Conditions and Maintenance of Certification Requirements Task Force

Transcript
March 14, 2019
Virtual Meeting

Members/Speakers

Name	Organization	Role
Denise Webb	Individual	Chair
Raj Ratwani	MedStar Health	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
Cassandra Hadley	Office of the National Coordinator	HITAC Back Up/Support
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

Operator
Thank you, on the lines are now bridged.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Good afternoon, everyone. Welcome to the task force of the conditions and maintenance certification group. We will get started with a brief roll call and then we'll jump right into it. Denise Webb?

Denise Webb - Individual - Chair
Present.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Raj Ratwani?

Raj Ratwani - MedStar Health - Chair
Here.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Ken Kawamoto, still on vacation. Sasha? Do we have Sasha yet? Okay. Les Lenert? And John Travis?

John Travis - Cerner - SME
Here.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Perfect. Okay. I will turn it over to Kate for another quick review of the charge and then we will proceed.

Kate Tipping - Office of the National Coordinator - Staff Lead
Sure, thanks, Lauren. So, the overacting overarching charge of the conditions certifications task force is to provide recommendations on the application programming interfaces, the real-world testing and the attestations, conditions, and maintenance of certification requirements. The updates to the 2015 edition certification criteria, modifications to the ONC Health IT certification program and deregulatory actions.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Thanks, Kate. So, did you want to – should we start with the Google Doc and review the recommendations there?

Kate Tipping - Office of the National Coordinator - Staff Lead
That is fine with me. Denise or Raj, does that sound okay?

Raj Ratwani - MedStar Health - Chair
Yeah, I think so. Let's start working through all the recommended changes.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer

Okay, Kate, you can go ahead and move the – the Google docs over –

Denise Webb - Individual - Chair
Do you want to cover the parts that, where you lead the meeting and I will cover the parts where I was leading the meetings or how do you want to do this?

Raj Ratwani - MedStar Health - Chair
Yes, that sounds like a great plan.

Denise Webb - Individual - Chair
Okay. So, I think that – go ahead, Kate for the introductory part.

Kate Tipping - Office of the National Coordinator - Staff Lead
Sure, this is -- we may not necessarily – we are going to have to go over the charge or you are going to have to go over the charge at the full high-tech meeting next week, so I just added it in here, but what we'll do is I can put this on a PowerPoint so you will have slides. But this is basically just the charge and the detailed charge that we have been going over every meeting.

Denise Webb - Individual - Chair
Okay.

Kate Tipping - Office of the National Coordinator - Staff Lead
Okay, so two here starts with the recommendations. I pulled out the overarching recommendation that I had heard about maintaining the 2015 edition so –

Denise Webb - Individual - Chair
Yes, and I added a comment, or some text on this if everybody is okay with it. If you want to scroll down a little bit? We had quite a bit of discussion about the implications on records retention, as well, with them not – with this not being the new edition, it sort of has this edition hanging out there in perpetuity if they keep it out, If ONC decides to keep it and continue to modify it. So, I added something about the records just to say that was another reason it did not make sense.

Raj Ratwani - MedStar Health - Chair
So, are there version control issues? I know there's some emailing back and forth on this, and –

Denise Webb - Individual - Chair
No, that was my mistake. What happened was I had clicked on the link that Kate sent, and I was in the latest version but then when I started putting in comments, it started putting the name of the person who owned the computer. I did not realize that they, well, of course, they were logged into Google and I did not know that. So then I backed out of it and rejected the -- what I had put in and then I logged her out and I logged in but for some reason, when I logged in, because I have never used Google docs, it showed me documents that were already being worked on so -- or had been open so I must have grabbed one that Kate sent earlier that I had opened on my iPad and didn't realize it so I started

modifying that one. But I don't think there are any versioning problems. I think yours should all be in here, Raj because I modified the one latest that had your comment.

Raj Ratwani - MedStar Health - Chair
Okay, good. I was going to say because I don't see the recommended changes or comments I made, but if you modified those, then than that is good.

Denise Webb - Individual - Chair
I would think -- I don't think you had anything up here. I think your first one was down below.

Raj Ratwani - MedStar Health - Chair
I think it was.

Denise Webb - Individual - Chair
Okay.

Kate Tipping - Office of the National Coordinator - Staff Lead
There. Is that -- okay.

Denise Webb - Individual - Chair
Yes, there is one in blue. That is Raj's. There is Raj's. Yes, yours are in here.

Raj Ratwani - MedStar Health - Chair
Great.

Denise Webb - Individual - Chair
Yes. That is how I knew I had a problem because I remembered when I first opened it, you had comments in there and then they weren't there anymore and I am like, what is going on here? So anyway, Google let me just keep going and then when I went to save it, I had to save it with a new name so obviously, it didn't let me affect what we are working on, so that's good. Okay, any comments on what I added for the group? I mean, is everybody okay with what I put in there related to the records issue?

Sasha TerMaat - Epic - Member
It seems fine to me.

Raj Ratwani - MedStar Health - Chair
Yes, I agree.

Denise Webb - Individual - Chair
Okay.

Carolyn Petersen - Individual – Member
This is at the top of page 2, is that right?

Denise Webb - Individual - Chair
Yeah, we are on recommendation number -- that was recommendation number 1 and now, Raj is going to walk us through the recommendations related to real-world testing -- starting with recommendation number – our preamble that we –

Raj Ratwani - MedStar Health - Chair
Yes, so everyone can see the preamble piece but recommendation two was around the timeline thing. I think this was the important point that Sasha first brought up and that everybody agreed with. Any changes to that one? Okay.

John Travis - Cerner - SME
No.

Raj Ratwani - MedStar Health - Chair
Okay, recommendation three? This is asking really for clarification around the care settings menu that's loosely described in the document.

John Travis - Cerner - SME
Well, maybe –

Denise Webb - Individual - Chair
Go ahead.

John Travis - Cerner - SME
No, just to say, maybe rather than saying guard rails and I see Sasha has kind of highlighted that, maybe she will address this. I think our real need is really understanding the meaning or the level of – detail is probably the wrong word, we are really after clarity as to the meaning of care settings in venues that the test plan must cover when it comes to the vendor choice or the vendor discretion. It is inadequate –

Denise Webb - Individual - Chair
It is really about sufficiency, right? Sufficiency and applicability?

John Travis - Cerner - SME
Right.

Denise Webb - Individual - Chair
So --

Sasha TerMaat - Epic - Member
-- Guardrails piece.

Denise Webb - Individual - Chair

What did you say, Sasha?

Sasha TerMaat - Epic - Member
I agree with John. I would say we should cut them or put guardrails piece. I don't think that's –

John Travis - Cerner - SME
Yeah, I think as the thing stands, we are after clarity. And maybe if it is important, clarity and par level meaning and by that I really mean, I don't think it's ONC's intent that one vendor goes and picks medical subspecialties and another vendor picks ambulatory.

Denise Webb - Individual - Chair
Well, can we put some – I thought we should have some elaboration that reflects our discussion and I think there needs to be some clarity around the minimum expectations in terms of choosing applicable care settings and sufficiency. What is sufficient?

John Travis - Cerner - SME
Yeah.

Denise Webb - Individual - Chair
In a test plan. So –

John Travis - Cerner - SME
I like the way you said it. I mean, honestly, if a vendor were wanting to go beyond the minimum, that is their discretion. I mean, who needs to stop them? But there needs to be a par level understanding of minimum.

Denise Webb - Individual - Chair
Do we want to say, in regard to applicable care settings and venue for the particular health I.T. product?

John Travis - Cerner - SME
Yeah, that is probably fair because it could vary – you may have very little differentiation if you are trying to test public health reporting or you are only presenting for the sake of hospital quality measures versus somebody presenting a broad waterfront that covers all the interoperability criteria, so that is fair.

Denise Webb - Individual - Chair
So, I also think part of the minimum expectations is not just which settings but what is sufficient, the number of settings.

John Travis - Cerner - SME
Yeah, yeah.

Denise Webb - Individual - Chair

So, I think there also needs to be clarity on what is considered a sufficient number. Right now, the field is wide open.

John Travis - Cerner - SME
Yeah. And it shouldn't be. Yeah.

Denise Webb - Individual - Chair
I think that is good, Sasha, what you put in there. Do you want to close it out? Yeah, close it out with your parentheses and period and then, yes, to the extent we can finalize these then Kate can just cut and paste them.

Raj Ratwani - MedStar Health - Chair
So, to me, there seems to be some amount of overlap in recommendations three, four and five, I think.

Denise Webb - Individual - Chair
I think four is much broader. It is about an overall template, not just the venue.

Raj Ratwani - MedStar Health - Chair
Yes, I think that you know, I guess we can walk through these and then make some decisions.

John Travis - Cerner - SME
Yeah, I took four as being, yes, it's broad but it is focused on the test plan and all of its characteristics. You know, and maybe four and five have more, granted, the scope is going to be part of the test plan so what we cover in 3 and outcomes, what we cover in five, is going to be part of the test plan but this really is on the plan itself.

Sasha TerMaat - Epic - Member
With four, I would --

John Travis - Cerner - SME
You'd want to speak

Sasha TerMaat - Epic - Member
I'm picturing like –

John Travis - Cerner - SME
Go ahead.

Sasha TerMaat - Epic - Member
That we use for a niche for usability testing, in terms of the format of the report.

Raj Ratwani - MedStar Health - Chair
Yes, I was thinking the same thing and then I was also thinking there are other niche documents, there's the template, whatever number niche document that is, and then there's also the niche

documents that do provide a little bit more guidance on types of settings and venues you should be thinking of and so forth.

Sasha TerMaat - Epic - Member
Three and four might be accomplished by the same document. Which would be fine, I think, but I would feel that they are worth making a separate recommendation.

Raj Ratwani - MedStar Health - Chair
Okay.

John Travis - Cerner - SME
Yeah, yeah. If they answer it with one, that's great but, yeah.

Raj Ratwani - MedStar Health - Chair
Okay, great.

Sasha TerMaat - Epic - Member
And then 5 was a slightly different recommendation just because they said that the three characteristics of successful real-world testing included some things that weren't applicable to all of the criteria proposed for real-world testing. So, I think that might be clarified in a variety of ways, but it is a little bit different.

Raj Ratwani - MedStar Health - Chair
Yes. Okay. So, is everyone comfortable with that said?

Sasha TerMaat - Epic - Member
Yes.

Denise Webb - Individual - Chair
Yes.

Raj Ratwani - MedStar Health - Chair
All right. Let's jump to the next section so 2213 is focused on the stereo and use case focused testing. Recommendations –

Denise Webb - Individual - Chair
I added a few comments in there to suggest. I mean, a few pieces of text.

Sasha TerMaat - Epic - Member
Wasn't there another word, too, besides scenario and use case? I feel like it was workflow or something.

Raj Ratwani - MedStar Health - Chair
I think you're right, Sasha. I remember that as well. Workflow was the word that was used.

Sasha TerMaat - Epic - Member
Would we want to add that in, too?

Raj Ratwani - MedStar Health - Chair
I think it makes sense to, yes.

Denise Webb - Individual - Chair
You could add a sentence after the sentence in six. Also, ONC should also clarify the term "workflow" as it is used in real-world testing.

Raj Ratwani - MedStar Health - Chair
All right, are we good to move on to seven?

Denise Webb - Individual - Chair
Any problems with the changes? I changed the text to take away everyplace in here where we ask questions. I tried to avoid asking questions and put it more in a clarified whether something was true or not or discusses in the text so that is all I changed on the next one. Those were all worded as questions and I changed it to statements.

Sasha TerMaat - Epic - Member
I think we actually were -- the nature of our conversation was to say that there were advantages to things like automated testing, regression approaches and so forth so is it really simply a question or are we recommending that those be also considered?

Raj Ratwani - MedStar Health - Chair
So, Sasha, are you on seven now, or –

Denise Webb - Individual - Chair
Yes. No, six. She is on the second part where I modified it and I obviously left the verb out there. I deleted it and then didn't type it back in. Clarify whether automated test can be used and what Sasha is suggesting is rather than clarify it, are we recommending that they affirmatively allow it? Is that what you were looking for, John, in this?

John Travis - Cerner - SME
Yes, I would say so and I guess, the cursor is kind of resting over the word regression. I was trying – I am getting a weird -- thank you. Yes, I think that ties in both. That makes a suggestion, although that's kind of a run-on sentence there. Clarify whether automated testing can be used –

Denise Webb - Individual - Chair
The can is missing.

John Travis - Cerner - SME

Yeah. Yeah. And whether regression approaches can be automated. I like the idea of saying, instead of making it a question, say we recommend automated testing be able to be used and that an automated approach could be applied to regression or something like that. Yes, I like the idea of making it a statement that asserts it because there is no reason why not and that may open up some opportunity to classify, when we were talking, I think we had gotten into, if nothing changes, is that really the same burden as if you are introducing something new? Any good testing methodology is going to recognize regression.

Denise Webb - Individual - Chair
Okay, I think this needs to be rewritten. If you just try to modify that, it is going to be a mess.

John Travis - Cerner - SME
Yeah, sorry about that.

Denise Webb - Individual - Chair
Yeah, it was just a bunch of questions before and I think in our recommendations, we want to avoid having questions. That is not really serving the purpose of what we are supposed to be doing.

Denise Webb - Individual - Chair
No. No. True.

Sasha TerMaat - Epic - Member
Should I accept these edits to try to clean this up so we can look at it legibly? Or does Kate want to do that?

Kate Tipping - Office of the National Coordinator - Staff Lead
Yeah, I mean, I think you can go ahead and do it, Sasha or I can do it, either way.

Sasha TerMaat - Epic - Member
Okay.

Denise Webb - Individual - Chair
We could say here, "we recommend permissible testing approaches include automatic testing, regression testing". And then does the last part fit into this?

Sasha TerMaat - Epic - Member
Perhaps not. I think that was part of the question. I don't know that it necessarily --

Denise Webb - Individual - Chair
Okay, so we could take –

Sasha TerMaat - Epic - Member
Maybe we want to work the end of it to say, "We recommend vendors be given the discretion to incorporate permissible testing approaches including – ".

Denise Webb - Individual - Chair
Okay.

John Travis - Cerner - SME
Yeah, that would be good.

Denise Webb - Individual - Chair
Then you really have just two kinds there. You could just put an "and" between the two and delete the rest.

Sasha TerMaat - Epic - Member
Should we say that those are examples?

Raj Ratwani - MedStar Health - Chair
Yeah –

Denise Webb - Individual - Chair
Including for example -- yes, I would say including for example automated testing and record regression testing.

Sasha TerMaat - Epic - Member
Because we are not trying to be exclusive to those. We are just saying there should be discretion and these are other testing methods we discussed that would be potentially viable, but someone might come up with other tested methods that might meet those same characteristics.

Denise Webb - Individual - Chair
Okay, so would this be a distinct recommendation from six? I mean, later Kate can renumber these, but do you want this to be a recommendation, or is it a part of six?

Sasha TerMaat - Epic - Member
I think it could be separate. I don't know, what do you think?

John Travis - Cerner - SME
Six is strictly definitional if that's a word. Seven is actually an active recommendation for assessment. I think that they should be distinct, because six, you want those definitions anyway.

Denise Webb - Individual - Chair
Why don't we just put the word "recommendation" and then a # and then she can just get these renumbered later? Because this might not be the only situation.

Kate Tipping - Office of the National Coordinator - Staff Lead
Oh, gosh, I am not good at numbering here, or at spelling.

Denise Webb - Individual - Chair
So, are we on seven?

Raj Ratwani - MedStar Health - Chair
Yes. Okay, so seven, I modified a little bit. We had human cognition, human elements but I think, for me, I was unclear as to whether we were saying that, and what the task force feels about, are we saying that we should be testing the use of the information as well, or just the exchange of information?

Denise Webb - Individual - Chair
Well, the regulation requires use, includes "use."

Raj Ratwani - MedStar Health - Chair
It does say use. My question is to what extent do we believe use should be tested?

Sasha TerMaat - Epic - Member
Well, and there's also maybe a question because back to recommendation five, not all of the criteria would have users in the same way.

Raj Ratwani - MedStar Health - Chair
Yes.

Sasha TerMaat - Epic - Member
So, like, if I think of some of the criteria that are about making APIs available, the system that would be doing the real-world testing would not necessarily be the user of the data. So, I don't know how you would have, like, use-based testing of that criterion? You could do technical testing of it.

Raj Ratwani - MedStar Health - Chair
Yeah, I agree, Sasha. I think if we're – I would be in favor of saying "use of data" when there is actually an end-user should be tested. Because that's a central part of real testing of interoperability. So, I think it makes sense to say that, but I think we'd have to have the caveat that that's only when there's actually an end user in the equation.

Sasha TerMaat - Epic - Member
Well, and end users of the product being tested.

Raj Ratwani - MedStar Health - Chair
Yes.

Denise Webb - Individual - Chair
So, do you want to say when there are end users of the product being tested? Or where there are?

Sasha TerMaat - Epic - Member
When there are no end users of the product being tested, use-based testing would not be pertinent.

John Travis - Cerner - SME
And they seem specific on the receipt, not so worried about the capture in terms of the use.

Sasha TerMaat - Epic - Member
Right. I think they use is really about -- I mean, the place where use is incorporated is in part three of successful real-world testing, which is received end use of electronic health information in the certified E.H.R. And so, it doesn't seem to me that testing data capture, which is part of other criteria like the other usability testing criterion, the usability testing of it, is pertinent here, because the use scenario is focused specifically on the receipt of data.

John Travis - Cerner - SME
Yeah.

Sasha TerMaat - Epic - Member
Which is part of why –

Denise Webb - Individual - Chair
We make the comment about the providers because they weren't considered in the cost estimates and the impact estimates.

Sasha TerMaat - Epic - Member
Maybe that statement would clarify the following part of this, which is that providers would need to be involved and they were not considered in the cost estimates.

Denise Webb - Individual - Chair
Yes.

Raj Ratwani - MedStar Health - Chair
Yeah, and I mean, I think the other piece that comes up here, is saying that when there is an end user, the use data needs to be examined and that introduces a whole host of other measures. And isn't this-this is also the area where I think they were pretty ambiguous on the measures and saying, at least one measure if I remember the language right.

Denise Webb - Individual - Chair
Right.

John Travis - Cerner - SME
Yeah, they didn't get into specifying the nature of the measure.

Denise Webb - Individual - Chair
We have another recommendation, I think related to measures. We could add that there.

Raj Ratwani - MedStar Health - Chair

I certainly think if we are saying that we want some kind of -- we are looking at user efficiency and effectiveness of using the received data. There's some – we could mirror the measures that are used in safety enhanced design in some way.

Denise Webb - Individual - Chair
Do we want to recommend that here, Raj? And tie it all together?

Raj Ratwani - MedStar Health - Chair
Yes, I would be comfortable with saying that standard usability measures like those in the safety-enhanced design should be used, or something to that effect, articulated better than that. But I think it makes sense to say that there are standard measures here to be used.

John Travis - Cerner - SME
Yes, and one thought there. I like that idea because it does introduce another thought whether or not at least one set, one manner or type a measure could be a real-world application of the same measures used in the SED testing.

Raj Ratwani - MedStar Health - Chair
Exactly.

John Travis - Cerner - SME
Yes, there's nothing to prevent that.

Sasha TerMaat - Epic - Member
So, the measures used in –

Raj Ratwani - MedStar Health - Chair
Safety enhanced design.

Sasha TerMaat - Epic - Member
SED testing would not be able to be gathered in actual use of the product, right? Because of some the way the data would need to be captured? I'm just trying to think this through. I hadn't really thought about this element before.

Raj Ratwani - MedStar Health - Chair
Yes so, I think it gets back to this issue that you brought up earlier, Sasha, around is this testing being conducted on the production system which I think we all think is probably not smart to do for a test system that closely mirrors the production system. If it's the latter, then you could certainly capture some measures of time on task and successful completion of the task and so forth. If it's on the production system, I think that raises some issues.

Sasha TerMaat - Epic - Member
Yes, and I think all of these – can I focus on some of these other points, too, right? So, one of the goals is to test compliance with code sets, for example. And I think you can have an automated way to do

that at a very large scale and so, if I'm answering the question about how many sites are appropriate for his type of testing, and I'm envisioning what if I did an automated test to assess the use of code sets? That's a very different type of test than if I consider we need to recruit provider test participants to do a simulation-based test, not their actual use of the product to be measured in kind of a lab setting where you can look at time on task and so forth, because then the number of sites that could be incorporated into the testing is obviously by the nature of that testing very different.

Raj Ratwani - MedStar Health - Chair
Yes, totally agree, and the cost is substantially higher for the –

Sasha TerMaat - Epic - Member
Absolutely. Absolutely. And so, I think to some extent either of these directions could work. They're – I mean, we've proven with the SED testing that that type of testing could be there. We know from other types of testing we do as HIT developers that other types of testing are also possible. I guess the question is here, I don't want us to end up with an inconsistent proposal. If the number of settings makes one assumption and the cost estimate makes another assumption, and then the nature of the testing in terms of looking at the use and the SED metrics makes a different assumption, then we'll really be in a pickle.

John Travis - Cerner - SME
Tying into what we were talking about earlier, that not every criterion that fits within this requirement is necessarily going to require the same manner of testing. For example, public health one-way submission isn't really going to test use. One of two things and maybe both, one is to say that, obviously the measurement is, I'm trying to remember did they bring the measurement down to B criteria level or is it broadly one measure? I can look at the measure.

Raj Ratwani - MedStar Health - Chair
I think it is broadly one measure.

Denise Webb - Individual - Chair
It's broadly, yes.

John Travis - Cerner - SME
Okay. So, what I was going to say is use in interoperability, if you accept those as the two main things to be tested, I would think the real point here is, I almost hate to open my mouth on this, but do we suggest the minimum to be a measure of interoperability and a measure of use? Because they are very different. Or that where it involves, the testing involves both, you do one measure of both? I'm just trying to reconcile what we've been talking about, different manners of measurement that really, are not at odds, they're just different.

Sasha TerMaat - Epic - Member
Yes.

John Travis - Cerner - SME

I don't know how burdensome it would be to say if you're going to do one general measure of something to say, do one general measure that focuses on use where ingestion or incorporation is part of what you do, and it's more towards what Raj was suggesting in that there's one measure of interoperability that's tied to conformance compliance or use compliance. I'm sorry, more like if you want to measure it based on production volume, or you want to measure it based on conformance, level of adherence towards the interoperability.

Denise Webb - Individual - Chair
So, I think if we're going to suggest that we wouldn't put it in this recommendation, we'd put it down in the recommendation around measures.

John Travis - Cerner - SME
Okay. That's fine.

Denise Webb - Individual - Chair
Rather than one that – a minimum of more than one measure if there's – you have to measure use and interoperability.

Raj Ratwani - MedStar Health - Chair
Yes, I think –

Denise Webb - Individual - Chair
I'm going to – let me just say, too, we need to really watch our time, we have over 30 recommendations to go through and we wrap up at 3:45 p.m. So, we do need to watch our time.

Raj Ratwani - MedStar Health - Chair
Okay. I mean, I think certainly we need to, I think we need to, we in the proposed rule needs to better articulate the difference between testing exchange versus testing use, given that not every exchange is going to require testing of use, given that there aren't end-users, and then, that's going to – different measures and some that are well-defined versus some that are open and the vendor gets to select what they believe is the appropriate measure.

Sasha TerMaat - Epic - Member
So, moving on to eight.

Denise Webb - Individual - Chair
I have some typos in eight, I just noticed. Sorry. I had to re-enter my changes. I was trying to clarify this because I thought the way it was worded was confusing and I wanted to make sure people understood what we were trying to say and hopefully, I captured what we're trying to say. There is additional within there, Sasha, on the third line. It says, "with with" and an additional –

Sasha TerMaat - Epic - Member
[Inaudible] [00:34:35].

Denise Webb - Individual - Chair.
Yes, I was cutting and pasting from the other document that I inadvertently edited. That was the wrong document.

Sasha TerMaat - Epic - Member
So, for the last example, I don't think it is reasonable to provide both endpoints in bidirectional testing scenarios. Some health IT developers will not have the mechanism for doing that. At least not in a real-world setting sort of way. If the idea is the developer has to build a test harness to do it. I mean, I guess that's technically possible if that's the goal of this. But if the goal is really like really to have a public health registry to test interoperability with, it's just not practical.

Denise Webb - Individual - Chair
Well, this is – I thought we were talking here with bidirectional if you go from one EHR product to another and you have a query response.

Sasha TerMaat - Epic - Member
I think we would need to clarify that, though. Because like immunization registry reporting is also bidirectional by definition. But you couldn't test it without a registry or a test harness. You could test one EHR connecting to another environment of the same EHR to see if it went back and forth. That's common. And if that is what you are intending with this, I think that would certainly be an option for some types of testing, but not all of the criteria, some of them are based on API usage, some of them are based on public health uses and they could be bidirectional, but they aren't necessarily **[inaudible] [00:36:36]**.

Denise Webb - Individual - Chair
I didn't – I actually was trying to clarify this, because I didn't understand what was being asked for, or what example was being illustrated in the original text. I think this was John's language. I don't – I mean, I find this confusing. What are we really trying to recommend here?

John Travis - Cerner - SME
I think what we were getting after there, and maybe we-we seem to have kind of conjoined two points. One is the expectation for the involvement of providers, is that a hard requirement? And that is kind of the first sentence and maybe the second. But then we move on to really getting at the role of external parties or third parties that may be necessary to carry out bidirectional testing. They're two separate points.

Sasha TerMaat - Epic - Member
Maybe if we say in the first sentence, ONC should clarify the expected involvement of providers and third parties to support the real-world testing.

John Travis - Cerner - SME
Yes, that – then the rest of the paragraph flows, yes.

Sasha TerMaat - Epic - Member

Right, because then we have one sentence saying providers should be involved but then they need guidance on that. Then they should also clarify how endpoints should work. The provider cost impact should be addressed. I also think perhaps there should be provisions for if you can't – if you are expected to recruit a public health agency into doing this testing with you, you make reasonable efforts to do so and can't. Then what?

Denise Webb - Individual - Chair
Oh, I think we addressed that in another comment. We actually say that they can be held harmless.

Sasha TerMaat - Epic - Member
Okay, that's great.

Denise Webb - Individual - Chair
If they can't get the third parties, yes.

Sasha TerMaat - Epic - Member
That sounds like we got that one. Okay, nine.

Raj Ratwani - MedStar Health - Chair
All right.

John Travis - Cerner - SME
Here you go. Yes, this is one I had brought up and I think it's worded for what it was after for the closing statement and then we're just bolting the things that should fit within that.

Denise Webb - Individual - Chair
Yes, and down below is a list of things that were questions.

John Travis - Cerner - SME
Yes. I don't have any issue with it, I don't think. I'm reading through it.

Denise Webb - Individual - Chair
I had a little bit, John, on production experience. For what already --

John Travis - Cerner - SME
Yes, I'm reading through it.

Denise Webb - Individual - Chair
Evidence and chemistry of operating real-world production requirements.

John Travis - Cerner - SME
Yes, I like that. I like that. The fourth bullet kind of sticks out a little bit. Because it's not – but it's a latitude of testing. I'm not – I'm fine with it, it just has a little bit different aim about unchanged capability or giving credit to other experiences. But it's a point that needs to be made.

Sasha TerMaat - Epic - Member
Yes, I think it is important.

John Travis - Cerner - SME
Yes, it's fine. It is a good recommendation.

Denise Webb - Individual - Chair
So, here's our measurement recommendation. Is this the place where we want to suggest that where there is testing of real-world use that there be a minimum of two measurement points?

John Travis - Cerner - SME
Yes, I think what we were saying is where the real-world testing is of both interoperability and you could say conformance if you want, but that may be too limiting. Just interoperability and use of received data. I was about to say EHI, but that's not exactly the term used here. Then there should be a corresponding measure for each.

Sasha TerMaat - Epic - Member
Is that the recommendation?

John Travis - Cerner - SME
Or that, yes, that's fine.

Raj Ratwani - MedStar Health - Chair
Although, if we're saying that the measuring use is now just measuring usability and safety in its design, would we just want to replicate those same measures which are measures of efficiency, effectiveness, and satisfaction?

John Travis - Cerner - SME
That might be a suggestion of a way that that could be done. I don't know if we'd want to limit it to that. I like that, Raj, what we talked earlier. We could point out as an example.

Sasha TerMaat - Epic - Member
One question, I guess just because I've only been thinking about that for the last five minutes or so, what if we suggested that that be a consideration after the pilot year? Because we recommended that they provide a template after the pilot year with recommendations and I think it could be reasonable to say let's adopt the SED measurements for use. But I don't want to, I guess, based on five minutes of consideration here, lock in something when there might be other approaches that would also be valuable?

Raj Ratwani - MedStar Health - Chair
Yes, that's a fair point. So, Sasha, you're saying keep it as one metric of use for the pilot year and then that can be refined?

Sasha TerMaat - Epic - Member
Yes. So, after the pilot year, consider updating metric expectations.

Raj Ratwani - MedStar Health - Chair
Yes, I think that's a great point.

Denise Webb - Individual - Chair
Okay, there you go. That's good.

Sasha TerMaat - Epic - Member
Okay did I get it?

Raj Ratwani - MedStar Health - Chair
Yes, I think so. Okay, on to 11.

Denise Webb - Individual - Chair
So, John you had brought this point out, I think Sasha did, too, about the fact that if there is that little nuance that ONC adopts the standard in the standards advancement process but it does not yet have testing tools available. And the current regulation allowed attestation by the IT developer. You were concerned about that. Like, well, then how do you really judge or determine conformance? So, I did reword this a little bit to be a bit clearer about that.

John Travis - Cerner - SME
Yes, I think you worded it pretty good.

Sasha TerMaat - Epic - Member
I'm comfortable with it.

Denise Webb - Individual - Chair
If you want to, do you want to –

John Travis - Cerner - SME
No, I think you worded it – it's really good wording.

Denise Webb - Individual - Chair
Okay.

Sasha TerMaat - Epic - Member
Oh, and here's -- 12 is the one you mentioned to me earlier.

Denise Webb - Individual - Chair
Yes. I think these had questions and I flipped them around.

Sasha TerMaat - Epic - Member

I think that makes sense.

Denise Webb - Individual - Chair
Does that capture it?

Sasha TerMaat - Epic - Member
It does to me.

John Travis - Cerner - SME
Let me give it a read here. Yes, that is fine.

Denise Webb - Individual - Chair
Raj, are you good with it?

Raj Ratwani - MedStar Health - Chair
Works for me.

Denise Webb - Individual - Chair
Okay.

Sasha TerMaat - Epic - Member
Denise, I answered your question about 13? Is that helpful?

Denise Webb - Individual - Chair
Yes, thank you, because I wasn't sure. There are so many estimates, time estimate to complete development and so forth. I think we just need to be kind of crystal clear. And I would assume that's if they're going to accept these suggestions that they would have to go back in and revise those estimates.

Sasha TerMaat - Epic - Member
Yes, I mean, we suggested, for example, accounting for the provider time, but then also depending on the settings expected to be tested, I could see that times estimated it could be far too low if they expect a large variety of settings to be tested, for example.

Denise Webb - Individual - Chair
Yes. Yes, I mean, maybe would say to ensure they are accurate and aligned with the clarified understanding of the proposal. And when you say the proposal for real-world testing you mean, right?

Sasha TerMaat - Epic - Member
Yes.

Denise Webb - Individual - Chair
And aligned to rather than aligned? Aligned to?

Sasha TerMaat - Epic - Member
Does that say to?

Denise Webb - Individual - Chair
Take your ED out. And aligned to. Yes, there you go.

John Travis - Cerner - SME
She hasn't done it yet.

Denise Webb - Individual - Chair
And then I got your word testing. The real-world testing proposal.

Sasha TerMaat - Epic - Member
The word's in my mind. Thank you.

Denise Webb - Individual - Chair
All right, there you go. Got it, thanks. I changed this because they actually require semiannual middle of the year and the end-of-the-year for attestations.

Sasha TerMaat - Epic - Member
Okay. I am fine with 14.

Denise Webb - Individual - Chair
And I did add that last sentence. I think I added that, too. Yes. That keeps it away from hot – when you pick the last Friday of the month twice a year. It keeps it away from any odd days and that kind of thing.

Sasha TerMaat - Epic - Member
Does this call need public comment or no?

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Yes, we will have it in about 15 minutes.

Denise Webb - Individual - Chair
Okay, let's keep cruising. On this one, I didn't think we were crystal clear about where we were really having an issue and I remember from the conversation it was the relationship between the API technology supplier and API user was never really discussed. In the rule or preamble at all.

John Travis - Cerner - SME
Yes. It seemed like they were, and maybe it was my reading of it, but I think it was in evidence and certainly by other things stated about who they assume fees can be between. It almost seems, and maybe they just regard it as out of scope, which is why the need for clarification, they weren't barring it, they were mum on it. But they seem to not consider there will be relationships between API users and API technology suppliers for the purpose of bringing applications to market that don't involve a

provider. At least not initially, and therefore may not involve an API data provider. So, the fact that there could be a collaboration between an API user as an app developer and API technology vendor, isn't given much regarding. Now whether that is intentional or it's just simply they don't speak to it and it's permitted, given that it's mum. I think it would help to make that clear one way or another. We're not asking them to necessarily go regulate further an area that they don't really, they may not need to. But they need to make it clear about whether or not the regulation speaks to it because people could make the wrong assumption about that.

Denise Webb - Individual - Chair
Right. And maybe it's just an oversight and this recommendation will help them think about that. Okay.

John Travis - Cerner - SME
Yes.

Denise Webb - Individual - Chair
All right. The next one is recommendation 16 and I had a comment attached to this. We did not elaborate here, and maybe Sasha, since you are typing, we can add just something brief on recommendation 16. On the – our major theme about why we're recommending option four.

Sasha TerMaat - Epic - Member
Okay, so we said it was the first normative version of fire.

John Travis - Cerner - SME
Yes.

Denise Webb - Individual - Chair
Yes.

Sasha TerMaat - Epic - Member
It supported enhanced capabilities over the other versions.

Denise Webb - Individual - Chair
Yes. And I know we were concerned about bulk patient data request. So, handling –

John Travis - Cerner - SME
Yes, handing – yes.

Denise Webb - Individual - Chair
Versus leaving at wide-open or a free-for-all for handling that other API in terms of population versus individual patients. So, that's good. Yes, I just thought we should, so when Raj and I present this, we can kind of give some elaboration as to why we're recommending this. Okay. And I just added some clarification on the next one. Just to say why this would be good.

Sasha TerMaat - Epic - Member

That makes sense.

Denise Webb - Individual - Chair
Okay. All right. Recommendation number 18. I just took the questions and said to please clarify who plays the role and how the determination is to be made on who plays what role.

Sasha TerMaat - Epic - Member
Is this list specifically about providing tokens to apps that can't be trusted to keep a secret?

Denise Webb - Individual - Chair
Yes.

Sasha TerMaat - Epic - Member
Should we spell that out?

Denise Webb - Individual - Chair
Yes.

Sasha TerMaat - Epic - Member
I don't know that we expect health IT developers to do it or do you mean you expect the app developer to keep the token confidential? I think we asked who is going to ensure if a persistent token is required to be given to the API user, who ensures that the API user is creating a product that is capable of keeping the token properly secured?

Denise Webb - Individual - Chair
Okay, we should probably say that, yes. Because this definitely was not clear. I don't think I – did I type that this is something we expect the health IT developers to do?

Sasha TerMaat - Epic - Member
I think that was my initial take on it. Sorry about that.

Denise Webb - Individual - Chair
Okay, no not a problem. Yes, I think we didn't know who was expected to do this. Do you mean the API users are creating products?

Sasha TerMaat - Epic - Member
Sure, they are creating apps, right?

Denise Webb - Individual - Chair
Oh, okay.

John Travis - Cerner - SME
Yes, the API user embraces both individual users as users in the traditional sense as app developers, by its definition.

Denise Webb - Individual - Chair
Add a comma after appropriately. Thank you. Who it is and how the determination – okay, that's good. That's good, Sasha.

Sasha TerMaat - Epic - Member
Okay, 19?

Denise Webb - Individual - Chair
All right.

Sasha TerMaat - Epic - Member
Should we – okay, I think this is also partially resolved by suggesting entire version four where there is a standard approach.

Denise Webb - Individual - Chair
Yes. We could reference this just for they're – reinforces our recommendation for option four. That is good. If we are going too fast and you want, please jump in. And then I reworded this a little bit.

Sasha TerMaat - Epic - Member
Twenty?

Denise Webb - Individual - Chair
Oh, sorry, no. I did have a question on this one, is this out of order because when I was looking in the preamble, I could not find this in the preamble. I looked before app registration, but it jumps from search to registration. Do you remember what page that was on?

Sasha TerMaat - Epic - Member
No, but I remember the discussion, which was that the requirement is to update API documentation within six months, but I think I asked what is it updated to show because the APIs themselves don't have to be updated to support the new requirements until 24 months. So, I didn't know, it seemed weird to update the documentation prior to the actual APIs.

Denise Webb - Individual - Chair
Right, so let's add the acronym API in front of the documentation. And then I would put CMC TF, I think that is the convention we are using to differentiate us from the other ones. Okay, great. All right. That clarifies it. I tried to find this, and I was like, okay, what is this? And Kate if this is not the right order, because it does help people just from a logical organizational standpoint to sequence this in the order that it is found in the preamble.

Kate Tipping - Office of the National Coordinator - Staff Lead
Right. Yes, I will go back and double check that.

Denise Webb - Individual - Chair

Okay, all right. I know you're going to be renumbering these because we have one additional recommendation. Okay. Now on 21. I didn't really take anything out of here, I just changed the wording to just tell them what we want considered to be done.

Sasha TerMaat - Epic - Member
Denise, do you mind if I accept all your wording changes and then read it, just for clarity?

Denise Webb - Individual - Chair
Absolutely. Yes, I just took it out of the question mode.

Sasha TerMaat - Epic - Member
I don't want to interfere with our change control but sometimes we get so many comments in there that I find it difficult to actually parse what we are proposing. Okay, I think we want to say who is – the way you had it was fine. Because they have to address the party responsible –

Denise Webb - Individual - Chair
You could put what the practice of registration consists of doesn't consist of and who the party responsible for keeping a list of registered apps is. And who is the party?

Sasha TerMaat - Epic - Member
Okay.

Denise Webb - Individual - Chair
Yes, that looks good. Yes. Okay. Missing space to describing the tasks on the next bullet.

Sasha TerMaat - Epic - Member
I think what we are really saying here is basically that –

Denise Webb - Individual - Chair
Not a liability?

Sasha TerMaat - Epic - Member
Right. That there is no liability.

Denise Webb - Individual - Chair
That the party is not liable, you could just say.

Sasha TerMaat - Epic - Member
That –

Denise Webb - Individual - Chair
Yes, the party is not liable.

Sasha TerMaat - Epic - Member

I'm just going to say we could give that just a little thought over the next 30 seconds or so while we break for public comment.

Denise Webb - Individual - Chair
Okay, sounds good.

Sasha TerMaat - Epic - Member
Okay. Operator, can you please open the line?

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

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Okay, and then while we're waiting for folks to dial in, so we have just about 10 minutes left. I know we hadn't gotten through everything yet, but Kate or Denise, do you have any thoughts in terms of just wrapping up here, or do you just want to keep pushing for the last 10 minutes?

Denise Webb - Individual - Chair
Oh, I think we should try to get through. I mean, I think the more difficult comments were upfront. It's where we had a lot of discussion around real-world testing. Maybe the rest of this might go a little faster, and I guess what we're going to need people to do is to read through the rest of the changes. Because I know, Kate, you need to get this out to the full committee, right? Today?

Kate Tipping - Office of the National Coordinator - Staff Lead
Yes, yes.

Sasha TerMaat - Epic - Member
So, just looking quickly, I am good with 22 through 25. I don't know if others have any thoughts on those. And now I'm looking at 26.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Let me just pause here. Operator, do we have any comments in the queue?

Operator
There are none in the queue.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Okay, thanks. So, I'll let us get back to this and it sounds like we will try to push through as much as we can.

Denise Webb - Individual - Chair

Can you enlarge that? Oh, thank you.

Raj Ratwani - MedStar Health - Chair
Yes, those all look good to me as well.

John Travis - Cerner - SME
Yes, I don't have any.

Denise Webb - Individual - Chair
And the electronic prescribing, I think we took that verbatim, pretty much.

Sasha TerMaat - Epic - Member
Yes, and like John said something that I had wrong in what we had proposed. I think this is fine.

John Travis - Cerner - SME
Yes, we were trying to make it largely match up to the current standard certification requirement leaving as optional the things that fell outside of that.

Denise Webb - Individual - Chair
On the quality piece, number 27 I did not put a comment in, we didn't really put any elaboration for what the –

John Travis - Cerner - SME
I think that was almost like a technical correction Sasha offered because they were not correct in the alignment of the QRDA to the domains where they apply.

Sasha TerMaat - Epic - Member
Yes, it really wouldn't work for importing.

Denise Webb - Individual - Chair
Pardon?

John Travis - Cerner - SME
Right.

Denise Webb - Individual - Chair
All right. So, do we want to specify that we think what they proposed is not technically correct, and this would correct the –

John Travis - Cerner - SME
Yes.

Denise Webb - Individual - Chair
Okay, there you go. So, then it should be apparent.

Sasha TerMaat - Epic - Member
Twenty-nine seems fine.

John Travis - Cerner - SME
Yes.

Sasha TerMaat - Epic - Member
Thirty seems fine.

John Travis - Cerner - SME
Yes. What do we have, one more?

Sasha TerMaat - Epic - Member
Two more. Thirty-one.

John Travis - Cerner - SME
That was with respect to their –

Sasha TerMaat - Epic - Member
Yes, 31 seems fine.

Denise Webb - Individual - Chair
I explained I gave just sort of an elaboration on this because it will help the rest of the committee understand what we're doing.

John Travis - Cerner - SME
Thirty-two was fine. Kind of a principal moving forward.

Sasha TerMaat - Epic - Member
Yes. I think we're good.

Denise Webb - Individual - Chair
Take it and apply it and see what else they can remove before they publish a final rule.

Sasha TerMaat - Epic - Member
Sounds good.

Denise Webb - Individual - Chair
Did we miss anything? I think Kate – thank you, Kate, you did a great job pulling things in.

Kate Tipping - Office of the National Coordinator - Staff Lead
Yes, I was just going to say, did I miss any?

Sasha TerMaat - Epic - Member
I'm not remembering any offhand.

John Travis - Cerner - SME
Pretty thorough there.

Denise Webb - Individual - Chair
Great job task force.

Kate Tipping - Office of the National Coordinator - Staff Lead
Go, team.

John Travis - Cerner - SME
Yes.

Denise Webb - Individual - Chair
Okay, so obviously, once you accept all these changes, you'll need to read through to make sure there are no typos. You know how it is with tracking changes and then accepting them. Sometimes there are unintended consequences. And some renumbering because we did add that one new recommendation. So, that puts us at what, 34? How many totals did we have, 33 plus one? No, 33 we'll have. Thirty-three recommendations.

Kate Tipping - Office of the National Coordinator - Staff Lead
And you will have 45 minutes to present.

Denise Webb - Individual - Chair
Plus, we have to save time out of the 45 minutes for questions and answers.

Kate Tipping - Office of the National Coordinator - Staff Lead
Correct. So, I think it's – Lauren, correct me if I'm wrong, is it more like 20 minutes?

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Yes, I'd say like between 20 and 25 minutes.

Denise Webb - Individual - Chair
All right.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
We can adjust if – some of the task forces may not have as many recommendations. So, if we need to adjust real time, we can do that. But we'll try to split that 45 minutes up in half.

Denise Webb - Individual - Chair

So, Raj, you'll probably want to – we can both look through this and see how we want to split it up. If we want to split it up how we led the meetings, or I'm open to whatever you suggest. And we can talk a few minutes about that when we debrief.

Raj Ratwani - MedStar Health - Chair
Yes, that sounds good.

Denise Webb - Individual - Chair
So, task force, is there anything else Raj and I need to make sure gets covered, and Kate, or are you all comfortable with this going forth to the whole committee now?

John Travis - Cerner - SME
Yes.

Sasha TerMaat - Epic - Member
I am ready for it to go.

Denise Webb - Individual - Chair
Okay. All right. I think that we might get the five gold stars. We got our job done. I don't know about the other task forces. Because Sasha and I are on another one, and I don't know where they're at.

Sasha TerMaat - Epic - Member
And they still have a lot of hours of meetings left, too.

Denise Webb - Individual - Chair
Yes, they do.

Sasha TerMaat - Epic - Member
Yes, so it's a mad dash to the finish line here.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Okay, it looks like we are in a good place at least for getting our first set of draft recommendations to the full committee next week. Kate, I will follow-up you off-line just in getting everything prepped and ready to go. Otherwise, Kate are you going to be in person?

Kate Tipping - Office of the National Coordinator - Staff Lead
I will not.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
Okay, you'll be on the phone, I take it?

Kate Tipping - Office of the National Coordinator - Staff Lead
Mm-hmm, yes.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
All right. Okay, so I think with that we can adjourn today. Otherwise, if there's anything else, we will follow up with email.

Denise Webb - Individual - Chair
All right, we will see everybody in Washington. I don't know if John, you're going to pay a visit and show up as part of the public?

John Travis - Cerner - SME
I would, that's on which day? That's on the 19th?

Denise Webb - Individual - Chair
Yes.

John Travis - Cerner - SME
Okay. Yes, I would actually like to. I will see if I can arrange that.

Denise Webb - Individual - Chair
And if not, certainly dial-in.

John Travis - Cerner - SME
Yes. No, I would like to try and make it in person. It is good to do that at times.

Denise Webb - Individual - Chair
Hear about the broader committee has to say about the work we did.

John Travis - Cerner - SME
Yes. All right. I will see if I can arrange that.

Denise Webb - Individual - Chair
Otherwise, I'll see the rest of the team there next week.

Lauren Richie - Office of the National Coordinator - Designated Federal Officer
All right. Thank you.

Raj Ratwani - MedStar Health - Chair
Thanks, all.

Denise Webb - Individual - Chair
Raj, we'll dial in really quick and talk to folks about any debrief.

Raj Ratwani - MedStar Health - Chair
Yes, sounds good.

Denise Webb - Individual - Chair
Okay, all right. Thanks, everybody.

Raj Ratwani - MedStar Health - Chair
Bye-bye.