# Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology

# Conditions and Maintenance of Certification Requirements Task Force

Transcript
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Virtual Meeting

## Speakers

| Name | Organization | Role |
|------|-------------|------|
| Denise Webb | Individual | Co-Chair |
| Raj Ratwani | MedStar Health | Co-Chair |
| Carolyn Petersen | Individual | Member |
| Ken Kawamoto | University of Utah Health | Member |
| Sasha TerMaat | Epic | Member |
| Leslie Lenert | Medical University of South Carolina | Member |
| John Travis | Cerner | SME |
| Lauren Richie | Office of the National Coordinator | Designated Federal Officer |
| 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. All lines are now bridged.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Good morning, everyone. Welcome to the Conditions and Maintenance and Certification task force. We'll do a quick roll call. And we have a lot to discuss today so we'll get started. I don't believe Raj has joined. Denise Webb?

**Denise Webb – Individual - Co-Chair**
Present.

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

**Ken Kawamoto – University of Utah Health - Member**
Present.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Hopefully, Les will be able to join us. Carolyn Petersen?

**Carolyn Petersen – Individual - Member**
Good morning.

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

**Sasha TerMaat – Epic - Member**
Present.

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

**John Travis – Cerner - SME**
Present.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Great. Denise and Kate, I'll hand it over to you to get us started.

**Denise Webb – Individual - Co-Chair**

Okay. Well, good morning, everyone. Thank you for taking the time to join us. We're getting down the finish line here on our recommendations. I had gone through the entire draft transmittal memo and I just want to give you an overview and let you know the areas that we're going to have to focus on today. We do need to get through the rest of the recommendations. I think we left off at the end of real world testing on measurement. And I think everybody knows we're here to finalize our recommendations on the certain conditions and maintenance of certification requirements, the updates to the 2015 edition certification criteria, changes to the certification program, and deregulatory actions. So, just to let you know. I went through the entire memo.

And at the suggestion at the last meeting from Lauren, I added some information at the introductory paragraph of the letter stating that we took into consideration the feedback we received from the March 18 and April 10 meetings. And since the April 10 meeting, we made revisions to provide clarity on whether each recommendation is seeking changes to the final rule preamble, the regulatory text, or both and responded to the feedback provided. So, I went ahead and put that statement in there. There were a number of changes or editorial changes that Kate had made. I just went ahead and accepted to kind of declutter some of the changes in the document as we're going through this. Also, you will see that I restated the beginning of every recommendation to say the CMC task force recommends to ONC and then, what we recommend ONC do. So, in every case, we had ONC should do this or should do that.

And you'll note, for instance, on Recommendation 1 here that's up on the screen, you'll note this is the only place where we said the committee recommends because we had already voted on this at the last meeting. And there is an example of where we took the should out. Recommends ONC introduce the new addition. So, you will see that consistently throughout. Those are some of the changes. So, that's not really substantive. It's more to put this in a thematic format. We had already talked about Recommendation 6 but I want to revisit that because, as I looked at it, there were some concerns I had after I reread the preamble text about what exactly we're asking for them to clarify related to work flow. So, I'd like to revisit that. Otherwise, we had made it through all the way to Recommendation 11 or up to 11 on our last call.

We do have one little item we need to revisit, Recommendation 8. We actually have in our discussion the word recommends. And I don't think we want to recommend in a discussion. We were trying to separate recommendation from the discussion. So, those are all really kind of actually minor things. And then, the four big ones that we have to hit today in terms of revising are Recommendation 19 that concerns the HL7 US Core Fyre Implementation Guide, Recommendation 21, which concerns privacy and security regulations and current uses of Fyre APIs as related to privacy and security. And Ken is going to help us out with that one with some feedback from Aaron Miri, which I emailed to all of you. And then, obviously, self-developers, the recommendation concerning CMC on self-developers, which is Recommendation 25. And the last of the four big ones is EHI export.

And I'm actually suggesting on EHI export that we sort of reorder this, in the same manner, we did with Recommendation 8 where we had a recommendation and then, put our discussion afterwards. I think it's a little jumbled up right now. So, we can start. First, let me ask on my change to the introduction to the letter, are there any concerns with that or requested edits at the top of the page?

**Sasha TerMaat – Epic - Member**
I think it's fine.

**John Travis – Cerner - SME**
Yeah, nothing.

**Denise Webb – Individual - Co-Chair**
Okay. All right. By the way, Sasha had done some editing the last time that was more or less to include final rule preamble and all of that. I just accepted those because it really wasn't substantive in terms of content but more to say where we said the change should go. But if anybody thinks that the way we reflected that is not correct, you can speak up. All right. Let's go down to Recommendation 6, please. I should ask does anybody have anything they want to raise on two through six, which we had covered last time, in case you weren't on the call? Ken, I don't think you were on the call.

**Ken Kawamoto – University of Utah Health - Member**
No, no concerns.

**Denise Webb – Individual - Co-Chair**
All right. So, Recommendation 6, at the end of our original recommendation, in the final rule preamble, the task force also recommends ONC clarify the term work flow as it is used. And what I added as where it is used, it's used in Section B5 of the proposed rule preamble regarding real world testing. I was trying to add some context around this because there are two places in the preamble where it mentions real world. And rather than us trying to bring this up, let me just read this to you. The first place it's mentioned is on Page 277 of the preamble. It says, "Real world testing should assess that the certified health IT is meeting the intended use cases of the certification criteria to which it is certified within the work flow, health IT architecture, and care practice setting in which the health IT is implemented."

That's the first place they mention work flow. But the place that I'm referencing here is on Page 283 where it says, "Additionally, while the developers plans must address each of the interoperability focused certification criteria in their certified health IT, developers can and should design scenario based test cases that incorporate multiple functionalities as appropriate for the real world work flow and setting." So, those are the two places where they introduced work flow in real world testing. Work flow is not used in the regulatory text. And also, in the second piece that I read to you, only scenario based is touched on and not use case. So, obviously, we're asking ONC to clarify are scenario and use case the same thing. If so, just use one term. But on work flow, I want to make sure we as a task force are being clear on what our concern is.

So, if they clarify the term work flow, relative to what? To the number of infinite test cases that a vendor would have to create to accommodate every work flow variation that each of their customers has? Because we know the customers don't all have the same work flows. And we're not dictating that they should. Or is it to generally test a common work flow? So, if you all can help me out, especially John and Sasha, in our discussion on this to make sure that we capture what I'm suggesting we put in here.

**John Travis – Cerner - SME**

This is John. Maybe I'll start it out. So, I think you start from a premise, and maybe it's something to make sure is clear, as it's worded by default, it has to put a lot of discretion on the vendor, which is, I think, proper. However, you want to make sure that that discretion operates within some assumptions, otherwise, you – maybe it's not a problem that there could be a wide variety in the way vendors apply the requirement. This kind of goes back to being informed by how you define venue or care setting. And that's why that matters so much. So, if I have a fairly high level definition of that then, I'm probably not going to do a lot of differentiation of work flow based on things that could vary within it.

So, let's say, for example, and I'm doing this on purpose to illustrate, I say ambulatory counts as what meets the test of selecting a relevant venue or care setting. Well, obviously, within ambulatory, there can be many specialties and subspecialties. If I choose to say work flow is ambulatory and, in my mind, I'm thinking about primary care and that's all I do then, who is to challenge me on that judgment? That's why that matters so much because there's kind of a synonymous relationship between picking a unique work flow and the level at which I choose to define a care setting. And that's where it really matters.

**Denise Webb – Individual - Co-Chair**

Yeah, I was thinking that, too, that work flow and care setting can dictate, depending on how you look at it, the type of test scenarios that you would do. And probably the word I used here is the task force is concerned about the degree of their ability. I don't think we're concerned about it. We recognize there is a degree of variability that exists in provider work flows. So, help me out, team. I tried to suggest something here and maybe I didn't get it quite right. Or maybe we just leave it to recommend that the final rule be clear on what is intended where the preamble states.

**John Travis – Cerner - SME**

I think a couple of things and, again, just certainly open to feedback. I think the first point I'd make is by the use of language, we assume that and maybe this is a minimum, but as it's worded that venue and work flow or setting and work flow are synonymous for the purpose of establishing an expectation by ONC of how many do you do. You probably at least have to do one per. Do you have any obligation to do more than that? Or is that at the vendor's latitude or the developer's latitude to do more than that? Barring anything else, it's one per. I think the other thing is that Sasha, I don't presume to speak for you, but I think we'd want to know that HIT developers are doing fairly consistent things out there in terms of how they understand their latitude and how many work flows they do test.

And that's the important thing. So, variability may not be quite the term as much as that – if ONC is expecting a fairly consistent resolve or comparability of resolve from this requirement then, they need to make that clear. And they need to put firmer guidance in place as to – I don't want to get all prescriptive but maybe it's a minimum statement or maybe it's an expectation that is clearly stated of when they correlate work flow to select a venue or care setting, they've got a fairly clear establishment of what that means to guide the developer in their developing of the testing plan.

**Sasha TerMaat – Epic - Member**
I agree with John. I guess I think the revisions that Denise has suggested are consistent with our earlier conversation and the goals that we have. I pulled the references to work flow into a comment in the document just for my own reference. If that's helpful, you can see it in the Google Doc there. But I think this accomplishes the concern, which was just that it's a very subjective term but it seems to be used as though there is a common understanding of what the work flow would be. Maybe there's an intentional use of that because they know it's not a common thing. That would be helpful to be clarified even if that is the case. I do think there will be a lot of variability within one product and the cross products and rightfully so. That's how we innovate in the industry.

**Denise Webb – Individual - Co-Chair**
So, Sasha, do you think what I have here presently that we should say instead of is concerned about the task force acknowledges a degree of variability that exists?

**Sasha TerMaat – Epic - Member**
The thing that I think confused me about this wording, and I appreciate that you clarified a bit more, is that it sounds like the concern is the variability not that the variability creates an infinite number of test cases. So, I think what we want to say is we acknowledge a variability and we're concerned that it creates an infinite number of test cases.

**John Travis – Cerner - SME**
Do we want to speak to – we already say ONC should clarify the term work flow. Do we want to make any statement about ONC making clear how they regard the relationship between venue and work flow? Are they synonyms?

**Sasha TerMaat – Epic - Member**
I don't think they are synonyms.

**John Travis – Cerner - SME**
Yeah, but I don't know ONC's state of mind. I guess that's my point.

**Sasha TerMaat – Epic - Member**
I think when they say the intended testing methods would need to address testing scenarios, use cases, and work flows that is independent of the settings in which they're tested because they say previously that the use cases would be per setting. And then, they call use cases and work flows different. I share your confusion overall about is there a test case per work flow,

per setting, per use case.

**John Travis – Cerner - SME**

Is there a way that we can put wording in that corals the infinite nature of the potential permutations that I hate making it more subjective than it may already seem to be? Do we want a reasonableness principle in there?

**Sasha TerMaat – Epic - Member**

Maybe what if we just said here where it says to be clear on what is intended, what if we said to be clear and reasonable with –

**John Travis – Cerner - SME**

Yes. I'd be fine with that.

**Sasha TerMaat – Epic - Member**

And that maybe accomplishes the goal of we want clarity but then, we're also just concerned that you avoid the infinite test cases problem. Is that reasonable?

**John Travis – Cerner - SME**

Exactly. Yeah. We want latitude. And I think it's there. But we don't want just an overwhelming amount of requirement that the – because these things are judged by ATLs and others that may say no, that's inadequate. So, I think there needs to be enough there that gives light to what is an adequate level that also serves to harness the entities that are going to be judging the adequacy of the testing plan from getting to a ridiculous level of requirement permutation.

**Denise Webb – Individual - Co-Chair**

Okay. So, I like the changes. I think that states what I hear you both saying now. Sasha, were you typing? Is that you typing or somebody else?

**Sasha TerMaat – Epic - Member**

Yes.

**Denise Webb – Individual - Co-Chair**

Can you add after infinite number add of test cases? I missed a word there. And I would actually put a period after customer based because this gets really long and just say the TF recommends the final rule. Yeah. Is everybody good with this?

**Sasha TerMaat – Epic - Member**

Yeah.

**Denise Webb – Individual - Co-Chair**

I appreciate you all relooking at this one. Okay. Thank you. So, if we can jump down to Recommendation 8, I made a tweak here because, when I read the recommendation, the

way it was originally worded, it didn't seem to make sense as written. So, hopefully, everybody is okay with this change for clarity sake on the first three lines here.

**Sasha TerMaat – Epic - Member**

Yes.

**Denise Webb – Individual - Co-Chair**

Okay. Now, the one thing we need to clear up here is we originally had the statement, "The CMC task force recommends the use of data testing to validate the data user receives," that part there. Scroll down a little more, please.

**Sasha TerMaat – Epic - Member**

So, remember last time we had this discussion, we changed our recommendation above to use usability testing as the phrase instead.

**Denise Webb – Individual - Co-Chair**

Yeah.

**Sasha TerMaat – Epic - Member**

So, then I think I confused myself reading the highlighted sentence. But since we moved the usability testing recommendation to sort of the second paragraph of the recommendation section, I'm wondering if we can cut the highlighted sentence because it's sort of a restatement of what we had said above.

**Denise Webb – Individual - Co-Chair**

Just as long – let's see. And I think we already said this about foreign data.

**Sasha TerMaat – Epic - Member**

Yeah. We heard feedback about the foreign data piece and we don't want to be prescriptive about design. So, it's like this is the feedback for consideration along with other user feedback as designs are done. But then, I guess, the sort of recommendation is do validation on received data is up in the TF recommends ONC expects that if health IT developers are testing the use of data received through exchange, they would have users involved in usability testing.

**Denise Webb – Individual - Co-Chair**

Go ahead, John.

**John Travis – Cerner - SME**

I was going to say I'm rereading the main paragraph under discussion right above the highlighted. And I actually just had a reaction. Presented in the same view as native data. What I'm after is I don't want that to be read as it must appear exactly as native data. And maybe the rest of that sentence about not to prescribe certain **[inaudible] [00:22:22]** approaches addresses that. I know this is there to make sure that it's presented and is able to

be usable and able to be acted upon. But it may be, depending on its form, it should be presented as distinct from native data. It may be history. It may be patient contributed. It may be distinguished as external.

**[Crosstalk]**

**Denise Webb – Individual - Co-Chair**
I have a suggestion. Why don't we combine what's in the part that's highlighted and say when certified health IT products receive foreign data, we have heard user feedback desiring that the data is viewable, actionable, and reportable alongside their native data to be useful and reduce the burden on providers using this technology. Maybe we can combine the two thoughts and then, just take this out, this part about being presented in the same view.

**John Travis – Cerner - SME**
Yeah, I think that's definitely in the right direction. I think that avoids –

**Denise Webb – Individual - Co-Chair**
The last acts as more than just a view.

**John Travis – Cerner - SME**
Right. Yeah.

**Sasha TerMaat – Epic - Member**
So, if I understand what you guys are suggesting –

**John Travis – Cerner - SME**
Certified health IT received foreign data. We've heard user feedback desiring it to be viewable, actionable, and reportable alongside – I like that.

**Denise Webb – Individual - Co-Chair**
Alongside I would put their native data to be useful. Yeah. And then, that doesn't get into a view or we're saying it needs to be on the same screen. I think that's much better. What does everybody else think?

**Sasha TerMaat – Epic - Member**
I like that.

**Denise Webb – Individual - Co-Chair**
Carolyn, Ken?

**Carolyn Petersen – Individual - Member**
Yeah, I'm good with it.

**Ken Kawamoto – University of Utah Health - Member**

I'm good.

**Denise Webb – Individual - Co-Chair**

All right. Good. As I said, I went over this with a fine toothed comb last night. I wanted to make sure we're crystal clear on what we're saying.

**John Travis – Cerner - SME**

Yeah. I appreciate that.

**Denise Webb – Individual - Co-Chair**

All right. So, this takes us down to eleven. And you'll see in each of these recommendations, I did add CMC task force recommends. Okay. Measurements. Oh, I see something. Sasha, can you add CMC before TF while we're in here on Recommendation 11? The CMC TF recommends.

**Sasha TerMaat – Epic - Member**

Oh, sorry, on eleven. Yes.

**Denise Webb – Individual - Co-Chair**

Do you see up there? And, hopefully, nobody has any opposition to the changes here. It was just to provide some clarity on eleven.

**[Crosstalk]**

**John Travis – Cerner - SME**

It was minor but I think you wanted "to" after the word "and" in the first sentence. The task force recommends ONC include in the final – yeah, right there. It kind of reads a little rough without the to.

**Sasha TerMaat – Epic - Member**

Include in the final rule and provide clarity.

**Denise Webb – Individual - Co-Chair**

A description – no, no.

**[Crosstalk]**

**Sasha TerMaat – Epic - Member**

I think it's okay.

**John Travis – Cerner - SME**

Yeah, that's fine.

**Denise Webb – Individual - Co-Chair**

What I'll do when we're done with this call, I'll go accept all of this stuff so you all can have a clean read. All right. So, we're on twelve. Is everybody good to go?

**John Travis – Cerner - SME**

Yeah.

**Denise Webb – Individual - Co-Chair**

Okay. Twelve. So, I did add that we're looking for the final rule preamble. And I did put the section to kind of help. And each of these where I can clearly identify the section I did add it so they can hone in on where we're talking about it in the rule. Is everybody good with this one? We did not get any feedback on this one in particular from the committee. And the main thing they wanted us to provide was whether this would show the preamble or the regulatory text, which we did. Okay. If nobody opposes, let's go to thirteen. In the last sentence, I added the final rule preamble should provide reasonable assurances for health IT developers rather than assurances to. The rule is not going to provide something to the providers but for the providers – I mean, the developers, excuse me.

All right. Any other changes? Is everybody good with thirteen? Good. I just want to give everybody a chance to read through it before we move on. Okay. Fourteen. I thought we meant expectations not proposal in the final rule. Because once they clarify the understanding of real world testing expectations, it's not a proposal. It's expectations we're asking them to clarify. Is everybody okay with that change?

**Sasha TerMaat – Epic - Member**

I'm good with it.

**John Travis – Cerner - SME**

Yeah.

**Denise Webb – Individual - Co-Chair**

Okay. Hearing no opposition. All right. Let's keep moving. I added some language in this so that it could stand on its own without the heading above it. So, if somebody was reading this, they'd know we were talking about attestations. All right. And unless I hear from any of you, I'm going to keep pushing us along here. All right. Let's move to 16. I was just trying to make this read more clearly.

**Sasha TerMaat – Epic - Member**

I'm okay with that.

**Denise Webb – Individual - Co-Chair**

Okay. Otherwise, no changes.

**Carolyn Petersen – Individual - Member**

I'm fine with it.

**Denise Webb – Individual - Co-Chair**
Okay. Seventeen.

**Sasha TerMaat – Epic - Member**
I think 17 is well edited.

**Denise Webb – Individual - Co-Chair**
Yeah. It was just to more make it actionable saying that this is why we think this is the recommendation, more readable. And is the last part there okay where I said that instead of having the negative, will focus and unify the industry on a single release of the standard versus multiple releases of the standard. And I did delete the S on standard.

**Sasha TerMaat – Epic - Member**
I think that makes sense.

**Denise Webb – Individual - Co-Chair**
Okay? All right, 18. The only change I made there was on the introductory just like I did on the others, which is not highlighted. I just went ahead and accepted that. Okay. The first big one of four that we need to sort through here based on committee feedback. Recommendation 19, the feedback principally came from Arien. And he did state that this should reference other voluntary consensus bodies. And I don't know if I captured this correctly. And I did add the regulatory text areas where this is discussed and the preamble section. And then, I think our second part here where HL7 IGs are not available we're asking ONC to assist in facilitating their inclusion, I think.

**Sasha TerMaat – Epic - Member**
I think that sounds reasonable.

**John Travis – Cerner - SME**
I think it's well written and I agree with removing this is because Argonaut. It's kind of an editorial opinion, which doesn't really –

**Denise Webb – Individual - Co-Chair**
Well, Arien felt that was inflammatory. But in my comment, I asked is it necessary to have the last line. And Ken, I know you originally drafted this recommendation.

**Ken Kawamoto – University of Utah Health - Member**
I guess I don't know. I thought what I stated was factual. But if folks and Argonaut do not feel strongly against it, I'm okay with watering down the language. I did talk to Micky Tripathi, I think project manager for Argonaut and explained why I was making the recommendation. And he was fine with it. I'm fine with updating language. That's fine with me.

**Denise Webb – Individual - Co-Chair**
Yeah. I guess –

**[Crosstalk]**

**John Travis – Cerner - SME**
Are we telling ONC something they already know? Is it necessary to state it, I guess, would be – as I read it now?

**Ken Kawamoto – University of Utah Health - Member**
I think the very fact that the pointed to Argonaut rather than US Core was what concerned me because they say specifically we should be using voluntary standards but we're going to use Argonaut.

**John Travis – Cerner - SME**
We don't want them doing that.

**Ken Kawamoto – University of Utah Health - Member**
We do not.

**John Travis – Cerner - SME**
Right. No, I think given that case, the point we definitely want is to stay within the framework of using recognized standards developers that follow good due process that are consensus based. And that would be the only – we mentioned HL7 in particular but we're more on the principle that you should be using standards development bodies that are recognized and follow a consensus process. Maybe we want to state the principle as opposed to necessarily specific data of HL7 or is that important to the content?

**Ken Kawamoto – University of Utah Health - Member**
No. I think the practical matter is Argonaut content is being pushed forward in US Core. So, it's not like it's a theoretical thing. There are US Core versions of the Argonaut specifications. And what actually happens is it goes to ballot. Folks comment, I comment and then, typically what happens is the question that's asked is would this be burdensome to EHR vendors. That is literally the question that gets asked. And if the answer is yes, it becomes not persuasive. We will consider this in a future release. And we're good with that. But at least it goes through the process of saying things like the way it's implemented, it could take you 10 seconds to get the results back.

We should put in a query parameter for this. And it's well, that may be too hard so we'll consider it at a future release. But at least it goes through the process. So, realistically, the US Core ends up looking very much like Argonaut, usually, with minimal if any changes. But at least it goes through that process of review. And I think we specifically do need to talk about the US Core Implementation Guides because those are, basically, the HL7 versions of the Argonaut profiles.

**Denise Webb – Individual - Co-Chair**

Ken, I have a question. Where I put or other voluntary consensus bodies, isn't HL7 a voluntary consensus body?

**Ken Kawamoto – University of Utah Health - Member**

Yeah.

**Denise Webb – Individual - Co-Chair**

Does that make sense what I put there? I don't know. Are there other consensus bodies that HL7 derives their work from?

**Ken Kawamoto – University of Utah Health - Member**

Sure. DaVinci is one of them, although I'm not –

**Denise Webb – Individual - Co-Chair**

Okay.

**Ken Kawamoto – University of Utah Health - Member**

I'm not sure I would consider Argonaut a voluntary consensus body.

**Denise Webb – Individual - Co-Chair**

No, I said or. Derived from Argonaut – maybe we need Argonaut project there. Oh, no. Derived from the Argonaut –

**[Crosstalk]**

**John Travis – Cerner - SME**

Stop there at the implementation guidelines and just delete everything. And where guidelines are not available for the corresponding, the TF recommends ONC facilitate their inclusion in the standard.

**Ken Kawamoto – University of Utah Health - Member**

I think that's what Arien was asking. He was just saying don't, basically, state that Argonaut has any – don't be negative about Argonaut was, basically, his recommendation. I'm okay with that. I think what Argonaut is saying is great it's just we should be using the US Core version.

**John Travis – Cerner - SME**

Yeah. I think that's true. I don't think that anything that was done in Argonaut that wasn't done in US Core would be appropriate.

**Denise Webb – Individual - Co-Chair**

All right. Is there any reason why we can't just say derived from the Argonaut? Because since

the rule currently states Argonaut, we're saying don't state Argonaut. State US Core derived from the Argonaut or other voluntary consensus bodies' implementation guides because I did hear DaVinci is another voluntary consensus body that HL7 may –

**Ken Kawamoto – University of Utah Health - Member**

DaVinci implementation guides aren't US Core implementation guides. We could put it. And US Core shouldn't have to come from Argonaut. It shouldn't be a requirement that US Core prior implementation guides must come from Argonaut. We're just saying because they specifically point to the Argonaut ones, my recommendation is to use the US Core versions of them.

**Denise Webb – Individual - Co-Chair**

Okay. Then, maybe we should scratch, as Les suggested, derived from the Argonaut or other voluntary consensus bodies' implementations guides and just scratch that whole thing and say rather than specifying the Argonaut or other voluntary consensus bodies themselves in the final regulatory rule. And then, we're acknowledging there are more than just Argonaut out there. And we're not going to specify or rather than specifying the Argonaut IGs period.

**Ken Kawamoto – University of Utah Health - Member**

Yeah. That sounds good.

**Denise Webb – Individual - Co-Chair**

And take the whole thing about – okay. All right. So, Sasha, we'll change this to the CMC task force recommends ONC require compliance with HL7 US Core Fyre implementation guides rather than specifying the Argonaut implementation guides in the final rule. That's our recommendation. Blah, blah, blah.

**Ken Kawamoto – University of Utah Health - Member**

Yeah. And we should say, if it's not available, you should actually do it.

**Denise Webb – Individual - Co-Chair**

Right. So, let's see. Did you strike derived from Argonaut?

**Ken Kawamoto – University of Utah Health - Member**

Yeah.

**Denise Webb – Individual - Co-Chair**

There we go. Rather than – that's defined in the Argonaut implementation guides. Where HL7 IGs are not available for the corresponding required Argonaut functionality, the TF recommends the ONC assists in facilitating their inclusion in the –

**Ken Kawamoto – University of Utah Health - Member**

Yeah. That's good. I think that meets what Arien was asking for and I'm cool with that.

**John Travis – Cerner - SME**

I like it, too.


**Denise Webb – Individual - Co-Chair**

Yeah, it's more to the point without adding all of the other information. That was helpful to our discussion though to understand where you're coming from, Ken, and others.


**Ken Kawamoto – University of Utah Health - Member**

And I think the bar is low. They literally just need to propose it as a specification. And the fact of the matter is almost everything Argonaut recommends and goes through and almost anything an EHR vendor objects to gets vetoed. So, I don't think it's a big ask.


**Denise Webb – Individual - Co-Chair**

Okay. Sasha, Carolyn, John, are you all good with this?


**Sasha TerMaat – Epic - Member**

I'm good with it.


**Carolyn Petersen – Individual - Member**

I'm fine.


**Denise Webb – Individual - Co-Chair**

Okay, good. We got that one done. Thank you.


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

Denise, this is Lauren. I just wanted to let you know that Les has joined.


**Denise Webb – Individual - Co-Chair**

Oh, I acknowledged because he was making suggested changes on 19. Thank you, Les. Okay. Recommendation 20. I was just trying to clear up there what we were talking about. I think we were talking about the application's ability to keep the token confidential. Is that correct? And rather than creating products, I thought developing was a more appropriate word.


**Sasha TerMaat – Epic - Member**

I think that's fine.


**Denise Webb – Individual - Co-Chair**

And then, I put the final rule preamble section at the end there where they would need to make this clarification. Is everybody good with that? Okay. You're on deck, Ken. What are we going to do with Recommendation 21?


**Ken Kawamoto – University of Utah Health - Member**

Was that right that Arien's comment there was that he thought we should just be more specific? I can be more specific.

### Denise Webb – Individual - Co-Chair
No, let me find my notes. Hold on a second. This was Aaron Miri who made the comments on this. He said the recommendation rather than saying that the ONC provides formal guidance that the ONC should work with OCR and other agencies regarding the scoping of data requests as it relates to CDS hooks and so forth. But I just have some kind of scribble notes here. There was some discussion of the minimum necessary and then, building off the work of the API task force of the previous health IT was it the policy committee, yeah, I think, the policy committee that had the API task force. And that's what he had in his email to me.

### Ken Kawamoto – University of Utah Health - Member
Prior ONC API task force. And just as a note, I just had an email conversation about this with Graham Reid, the project manager of Fyre, and he agreed these were issues that were not covered by the standards and that they were looking to see if they can be included into Fyre. But, currently, these need to be done in policy and such outside of the standards. I think, big picture, there are gaps in the standards or we need agreement that an outside system can be considered a healthcare provider and is exempt from these minimum necessary requirements.

### Denise Webb – Individual - Co-Chair
Sasha, I would add the deliberation can leverage the work of the prior and I don't think it's ONC. What was the name of that committee prior to us? Was it the health IT policy committee's API task force?

### Carolyn Petersen – Individual - Member
That sounds pretty close. If not, I'll look it up while you guys keep talking. I think it's all archived on the web.

### Denise Webb – Individual - Co-Chair
API task force as a starting point. Because that was his point. We don't need to start from scratch here.

### Ken Kawamoto – University of Utah Health - Member
Sounds good.

### John Travis – Cerner - SME
Someone came to me in response to this particular recommendation, the second part of it, a kind of parenthetical note. I'm not sure it's parenthetical but speaking of some of the issues around what ONC should provide formal guidance on relative to HIPAA security and privacy. They thought the key was what do you do in circumstances where you receive more demographic information than you may need for the purpose at hand. But they wondered if there is a problem of broadly scoped data aspect tokens. They seem to think that the tokens are probably, in most cases, appropriately scoped to need not more than what is needed. But

there are issues of returns of more information than matches the need.

**Denise Webb – Individual - Co-Chair**

But isn't that just what we're getting at?

**John Travis – Cerner - SME**

Yeah. But I'm not sure they thought that the use of the scope data access tokens, and maybe they misread it, I can see it in a couple of ways. The first part of the issue sending the full patient demographic details was the greater problem. They weren't sure the second part was a real problem.

**Ken Kawamoto – University of Utah Health - Member**

Yeah. The second one is more along the lines of if a third party only needed to know how much I weighed and how tall I was because they need to check what my body mass index is. The EHR system and the healthcare provider has to provide it with an observation read token, which would allow it to access things like if I had HIV test results. There's nothing technically that prevents the third party app from pulling that, requesting it and pulling it and retrieving it. Now, the question is is it sufficient for the healthcare system, for example, to have a business associate meet with the vendor saying you will only pull the data that you need. And if they pull it, do we not have to do a breach notification and put out ads in the newspaper and things like that?

So, it's kind of the equivalent of if we were giving a data set to another health vendor and they needed only access to the BMI. We would typically write a database querying send them height and weight. The current way that the standards are set up is the equivalent of giving them full read access to our data warehouse and saying but please only pull what you need.

**John Travis – Cerner - SME**

So, the discipline of what you respond with is the problem of the EHR responding to that request? I guess I'm trying to understand. I agree with the point, particularly through treatment related disclosures where minimum necessary doesn't really apply. There's still the discipline that you're responding with only what is needed. But is that a burden that is placed on the responding EHR? Or is it a problem of –

**Ken Kawamoto – University of Utah Health - Member**

Yeah. I would be happy if the deliberations have the smart app or the CDS service or whatnot can be considered a healthcare provider and, therefore, giving them full access to the record is fine. But right now, I don't know if that's the case. I think it would be a reasonable detail –

**[Crosstalk]**

**John Travis – Cerner - SME**

I guess the response – believe me, I'm absolutely for constraining the response to what is needed. Are we after heading off of real – I don't mean to disparage this at all. Are we looking to head off a potential issue or are we aware that this is an issue? In other words, is it

an issue with the standard the way it's constructed that we want to see ONC provide guidance on whether or not it's actually a current problem or it could be a problem?

**Ken Kawamoto – University of Utah Health - Member**
Yeah. It's the kind of thing where it could be a problem in the sense that, even if the third party gets hacked or they're unscrupulous in their business practices. There are pretty severe penalties on healthcare systems and providers. It involves jail time and lots of fines and taking out newspaper ads and all of that kind of stuff. I think that's a real risk. It's preventing us from doing things like cloud hosted smart apps because we're uncertain whether that would be compliant.

**John Travis – Cerner - SME**
My suggestion would be instead of broadly use the word inappropriately if that makes sense.

**Denise Webb – Individual - Co-Chair**
Okay. Can we come back to that after public comments?

**John Travis – Cerner - SME**
Sure.

**Denise Webb – Individual - Co-Chair**
We need to go to public comments. All right. And then, we'll continue this discussion.

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

**Operator**
If you would like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the question cue. You may press star 2 if you would like to remove your commend from the cue. 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 for Health Information Technology - Designated Federal Officer**
And thank you. And any comments?

**Operator**
No comments at this time.

**Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer**
Okay. All right, Denise, I'll hand it back to you. I know you want to wrap up here.

**Denise Webb – Individual - Co-Chair**

Right. Okay. So, John and Ken, are we changing something on this recommendation?

**John Travis – Cerner - SME**

The reason I –

**[Crosstalk]**

**Ken Kawamoto – University of Utah Health - Member**

The word inappropriate –

**John Travis – Cerner - SME**

Go ahead, Ken. I'll let you finish. Yeah, I like that. To me, inappropriate broadly judges that only a broad request is inappropriate. An inappropriate request is inappropriate no matter how broad it is. So, I just suggest that word – yeah.

**Ken Kawamoto – University of Utah Health - Member**

There are certainly a lot of use cases where it is totally appropriate to give full access like data aggregation, visualization tool, etc. It's just –

**Denise Webb – Individual - Co-Chair**

Okay. So, now that we've added inappropriate in two places here, I don't think it makes sense to say in all cases after the inappropriate sending of full patient demographic details. You can take the "in all cases" out of there because we just clarified we're talking about inappropriate –

**John Travis – Cerner - SME**

Yeah, I like that.

**Denise Webb – Individual - Co-Chair**

Okay.

**[Crosstalk]**

**Denise Webb – Individual - Co-Chair**

Is everybody good with this now?

**Ken Kawamoto – University of Utah Health - Member**

I think this looks good.

**John Travis – Cerner - SME**

Yes.

**Denise Webb – Individual - Co-Chair**

Okay. All right. We've got five minutes so we'll hit a couple more here and then, I want to summarize and have Kate and I go over the timeline on what's left to be done. Recommendation 22. I was just trying to create some clarity that we're talking about how the search for a single patient data – let's see. All queries but on a different timeline – yeah. So, R4 implementation guides are fairly well established for supporting the search of a single patient's data but not so for multiple patients. Is that what we're trying to say here and that we suggested proceed with the requirement for single patient data search implementation but possibly wait until we have some successful implementation of searches for multiple patients using the Fyre R4 standard? So, I was just trying to clarify at the end what we're trying to tell them we're looking for. Does this help clarify?

**Sasha TerMaat – Epic - Member**

The one thing I'm thinking through is whether we really want to see successful implementations of searchers or products that search for multiple patients.

**Denise Webb – Individual - Co-Chair**

Oh, yeah. I can say of products that search.

**Sasha TerMaat – Epic - Member**

It looks good.

**Denise Webb – Individual - Co-Chair**

Are all good with that?

**Sasha TerMaat – Epic - Member**

Yeah.

**Denise Webb – Individual - Co-Chair**

Hopefully, this will help the rest of the committee so they won't go what are you asking for. Okay. Recommendation 23. And I just clarified we're talking about the publication of API documentation here and which area of the preamble text that we want to be revised. I really didn't change anything else here. All right? And 24, no changes other than to say put this in the final rule preamble. And I couldn't figure out which section that went in because there were different places that registration was talked about. So, we'll let ONC figure that out unless one of you has a particular area to add there.

**Sasha TerMaat – Epic - Member**

I don't have one.

**Denise Webb – Individual - Co-Chair**

Okay. We'll just leave that as is and they can decide where that goes. Okay. so, we're at 10:28. And I'm going to ask that we finish the remaining I believe it's 11 recommendations.

This was one of the big ones and EHI export. So, I think we have a call tomorrow, right, Kate?

**Kate Tipping – Office of the National Coordinator – Staff Lead**
Yes, we do.

**Denise Webb – Individual - Co-Chair**
And Les, will you be able to be on that call tomorrow?

**Leslie Lenert – Medical University of South Carolina - Member**
What time is it, I'm sorry?

**Denise Webb – Individual - Co-Chair**
Because this really – or if you can be on part of it to address Recommendation 25. Just a second, I'm looking.

**Kate Tipping – Office of the National Coordinator – Staff Lead**
I think it's at 8:30 Central.

**Ken Kawamoto – University of Utah Health - Member**
At 9:30 Eastern.

**Denise Webb – Individual - Co-Chair**
At 9:30 Eastern.

**Leslie Lenert – Medical University of South Carolina - Member**
I just confirmed I can do that, yeah.

**Denise Webb – Individual - Co-Chair**
Okay, good. So, if you look at – pardon?

**Leslie Lenert – Medical University of South Carolina - Member**
That's good, yeah. Thursday is fine.

**Denise Webb – Individual - Co-Chair**
We will resend the link to the Google Doc. And if you could start – well, go ahead and read through the entire thing in case anything else catches your eye. But we're going to start with Recommendation 25. I did put some comments in there. And Kate, I did not see the text proposed by Les that you said you had inserted. Maybe I just was looking in the wrong place.

**Kate Tipping – Office of the National Coordinator – Staff Lead**
My comments aren't showing up. I can put in the original document.

**Denise Webb – Individual - Co-Chair**

Let's just email that email you sent to Raj and me just prior to the last HITACC meeting because it shows what was proposed and what he suggested. And I added some comments in there. I was really struggling with what we were trying to suggest on our original recommendation here two and three. And then, I did add some comments on Recommendation 26. I got a little confused. I think we need to reorder this. So, if I could ask the task force members to take a close look at 25 and 26 and be ready to discuss tomorrow. And then, you'll note that for the rest of the recommendations, there is nothing of substantive nature in the rest of this. It's more just adding the regulatory text and preamble sections. And Recommendation 32, I did a little bit of rewording on that. So, timeline. We do want to get this transmittal out to the full committee Friday afternoon.

So, I kindly ask all of you to take a thorough read and especially focus on 25 and 26 so we can get through that tomorrow and we can accept all of our changes and let you all take one last review with a clean version after tomorrow's meeting. And then, our goal would be to get it out to the full committee Friday afternoon so they have time to go through this. Did I hit that right, Kate?

**Kate Tipping – Office of the National Coordinator – Staff Lead**
Yes. I can clean it up after we talk tomorrow and then, send it back out to folks and we'll try to turn it back Friday afternoon to the full committee.

**Denise Webb – Individual - Co-Chair**
Okay. All right. I thank everybody for making it onto the call today and I hope you all can be on tomorrow. We're almost done. We get to see what the committee has to say. All right. Thank you very much and, Lauren and Kate, I'll call in for a debrief.

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

**Denise Webb – Individual - Co-Chair**
Sasha, thanks for editing today. I appreciate it

**Sasha TerMaat – Epic - Member**
No problem.