the word "those." That was the big thing, who that meant. Are we good? Do we want to take a vote?

Ken Kawamoto – University of Utah Health - Member
I think it's okay.

Denise Webb – Individual - Co-Chair
All in favor.

Carolyn Petersen – Individual - Member

Aye.

Sasha TerMaat – Epic - Member
Aye.

Denise Webb – Individual - Co-Chair
Aye. Any objections? Abstentions? I think I heard "aye" from everybody. Okay, good. All right, next. We've got four minutes to public comment.
Okay, search support. This one I felt like we went round and round on, but it seemed like most people were okay with it.

Sasha TerMaat – Epic - Member
Well, I think Arien raised an interesting point. I do think everyone – and I think Arien would agree also – that using standers is preferential to not using standers for something like this. Arien's point was that when there is no clear standard to adopt, which was part of the concern we had raised, ONC had proposed a reasonable mechanism for that in the previous round of certification by letting people pick, and hinting which standard they thought people would pick. That would be an okay way to do this. But I think it leaves open some of the same concerns that we had aired, which are that people might invest in different ways, and also that the standard that, maybe, they would hint people would pick is not firmly established, and is on, then, a pretty fast timeframe.

Denise Webb – Individual - Co-Chair
So on this bulk patient, do we want to instead recommend that the policy framework – based on what Arien said, if they have the policy framework right about how they're going about this, then probably what the issue here is, is why should this be a part of certification – the bulk patient – in the same timeline as everything else?

Sasha TerMaat – Epic - Member
That would be one way to address it, is to just propose an extended timeline.

Denise Webb – Individual - Co-Chair
Right, so that there would be time to – and to specify that – so they go as far as R4, but for the individual patient they require the timeline to meet certification. But then they have an extended timeline for the population health or the bulk data, multiple patients, with the idea that – well, yeah. When R4 is ready. I don't know. Ken, how long do we think this is going to take? Or **[inaudible] [00:46:30]**.

[Crosstalk]

Ken Kawamoto – University of Utah Health - Member
For the bulk data stuff?

Denise Webb – Individual - Co-Chair
Yeah.

Ken Kawamoto – University of Utah Health - Member
Is it primarily around bulk data? I actually did review the ballot content today. I think it's potentially – well, I don't know. Potentially going to be a while, especially if we're expecting it to actually allow you to specify either who you want to pull data for because currently, it says you've figured that out of band. The standard speaks nothing to you how you identify which patients you want to pull data for and for what data you want to pull. It's completely optional now whether you restrict the data. So looking at those, I would think it's going to be a while. It was the first time I actually really reviewed the spec. What's there is good, but there is a lot left to be defined, still, for what you might typically expect, which is who do you want to pull data for and which specific data do you want pulled for them?

Denise Webb – Individual - Co-Chair
So maybe we should withdraw this comment and leave it be.

Sasha TerMaat – Epic - Member
Well, they are proposing to adopt it as a requirement in 24 months with no standard. Right? So if we don't make a recommendation, then it will be required to be done in 24 months. And since the standard isn't really ready for that, everyone will just make up their own way to do it.

[Crosstalk]

Denise Webb – Individual - Co-Chair
Isn't that what they're going to do anyway?

John Travis – Cerner - SME
I was going to say, here's an interesting point for the TEFCA Draft 2, they withdraw bulk data, at least relative to this manner of interoperability. So does that inform something about what we say here?

Denise Webb – Individual - Co-Chair
We need to go to public comment and then let's continue on this. Sorry.

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

Operator
If you would like to make a public comment please press star-one on your telephone keypad. A confirmation tone will indicate your line is in the comment queue. You may press star-two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. Our first comment comes from the line of Marie Savickis with CHIME **[00:49:05]**. Proceed with your comment.

Marie Savickis – CHIME

Hi, everyone. Hi Sasha, Denise, John, and all. I had a question for you guys. I know, typically, you don't take questions, but I just wanted to highlight something that we found on Page 77 regarding the real-world testing. I was trying to figure out if – there's a line in there. It starts right before the No. 2, and it says, "For the purposes of meeting this compliance timeline, we expect Health IT developers to update their certified health IT without new mandatory testing and notify on their ONC ACB on the date on which they have reached compliance."

It seemed to us from the provider perspective that what it was saying was that for the first go round there wouldn't have to be real-world testing for these changes to 2015 start. So I think, from our standpoint, if this is in fact what ONC intended we would like to see the real-world testing happen and that the timeline be stretched out instead of the 24 months, which they say – which I've talked to some of you – this is far too aggressive, from our perspective – have that stretched out and accommodate the real-world testing, rather than leaving it for whatever the next addition would be after that. Thanks for taking my comments.

Denise Webb – Individual - Co-Chair
Thanks, Marie.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Main operator, do we have any other comments?

Operator
There are no other comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay, Denise, I'll hand it back to you.

Denise Webb – Individual - Co-Chair
Okay, let's finish our discussion on that. I want to look and see what Marie was talking about. Search support. Let's see. What were you saying, John? Do you want to finish your thoughts?

John Travis – Cerner - SME
Yeah, and I could pull up the particular language, but I believe the proposal for the TEFCA draft 2.0, did withdraw bulk data use case as an exchange purpose for methods. So it's informative to what we're talking about here, I think. It's not exactly the same thing, obviously, but it's going to involve a lot of the same parties, and that does set the frame for a timeline of expectation if it had been in the proposal. Obviously, maybe, it finds its way back in there as a result of public comment. I find it interesting. It's almost as if ONC made a conclusion on their own that it wasn't ready for adoption in this same timeframe we're talking about here, which would be in the next 24 months.

So just looking for consistency across programs in terms of priority and in terms emphasis, and that seems to express a belief, tacitly or explicitly, about the bulk use case being something that should be included at this point. It, kind of, speaks to the longer timeframe of certification, too.

Denise Webb – Individual - Co-Chair
Do we want to recommend that because this is rather nascent that we recommend ONC provide more time than 24 months?

John Travis – Cerner - SME
I think that is the minimum. Like, 36 months.

Denise Webb – Individual - Co-Chair
Because right now it's 24 months. And what I'm looking at what Marie was referring to, it says "We propose a main certification requirement for real-world testing conditional certification those that are certified to the six above certification criteria prior to the effective date of the subsequent final role would have to update such certified health IT to the proposed revisions. And further, for those who already have certification as a part of maintenance of certification requirements for real-world testing, the developers would have to provide the updated certified Health IT to all of its customers with health IT previously certified to the identified criteria no later than 24 months after the effective day of the final rule." But then what it says is, "For the purposes of meeting this compliance timeline," the vendors aren't going to have to do new mandatory testing. They just have to notify their ONC ACB on the date at which they've reached compliance within those 24 months.

John Travis – Cerner - SME
I guess a real comment of correlating the TEFCA treatment of this – and I've got the language in front of me for the withdrawal. It is more on the certification requirement itself and the real-world testing is a ripple effect or corollary effect of that. And the real place to make that point would be in the actual requirement for certifying and rolling that update out to your client base as part of the API requirement for certification. That's really where that statement goes, and it probably should be. I don't know what statement is being made there. That might be interesting to find out, but it's probably informative here because if the task force had had that actual duty, was mum on it, and we say, "Extend it here," it's kind of on sand and not a stone foundation to make that recommendation.

And the concern here could be resolved by the way you treat the initial requirement of whether or not we all have to get real-world testing done in 2020, assuming this is adopted timely to that. I think we've said in other places, to consider giving more – I'm trying to remember what we said there and I apologize. Did we suggest –

Denise Webb – Individual - Co-Chair
Go ahead, John. Did we suggest what?

John Travis – Cerner – SME

No, I was just going to say, did we make a suggestion in our recommendations – and I'm fuzzy on the recollection – about slowing down that first year timing of when the first round of real-world testing had to be done? Because if we did, then –

Denise Webb – Individual - Co-Chair
No, we didn't. We just said that there should be a **[inaudible] [00:56:17]**.

So we're just about at the top of the hour. I don't think we're going to finish 22. We have two meetings scheduled next week. I wanted to ask the group because I really do want to be in on the discussion on self-developers and I'm not able to be on the call on May 1st. We have a call on May 1st and May 3rd. I don't know if anyone would be okay with moving the May 1st meeting to a later time that day? But we would need to have Les – I don't know what his availability is, but he needs to be involved in the conversation on Recommendation 25. Or do we really need two meetings next week? Do we think we accomplish 22 and 25 in one meeting next week? Or do we just want to –

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise, this is Lauren. Maybe I could reach out to Les to see if either the first or the third is better for him to ensure that he is able to join that call. I think we can probably knock it out in one meeting, but I do want to make sure Les is available.

Sasha TerMaat – Epic - Member
And then we could move the first later in the day, you're saying, if we had it that day?

Denise Webb – Individual - Co-Chair
Yeah, because I have an interview for the Global Entry down in Rockford at the same time. Well, I'll be going down there to get that interview so we can get our Global Entry. And it was hard to get that interview. It took a month. So if you all could let Kate know, or just reply to all of us, what your availability is on May 1st in case that's the date, that's the time that Les is available. But we should have one meeting and even if we extend it to an hour and 15 minutes and knock these two out.

Carolyn Petersen – Individual - Member
Well, I can tell you that there's no time on May 1st that would work for me because I'm going to wind up being at the AMIA BIC meeting in Atlanta.

Denise Webb – Individual - Co-Chair
Right, so Friday would be better for you.

Carolyn Petersen – Individual - Member
Yeah, Friday is really the only day I can do it.

Denise Webb – Individual - Co-Chair
Okay. Is everybody else available for that Friday time slot we already have?

John Travis – Cerner - SME
Yeah, I am now.

Sasha TerMaat – Epic - Member
The Friday timeslot works for me.

Denise Webb – Individual - Co-Chair
Okay, Ken?

Ken Kawamoto – University of Utah Health - Member
I have to board a plane right as the meeting ends, but I think I should be okay.

Denise Webb – Individual - Co-Chair
Okay. All right, so Lauren, do you want to reach out to Les and see what we come up with?

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

Denise Webb – Individual - Co-Chair
See if he can make the Friday meeting?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Friday at 11:00 Eastern. Okay.

Denise Webb – Individual - Co-Chair
Yeah, is it in the morning? Okay. Yeah.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
It's 11:00 to – wait, I'm sorry.

Sasha TerMaat – Epic - Member
No, it's at 2:00 to 3:00 Central, or it's 3:00 to 4:00 Eastern.

Denise Webb – Individual - Co-Chair
Yeah. I thought it was the same time as today. Okay. All right, good. Thank you, everyone. I really appreciate it. And just be thinking about what we might want to do with 22 and whether we want to propose – changing the timeline, you're right, John. It cuts across the other task forces and things. It's not just our area.

One thing I do want to ask all of you to closely look at before our next meeting, on Recommendation 25, I went back and read the regulatory text for API, the actual – not the preamble, but the regulatory

text – and I have to say that I'm not certain that the requirements around fees don't also apply to self-developers because in my last role, we actually did charge other health systems, and the EHR we self-developed, it was not commercially available. So we might have to address that nuance of a self-developer charging fees to other entities through a contract and not through a commercial sale.

So I would ask that you all look at that regulatory text on fees because just because a self-developer doesn't put something out for commercial resale doesn't mean they're not out there charging fees for things because we did. So consider whether we should say that that is not applicable or not. Because right now I think we're proposing that it's not applicable if they are not commercially reselling their self-developed certified health IT modules.

And any other thoughts that you have on that, there is a Google doc out there. You all should have the link for that recommendation. Okay?

All right, well, everybody, enjoy your weekend. Thank you for your time. Kate and Lauren, I'll dial in real quick with you to see if we have anything that we need to talk about.

Kate Tipping – Office of the National Coordinator – Staff Lead
Okay.

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

Denise Webb – Individual - Co-Chair
All right, bye, everybody.

Ken Kawamoto – University of Utah Health - Member
Bye, thanks. Bye-bye.