Conditions and Maintenance of Certification Requirements Task Force

Transcript
March 6, 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
Katie Tipping	Office of the National Coordinator	Staff Lead
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

Operator

All lines are now bridged.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Okay. Good afternoon everyone, and welcome to the conditions of maintenance and certification task force under the health information and technology advisory committee. We will jump right into things, starting with rollcall. 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

Carolyn indicated that she was going to be absent and I believe Ken is still on vacation, as well. Sasha Termaat? **[Inaudible] {00:00:37]** not yet. 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 our chairs to just a quick review of our charge and our roster again before we dive into discussions around real-world testing. Either Kate or Denise?

Denise Webb – Individual – Chair

Kate, do you want to go ahead and do the review of our charge? And then I think Raj is going to lead the discussion real-world testing.

Raj Ratwani – MedStar Health – Chair

Yes.

Kate Tipping – Office of the national Coordinator – Staff Lead

Sure. So, just another review of the charge. So, the commissions and maintenance of certification requirements task force, we will be looking at the conditions of certification. The three we will be looking at are the real-world testing, the application programming interfaces, and attestations. This task force will also be looking at the – any updates to the 2015 edition certification criteria, modifications to the ONC health IT certification program, and the deregulatory actions noted in the proposed rule.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Thanks, Kate.

Raj Ratwani – MedStar Health – Chair

Great, and today we are going to continue addressing the real-world testing criteria. I think we got a relatively good start yesterday, and we'll get moving on that. And then if time, we'll hit the attestations piece. Kate was kind enough, at some odd hour, I think late last night, early this morning, thank you for all the hard work there, put together a Google doc where

can pull up each of the proposed criteria and start walking through those in a more systematic fashion.

So, at a high level, what you have up in front of you right now, just to remind you, is the general conditions of certification for real-world testing that now would require that health IT developers have a successfully tested the real-world use of technology for inoperability. And we started getting into some of the issues yesterday around what types of settings and scenarios and test cases, etc. So, why don't we dive right in and pull up that, maybe pull up the doc, and start walking through those criteria.

Kate Tipping – Office of the national Coordinator – Staff Lead

Great. Let me go ahead and share my screen. Okay, can you see it?

Denise Webb – Individual – Chair

Not yet.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

I know sometimes there is a little bit of a delay, but we'll give it another couple of seconds.

Denise Webb – Individual – Chair

And did Katie stop sharing so Kate could share?

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

I think it is starting now.

Denise Webb – Individual – Chair

Okay.

Kate Tipping – Office of the national Coordinator – Staff Lead

Can you see it yet?

Raj Ratwani – MedStar Health – Chair

Not yet.

Denise Webb – Individual – Chair

All right, now it's up.

Kate Tipping – Office of the national Coordinator – Staff Lead

Okay. So, this is starting with real-world testing. This is the regulatory – proposed regulatory text. And down at the bottom here I just added some comments that were made yesterday that John had submitted.

Raj Ratwani – MedStar Health – Chair

Great. Thank you, Kate. And John, thank you for sending that list of items. It's going to be really helpful. So, why don't we should jump to the top of the document and start going through the proposed rule here. Some of these things we may have addressed yesterday, and so we can just kind of tag them as such, and we can start delving into the others. Does that work for everybody?

Kate Tipping – Office of the national Coordinator – Staff Lead

Mm-hmm.

Raj Ratwani – MedStar Health – Chair

Okay, great. All right, so, I know yesterday there were some comments around the timing of this in terms of when the testing plan would have to be kind of executed upon. So, the first item – so, I am jumping down to B1. It has December 15 of the calendar year for the certified health IT modules. I do not know if that is actually when the testing is done or posting.

Denise Webb – Individual – Chair

Well, as I read through this, I was just going to say, as I read the text on this, both the ONC ACB and the health IT developer have the same due date for the test plan being published on the CHPL site by December 15 to make it available to ONC. So, that will require coordination between the health IT developer and the ONC ACB, so that they mutually or together hit that date. So, I would defer to John, as a health IT vendor representative on whether there is something we would want to propose differently regarding that timeline. I know Sasha had some concerns about the time of year. Of course, this is to submit this in advance of the holidays. It's probably more the deadline for the testing results that might be more of an issue.

John Travis – Cerner – SME

Yes, she had suggested, I do not know that she had a specific date in mind other than that, but just that that would run into a potentially problematic time frame for being able to compile things effectively by then. And I had made a suggestion if another – I realize that ONC probably wants everything batched together from a given vendor so that they're not dealing with piecemeal. But an alternative might be to use the anniversary date of a product certification. They deal with so much that gets submitted in a certified product specific context. That would be an alternative.

I realize – I think they probably value having a comprehension of all that a vendor does and all that a vendor might do across the waterfront of their certified H IT. And that may be a

compelling interest, it just kind of rules the day on it. The one major alternative, again, would be to focus it on, since we have to do it per product per domain, to consider doing it based on something like the anniversary date of a certification. So, we throw that out there, that's one –

Denise Webb – Individual – Chair

That would present some flexibility. In fact, I did note that the vendor, the health IT developer vendor, could compile their test plan to address their suite of product particularly where the testing is done across different modules or products by the vendor anyway. But I guess one thing I think about having everything have to come in on the same date, that also presents a workload for the federal government and for the ONC ACB versus staggering it based on last certification date.

Raj Ratwani – MedStar Health – Chair

Just because we have a long list of items to get through and a short amount of time, I think there's a general consensus that the date should be thought through, perhaps to avoid the holidays, perhaps to avoid a glut of reports coming into the federal government for processing, etc. So, maybe we can, kind of, for now, leave the note at that and have something that says perhaps this date should be revisited given those concerns. Then we can sort of keep moving on.

Denise Webb – Individual – Chair

Right. We can form a recommendation around that, to possibly suggest staggering those submissions based on another criterion.

Raj Ratwani – MedStar Health – Chair

Perfect. So, B2, I'm sorry, BI is where we are now. Any concerns around the plan must be approved by Health IT developer authorized representative?

John Travis – Cerner – SME

No, I don't think so.

Denise Webb – Individual – Chair

That makes sense.

John Travis – Cerner – SME

The only thing I'm trying to remember, Raj, is – I mean it's probably to be interpreted by the HIT vendor themselves, as to what they mean by an authorized representative. I don't know if there is any language ONC would offer to say, you know, kind of a minimum acceptance whether it's an officer or an executive. I don't want to make it too complicated. That's the only thing we get into sometimes in our own policies around who can sign and represent. If

ONC wants to leave that up to the vendor, it's not any big deal, but they might actually be looking for somebody who speaks a little higher authority than somebody who is like a senior manager or a director over a specific certification function or something like that.

Denise Webb – Individual – Chair

So, John, you know because I dealt with this when I was at Marshfield, who had authority to sign what. I think it is specified in most company's policies who can bind the company for different types of **[inaudible] [00:12:29]**. But I don't know that the federal government would want to get into being prescriptive on that, setting a lower bar. I would suggest that that's probably – this is pretty standard practice.

John Travis – Cerner – SME

Yes, that's fine.

Raj Ratwani – MedStar Health – Chair

Okay, great. Okay, then we jump into the certification criteria that the plan must address and so I think this is some more of the meat of it, so –

Denise Webb – Individual – Chair

So, clearly, the test plans have to address the certification criteria related to interoperability. ONC does ask and solicits for comment on whether to also include patient health information capture certification criteria on page 279. So, I do not know if we as the task force want to discuss that. Whether – not only what is being covered, but what about that addition? Right here at the top of the page.

John Travis – Cerner – SME

Let me look at one thing real quick. As we were going through in our internal review we noted –

Denise Webb – Individual – Chair

The previous page lists all the criteria that are applicable on page 278 that would have to be addressed in the test plan. So probably John, I would be interested in your perspective on whether you had any concerns.

John Travis – Cerner – SME

Definitely not with the interoperability criteria. I think that's fair. And that's obviously what's important to them. The patient health information capture I do not think it took any particularly strong reaction to, although, it is a pretty open-ended criteria requirement in terms of what a vendor may do to test for it. And so, it's not quite in the same vein as the other criteria. So, I do not know if it fits really well on that basis. But there is nothing inherently wrong with it. Maybe it can be considered an optional item at best, but at least for

this.

Denise Webb – Individual – Chair

Raj did you have any strong feelings on this? Because if none of us has any strong feelings on it, I don't know that we have to provide a comment. It's just I wanted to make sure we collectively hit any area in here where they asked us to consider comments.

Raj Ratwani – MedStar Health – Chair

Yes, good point. I don't, either.

Denise Webb – Individual – Chair

Can we back up on this page, back to the list, because I want to speak from my experience in public health? I know we were supposed to have somebody in the group that was representing the public health, weren't we, Lauren?

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Yes, that's Les. I don't think he is on today, but I will reach out to him and make sure that he is on the calls moving forward.

John Travis – Cerner – SME

No, I was going to say the one thing to take care with the F criteria is that not all of them are required in any way. They're not part of the base EHR. They're not part of the definition of certain quite the same way that the interoperability requirements are. So, it may be that there is a relative statement conditioned on – I mean obviously the vendor hadn't certified to it, but I don't want it to be taken that there is an implication that everything necessarily must be tested for every venue. Because not all of them also are necessarily appropriate to every venue. So, that could be accounted for in the plan, I just would want to make sure it's –

Denise Webb – Individual – Chair

But I think if you're going to deliver your product to a health system it has to be able to exchange information with public health –immunizations, **[inaudible] {00:16:58]** surveillance data, lab results, reportable lab results, at a minimum. Those are all interoperability exchange functions.

John Travis – Cerner – SME

No, I am really just referring to the fact that I think if it's self-defining in here already that the vendor must include in their real-world testing plans to the degree that they'd certified to those criteria, absolutely. I think that's where it stays. It doesn't imply anything else like you must necessarily test for each of those criteria and each venue. If not already part of – it really should be self-defining I guess is what I'm saying.

Denise Webb – Individual – Chair

Well, that second part is where I was going to make some comments, having my public health experience and having worked –

John Travis – Cerner – SME

Okay, please go ahead.

Denise Webb – Individual – Chair

So it's not so much about the fact that this should or should not be included as criteria that would have to be part of the test plan. I guess what I would be concerned about testing in real-world with the public health agencies and all of the states in the nation if your product covers all of those different venues. Again it points to a concern that you and Sasha had yesterday about the broadness. That there are really no guardrails around care setting and venue, to what extent the test plan has to cover. What proportion of health agencies and that kind of thing. So, that would just be my general comment.

John Travis – Cerner – SME

No, I think that's fair and I think this ties into some of those comments we did include in what I sent on the potential role of third parties. Who is going to set up to be a legitimate and recognized entity as a testing partner to be submitted or to engage in bidirectional communication with? And that, to your 50-state comment, there is a scalability question in there. Again, maybe it's what the vendor proposes, as long as it's accepted, but there aren't many guardrails around that criterion or that set of criteria in particular.

Denise Webb – Individual – Chair

So, Raj, I think it's worth noting – I mean I guess the concern is the broadness of this. It probably would probably be helpful to health IT vendors if there was some kind of guardrail around care setting, and I know we have a specific line on that, so I'll let you continue, Raj.

Raj Ratwani – MedStar Health – Chair

I think those are good points. I did a more detailed reading of the exact language this morning, and what it seems like is happening is that it's been deliberately made quite broad, allowing the vendor for some flexibility here. And I think perhaps one recommendation we should be making is to provide them guidelines or templates of kind of a test plan. And I think that could be quite effective and that's been done for some of the safety-enhanced design requirements in the past. NIST (the National Institute of Standards and Technology) provided a template for vendors to follow for user-centered design and somewhat of usability testing. And so, something like that, it doesn't have to be a required template but a suggested template I think could help this process a lot. That could potentially be a strong non-regulatory way of handling some of this.

Denise Webb – Individual – Chair

That could be a good recommendation because I know that a health IT vendor has to specify what care settings they chose and justify why. And they have to adequately represent a portion of their customer base in terms of volumes and those kinds of things.

Raj Ratwani – MedStar Health – Chair

Yes.

John Travis – Cerner – SME

This becomes one of those things where you give guidance to the vendor on how to set up what the market will take as a legitimate test. While they give the vendor a lot of discretion, I can't believe ONC would want to leave it so much up to the vendor that you wind up with a very wide variability in the quality and scope of the test plans.

Raj Ratwani – MedStar Health – Chair

I agree.

Denise Webb – Individual – Chair

I think some guidelines/ guardrails would be nice.

Raj Ratwani – MedStar Health – Chair

Yes, I agree. So, let's kind of note that maybe as a templated test plan that could be provided as a suggested process or something like that. So, jumping back to the doc that's up now, we're walking through each of the certification criteria that have to be in the plan. So, a) is the testing methodology that'll be used to demonstrate real-world interoperability including scenario and use case focus testing. I think we yesterday discussed the recommendation, or at least the issue around what is a scenario versus a use case testing?

Denise Webb – Individual – Chair

Or are they the same? We should make a recommendation on clearing that up because as I read further into the preamble, there is a section where it talks about, for example doing a scenario base. Let me see, I think it was on page 283. "Developers can and should design scenario-based test cases that incorporate multiple functionalities as appropriate for the real-world workflow and setting." Well described that way, that sounds like use case. Are they one and the same? So, I think they need definition.

Raj Ratwani – MedStar Health – Chair

I agree. I think there needs to be clarification around scenario versus use case versus workflow. And I think the other clarification that is needed, and this came up yesterday as well, is this about testing the exchange of information or is it about testing the exchange and use of information? And I think that's an important point because testing the use of that information requires much more of a human cognition, human factors, and usability element

to it. And the definition of interoperability that's provided under the real-world testing description says the use of electronic health information – it's not exchange and use. And so, if we're testing use that means I think we should consider whether we need to have – that would suggest that we would need to have the providers involved in the testing and being able to determine whether the providers can actually process and digest the information that's being exchanged.

John Travis – Cerner – SME

Yes. I think it builds a lot more on some of the current state usability – you know an SED testing type of an approach, where you do have to involve the providers. And I might add –

Denise Webb – Individual – Chair

Yeah, it does play – Go ahead John, sorry.

John Travis – Cerner – SME

I was just going to say, to add to Raj's comment, I think it's dealing with recording and use. So, is that a part of what the boundary of testing is? Because they do want it distinguished from what certification testing accomplishes. I mean they don't need us to go literally repeat what is done in the testing laboratory to attain the initial certification. They want it to be grounded in a practical utility of real-world use so that does suggest I think those things are part of it. I just want to make that clearer.

Raj Ratwani – MedStar Health – Chair

I think that is a very important point. Go ahead, Denise.

Denise Webb – Individual – Chair

On the top of 278, it gives three bulleted items that define what successful real-world testing means. The last bullet does say electronic health information is received by and used in the certified health IT. It doesn't say used by the provider but used in the product. So, if you receive, you know, if you receive the data element defined in the USCDI, are they incorporated and made available to the provider to reference in their workflow and so forth? So, it's used in, it doesn't say used by providers in the certified health IT. It's really talking about the product ingesting the information. Not just receiving it, but then doing something with it.

Raj Ratwani – MedStar Health – Chair

Yes, I agree.

Denise Webb – Individual – Chair

I think that is testable, I mean right John? You can demonstrate that. That when information comes in through an exchange that your product does something with it.

John Travis – Cerner – SME

Yes. It resolves matching to a record. It shows its ability to be brought up and displayed. It may also include some processing attributes if that's part of it. I think of the way that they constructed clinical reconciliation, for example.

Denise Webb – Individual – Chair

Yes, I think it is worth having that clarification, Raj, because if there's ambiguity about whether providers physically have to be involved in this testing –

Raj Ratwani – MedStar Health – Chair

Yes, I think that's right. What I'm seeing I think is a little bit of a nuance, Denise, from what you're highlighting and what's here. So there's, in my mind, there's information being exchanged. And in this case, it's articulating that it's being received. That's the health IT system receiving the particular data elements that were sent over. That's all and well. Then used in the certified health IT – so to your point, Denise I take that as meaning the receiving health IT system can now process that information in some method. So that's the health IT system using the information that's being exchanged. The other thing that is critically important that we need clarification on, is the information then usable and useful to the provider that it's being sent to or the patient that it's being sent to? And, to me, that's the whole point of exchanging this information is so that eventually it's getting into the hands of a clinician or patient in a useful and usable format. And it seems like real-world testing, the point of real-world testing, is to get at that very last piece and to make sure that after we go through this exchange process that it's actually usable and useful. And so I think there has to be clarity there as to what real-world testing is trying to get at.

Denise Webb – Individual – Chair

Right, and if that's expected then I agree with John and Sasha that there has to be some estimate of the impact on provider organizations being involved in that testing.

Raj Ratwani – MedStar Health – Chair

Absolutely, I completely agree. I think that is – potentially it'll be more work. Okay so, we're turning back to our document right here. So, for part A I think we discussed that. Part B, we talked about needing some clarification on the care settings themselves. John, any more specific thoughts here? I know some things came up yesterday.

John Travis – Cerner – SME

Yes. I think what we were looking at is, things that could be, they're not necessarily suggestions because I'm not sure they're the right level. But in the past, we've had a couple of sources that could be examples. Well one, so the early programs, the early editions differentiated between hospital and ambulatory. CCH IT used to have some further differentiation on domains that were not part of the certification program as ONC recognized

it but were offered up for long-term care venues, pediatrics, a few like that. You also have – there is a suggestion in the rule that draws on the way that use data used to be presented attestation data and performance data for the meaningful use program, and how CMS presented the data. They outright, I think, call out an exhibit of that kind to say well this could be a way you do it. But I think there needs to be a consistency of what the expectation is so that you get par level test cases.

I don't think that should be that variable as it seems to be in terms of what the rule calls for, for the vendor to kind of – it's fine for the vendor to say these are the venues we market into, and there may need to be some accounting for the difference in the way they understand venue but it should be pretty par level, so that vendors are testing at a fairly consistent level with regard to how they develop and describe their test plans and their testing approach and results. You could consider using some of the higher levels of provider taxonomy if you're getting into the ambulatory space, which is where you really could get variability of approach.

Raj Ratwani – MedStar Health – Chair

Right. Okay, I think between the conversation yesterday and your comments now, John, I think we have a recommendation we can formulate around that if we want to move in that direction.

John Travis – Cerner – SME

Okay.

Raj Ratwani – MedStar Health – Chair

Are we down to C?

John Travis – Cerner – SME

I think one other thing, and I don't know if it belongs under A but I know we talked about it is the role – it's the word methodology, so, the use of automated testing or the use of regression testing, especially where you have prior capability that has already been taken through this exercise at least once. And the capabilities don't change. The requirements don't change, and the venues don't really change. Is there a role for either a regression approach or is there a role for attestation to things not having changed? Or, is there a role for relying on real-world performance, actual production performance as evidence that would allow you to get some lift or some leverage from the fact that the capabilities used in production on a daily basis on a wide number of sites. Does that have any standing for being accepted as a result or moot point?

Denise Webb – Individual – Chair

So is your concern, John, on that that if, let's say, in 2019 you submit your results for your current certified products for your real-world testing – that's assuming that this is all in place

so I'm just using artificial dates here – and then when you go to submit your plan for 2020, or excuse me, the plan that you submitted for the 2019 testing. The 2019 results that you supplied were for 2018. But your plan for 2019, let's say you don't plan to make any substantive changes or go to a new version under the version advancement process of ONC or any of these criteria that are subject to this real-world testing, are you suggesting that you would be able to instead just attest that you were not making any changes and therefore you are not submitting the new test plan, the test plan that you have there. I guess that was the part that was unclear to me – what if the vendors are changing certain things on their product.

John Travis – Cerner – SME

That is a fair question. I think there would have to be conditions that would govern nothing changed. So, a couple of things. I think there are probably three things I would say. The first if it's not a new capability, and it was part of a prior year's test plan and results submission, I think the minimum case is there needs to be an opportunity to differentiate by the testing approach – something that allows for efficient regression testing. So, you know, maybe I do test it again, but I don't need it to be as rigorous around constructing a formalized use case approach if I can provide a regression. It's existing software. It's been through this before and maybe that's only allowed if I – I may need to make attestation statements that the capability really has not changed or nothing material has occurred and that a regression result should be accepted and furthermore could be automated. Or there is an allowance for that. The vendor could choose to submit those things.

The idea of saying I could attest to that without having to test it would be an alternative on that same type of idea. If I did nothing to adopt new versions of the standard that's subject matter here I, in fact, didn't really do any material enhancement to it that would raise concerns about the capabilities of the certified product being aggregated by new development –things of that nature. I know that is probably –it's still something that would be subject to surveillance activities of other kinds. There are other accountable points the vendors are held to that could serve to be supportive points to keep the vendor accountable – that they're not just trying to get by something. Is there any room for that?

And the third statement would be, and perhaps it's only something available to products that have been testing before and the capabilities have been proven through the real-world testing approach. But to be able to look at the role of actual production use and that goes towards measurement side of this if there are ways to demonstrate that it is a high use production capability. What is real-world testing going to prove that real-world production use doesn't? So that's kind of the point of it. And maybe what we're really describing is a menu of things that it's flexibility the vendor could have that could be deemed acceptable by the ACB and not just insistent on it's always got to be use case scenario-based testing each and every time, every year.

Denise Webb – Individual – Chair

I think that that's worth having some clarification on or making those recommendations for consideration.

Raj Ratwani – MedStar Health – Chair

I think a lot of that comes back to the discussion we had earlier about the goal of the testing itself. If it's about the exchange of information – John, I think you are absolutely right – there are probably some other ways that they could be done instead of going through the more intensive actual testing on the production system or production life system. If, however, the goal is to also get the use/usability **[inaudible] [0:38:29]** then I think that's going to require provider participation. I think we need clarity on these.

John Travis – Cerner – SME

Yes. Given the fact that they give flexibility for standards advancement to be criteria specific, so even for the same specification if it shows up in more than one standard, kind of suggests that there's a dimension to this that I could have a resting state for a given criteria year over year where I really haven't done anything. Others progress and should be subjected to a fresh round of the most rigorous level of testing that the methodology calls for. And not everything's at the same level in that kind of a situation.

Denise Webb – Individual – Chair

So, thinking about this from the government's perspective, and how broad this regulatory language is in terms of this testing, on one hand, we don't want the government to be overly prescriptive because then it sort of boxes people in, they do have the ability to, through the ONC ACB, the certifying bodies to actually have them provide guidance. And I like the idea, and it mentions on page 284 about having a pilot year. I absolutely think we should recommend that that does happen. You know, even if there are even nine months available.

I think it would serve the entire community including the government well if there was a pilot year for putting together a real-world testing plan and trying it out and having the ONC certifying body to be able to assess the various types of plans that come in and what the results look like and maybe then create a templates around what makes sense going forward. That wouldn't require rulemaking. So, if they get too prescriptive in the rule, the actual regulatory text, it takes away that ability, I think. Maybe our ONC team can clarify whether that's true or not but –

Raj Ratwani – MedStar Health – Chair

Denise, on page 284 they do talk about potentially treating 2020 as a pilot year for real-world testing.

Denise Webb – Individual – Chair

And so they're asking for comments on this potential approach and I think it would be worthwhile for us to make a recommendation on this.

Raj Ratwani – MedStar Health – Chair

Yes, I think that's a great point.

Okay, so continuing through on the items that we need to go in the plan, there's the schedule of key real-world testing milestones, a description of the expected outcomes and then at least one measurement metric. I think these items, to me, fall into that bucket of a template or some guidelines and suggestions as to what this might look like would be helpful.

John Travis – Cerner – SME

I think on the measurement, Sasha and I were talking a lot about, we probably need a good description of what the goal of measurement is. There is a difference between measurement to prove throughput or to prove success in transacting, things of that nature, from looking at data quality or some things you're bringing up, Raj, around being able to really do something with the received transaction or the received data sets and they only say one. Not that every vendor would literally only do one, but if you're going to do one you want to make sure it's providing real value.

Denise Webb – Individual – Chair

Well, it does say – they give an example on page 282. We encourage health IT developers to consider metrics of use in exchange from existing networks. That would be Commonwealth is an existing network – Communities and tools, including but not limited to Sure Scripts, Care Quality, Commonwealth, Health Alliance and so forth. They have Direct Trust in here. It's interesting because Care Quality and Direct Trust are not networks – they're frameworks. Funny how people use that interchangeably.

John Travis – Cerner – SME

And, as discussed, they highlight use or they highlight volumes or potential metrics of adoption.

Denise Webb – Individual – Chair

That is the exact exchange of information. It doesn't necessarily have any measure of the usability that Raj is talking about.

John Travis – Cerner – SME

Right, right, right.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Just as a reminder we should probably break for public comments in a few minutes. I know we are kind of right in the middle of this but just a quick time check.

Raj Ratwani – MedStar Health – Chair

Yeah, so Lauren, is that at about ten til that we should break?

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Yes.

Raj Ratwani – MedStar Health – Chair

Ok. So why don't we just use the next two or three minutes to just summarize all of these – I think it's A through G – that relate to what needs to be in the plan. So, we just talked about the measurement metric. The last point, G, a justification for the health IT developers real-world testing approach – any comments on that?

John Travis – Cerner – SME

I think that goes back to the earlier things that we were talking about if you're speaking of A, dealing with allowing for methodologies, use of real-world results, or production results and things of that nature that we were talking about before. I don't have anything further on any.

Raj Ratwani – MedStar Health – Chair

Okay. So, I think as we articulate the recommendation here, a lot of this again I think ties back to what's the goal of the testing itself? And then that is going to – you know, what are the measurement and metrics that need to be used. Depending exactly on that goal, who the participants actually are, whether the vendor can do it alone or whether the providers are involved so I think we can tie each one of these back to those points?

So, the next section, I believe, looking down at number two here toward the **[inaudible] [0:45:29]** page is about the actual report itself which much of this I believe mirrors what's in the plan and is kind of just the report out phase here. And given that we didn't do public comment I think maybe we should just pause and jump into public comment first.

Denise Webb – Individual – Chair

Before we do, Raj, I think yes this does mirror and I think the only point that we did hear about yesterday was possibly the issue with January 31st date – so the timeline, and I think we're already making a recommendation or a comment on that.

Raj Ratwani – MedStar Health – Chair

Yep, agreed. Okay, so let's go over to comments.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Operator, can you please open the public lines?

Operator:

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

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

And I see we don't have a large group today, but do we have any comments in the queue at this time?

Operator

There are currently no comments.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

I just want to confirm. I don't see Les has joined either. Okay, great. So maybe we can just use the last 10 minutes to wrap this up. We do have to have a hard stop at 4:00 because we have another task force call right after this one.

Raj Ratwani – MedStar Health – Chair

Are there any additional comments, I guess John, Denise, around the report itself, the reporting out? So, Denise noted the timeframe. Were there any other things there because perhaps we can stop after?

John Travis – Cerner – SME

I was going to say, nothing came to mind that we haven't already covered. Most of our approach and our comments I think were more on the principles behind the testing, the objectives and its structure – not so much the reporting out of the result.

Denise Webb – Individual – Chair

And I didn't have anything to add on that, Raj and I think the only piece that we really didn't get to talk about, I know attestations is a very short part, but we did need to have a little bit of discussion on the advanced, the leveraging the standards version advancement process and whether – I mean I actually think that was well thought out. But I don't know if John has any specific concerns from a vendor perspective about the ability to leverage the standards version advancement process that ONC is proposing. So, I mean, probably the only thing that I found in there that really I had a question about is if one vendor advances to a version that ONC has approved in this advancement process, what about compatibility from an interoperability perspective with the lower versions on another vendors' health IT? That was the only thing that I didn't really see addressed in this preamble.

John Travis – Cerner – SME

I think there were a couple of things that we were kind of curious about with the practical nature of applying the process. So, one was, would existing certified EHR technology be subjected to the real-world testing requirements, or would it apply only to new certified EHR technology? And I'm not sure I'm being really clear with that but just to be clear if that testing requirement applied to newly certified products for real-world testing purposes versus those that have been around for a while. I think the answer to that is that it's up to the vendor's discretion about where they make the claim since that's criteria specific about where they choose to voluntarily assert that they support a new version.

Denise Webb – Individual – Chair

I think they were pretty clear John that everybody had to have a test plan for these certification criteria related to interoperability whether you had an existing product for real-world testing.

John Travis – Cerner – SME

I was more on the point of you have discretion about which criteria you elect to outpatient physical therapy to assert a claim that you support a higher version of standard. I assume that that's – it seemed pretty clear. I don't think that was controversial. But that wouldn't compel you to test a standard for anything more than you claim it. I'm trying to see if we really had any other question about it. I was going to say, most of our questions are off into other considerations about how the claim is communicated. It didn't really have to do with real-world testing.

The one thing I was going say – sorry, the one thing that did come to mind there is a little bit of a quirk that the rule highlights that the vendor if they elect to certify a claim for a version of standard for which there is not tooling yet. I think the part of this that we're a little uncertain about is the role of how the conformance testing is to occur. Discretion seems to accrue back to the vendor to support a claim and perhaps to also utilize in real-world testing because I think that's where the statement was made that it is purely based on a vendor statement and it may not be something that's testable in any independent way or subject to tooling that would be available for a new certification that would ingest that same standard. So there seemed to be kind of a timing quirk in there. And I don't know if ONC has an actual point of experience with that. It can happen at any point in time because there is a time lag between normative balloting and incorporation of a new standard version into tooling but the vendor may be making a claim that it was a little bit fuzzy how that would be proven through real-world testing when there is no conformance capability other than what the vendor would themselves assert. So, I couldn't go to a test harness. I couldn't go to **[inaudible] [53:10]** tooling.

Denise Webb – Individual – Chair

I think that's what the preamble sort of left it to was the vendor to make that attestation to the –

John Travis – Cerner – SME

But an attestation is not a proof of conformance through real-world testing. It just seemed a little – I don't know exactly what I'm trying to say other than it's a hard point to prove through real-world testing that is predicated on proving an attestation statement by more than an attestation statement if I'm making any sense.

Raj Ratwani – MedStar Health – Chair

Yes. There is a difference, attestation versus more evidence base showing results.

Denise Webb – Individual – Chair

And I don't think they were alleviating the vendor or the IT developer of doing real-world testing. I think it was referring more to the certifying body, not having the tooling available yet to do the conformance testing with the vendor to certify to that standard because the standard was just adopted and accepted in this advancement process by ONC. So, there is a little timeframe in there but once that tooling is available I'm sure that – well if it doesn't show up in the real-world testing and through surveillance of the real-world testing it's subject to conditions of maintenance –

John Travis – Cerner – SME

It's a timing quirk. It might not really happen all that often, but it seems to be a loose end to me for real-world testing, that, to be honest, a lot of vendors are going to rely on conformance tooling or conformance testing capabilities to prove their attestation claim, or to me I'd question why they would be making it. And it's an odd chicken and the egg because the very tooling that isn't available is probably what in normal cases would be important to rely on to prove a point for a vendor as attesting to supporting a new version that's not independently subjected to a new round of certification testing, because that's kind of the point of the voluntary adoption in a way. You have to prove it in real-world testing and yet you don't have the tooling that you might normally rely on to prove it in any case in any testing. So, it just – I'm not sure it's of value to have attestation to a level of standard that's not able to be tested I other words.

Raj Ratwani – MedStar Health – Chair

I think those are good points.

We are at the top of the hour and I know everybody has stuff they have to run to now. I think we made it far, which is great, and I think we have some good recommendations at this point. I believe the next meeting is tomorrow where we plan to go into APIs and I think it may make sense for us to make that transition, but Denise, we can talk after this and then you'll be driving that next call so we can go from there.

Denise Webb – Individual – Chair

Okay, that sounds good.

John Travis – Cerner – SME

Just so that you know, Denise and Raj, I won't be able to join until about after the first 30 minutes of the call tomorrow.

Raj Ratwani – MedStar Health – Chair

Okay. Well, thank you, John, for being so being such a great participant on this one. We appreciate it and we'll talk with you tomorrow.

John Travis – Cerner – SME

All right, very good. Thank you.

Lauren Richie – Office of the national Coordinator – Designated Federal Officer

Thank you, everyone.

Denise Webb – Individual – Chair

All right, and we'll re-dial into the other number.

Raj Ratwani – MedStar Health – Chair

Heads up – I'm going to be like three minutes late.

Denise Webb – Individual – Chair

Okay.