

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) ADOPTED STANDARDS TASK FORCE 2022 MEETING

July 19, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Hans Buitendijk	Oracle Cerner	Co-Chair
Steven (Ike) Eichner	Texas Department of State Health Services	Co-Chair
Jeffrey Danford	Altera Digital Health	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Jim Jirjis	HCA Healthcare	Member
John Kilbourne	Department of Veterans Health Affair	Member
Hung S. Luu	Children's Health	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Vassil Peytchev	Epic	Member
Samantha Pitts	Johns Hopkins University School of Medicine	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Ram Sriram	National Institute of Standards and Technology	Member
Raymonde Uy	National Association of Community Health Centers (NACHC)	Member
Debi Willis	PatientLink Enterprises	Member
Seth Pazinski	Office of the National Coordinator	Acting Designated Federal
	for Health Information Technology	Officer
Josianne Charles	Office of the National Coordinator	ONC Staff Lead
	for Health Information Technology	
Liz Turi	Office of the National Coordinator	ONC Staff Lead
Ocett Dahar	for Health Information Technology	
Scott Bohon	Office of the National Coordinator for Health Information Technology	ONC Staff Lead



Call to Order/Roll Call (00:00:00)

Seth Pazinski

Okay. Hello, everyone, and thank you for joining the Adopted Standards Task Force meeting. I am Seth Pazinski with ONC, and I want to thank all of our task force members for continuing to volunteer their time to support this task force and lend their expertise. I want to thank any of the members of the public who joined our task force meeting today as well. As a reminder, your feedback is welcomed and can be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled for approximately 11:50 this morning.

Let us begin the roll call of the task force members. When I call your name, please indicate you are present. I will start with the co-chair. Hans Buitendijk?

Hans Buitendijk

Good morning.

<u>Seth Pazinski</u> Good morning. Steve Eichner?

Steven Eichner Good morning.

<u>Seth Pazinski</u> Jeff Danford? Raj Godavarthi? Jim Jirjis? John Kilbourne?

John Kilbourne Good morning.

<u>Seth Pazinski</u> Good morning. Hung Luu?

Hung Luu Good morning.

<u>Seth Pazinski</u> Clem McDonald? Deven McGraw? Eliel Oliveira? Vassil Peytchev?

Vassil Peytchev Here.

Samantha Pitts?

Samantha Pitts Here.



Seth Pazinski

Alexis Snyder?

Alexis Snyder Good morning.

<u>Seth Pazinski</u> Good morning. Fil Southerland?

Fillipe Southerland Good morning.

<u>Seth Pazinski</u> Ram Sriram? Raymonde Uy?

Raymonde Uy Good morning.

Ram Sriram I am sorry. This is Ram Sriram. Good morning. I was on mute.

<u>Seth Pazinski</u> Oh, good morning. And Debi Willis?

Debi Willis Good morning.

<u>Seth Pazinski</u> All right. Thank you everyone. I will turn it over to Hans and Steve for their opening remarks.

Hans Buitendijk Steve, would you like to kick it off?

Steven Eichner

Good morning, and thank you for joining us for our second major working meeting for the task force. We are excited to go through a number of the additional standards, continue our work, and have some good discussions today. Again, welcome. Hans?

Hans Buitendijk

Welcome, everybody. We are going to look at the progression of the work. You will see a couple of things that are happening. One is that we are progressing with Group 2 where we left off last week. We are going to go back to one of the early ones on which we have some review to do. Then, assuming that we can make it through Group 2, you will see that we are jumping to Group 5. The reason for that is, based on some additional input and insights from Groups 3 and 4, public health quality measures are being scheduled





shortly so that we can have the opportunity to get that insight. That is why you see Group 2 and then a jump to Group 5. Hopefully, we will have a chance to go through the materials a little bit more.

The other thing that you will notice is that in the spreadsheet there are some follow-ups left to be done, but for the code systems there is, as of this morning, a draft. It is marked as "draft recommendation." It might sum up the discussion that we have. We will not review that today, but if you have any comments or suggestions around that, in the spreadsheet you can use the column right in front of it to make any suggestions on how to improve upon that or clarify that. We are not going to expand on that today.

It looks like for public comment we already have at least one person lined up once we get there. We might have something. We will see. Seth will help us through that today. Steve and I should not forget to move on to that. Seth will keep on us there. So, we will see what is happening there.

Steven Eichner

Before we get into the meat of our meeting today, we have a couple of minor housekeeping things we would like to take care of. Dr. Raymonde can join us. We are sorry he is feeling a little bit ill, but we welcome him and would like to allow him to introduce himself.

Raymonde Uy

Thank you, Steven. My name is Raymonde Uy. I am a physician informaticist with the National Association of Community Health Centers. I have been out this past two or three weeks for multiple fractures of the left upper extremity and COVID, finally, after two and a half years. My background is in clinical medicine, and I did a postdoc fellowship in bioinformatics with Dr. Clem McDonald from the National Library of Medicine. In the interim, I teach clinical informatics in the Philippines as well as do some consulting in the industry. Now I do clinical terminology across multiple projects with the CDC and HRSA. Thanks for having me in HITAC. It is nice to meet everyone.

Steven Eichner

Thank you so much for joining us. Glad you are feeling better. Seth, can you give us a quick reminder about making comments in the chat, what can be seen by the public and what cannot?

Seth Pazinski

Yes. If you want to make a comment that can be seen by everyone, you just select the public tab to "everyone." And if you want to send a message just to the panelist, you can just indicate "host and panel."

Steven Eichner

And is it correct that comments to everybody will be included in the records, but comments to individuals are not included in the meeting materials for the archive?

Seth Pazinski

That is correct. If you want to have your comments included in the public archives just send those to everyone, and then we will record those. Again, you have the opportunity to submit your comments there or at the end verbally during the public comment period.

Steven Eichner

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Thank you so much. Hans, I will turn the floor back to you.

ONC Standards Review – Groups 2 & 5 (00:06:59)

Hans Buitendijk

Thank you. All right. We will go to the spreadsheet as we continue to work. What you will see when we arrive there is that they are currently filtered on Groups 2 and 5. That is where we are going to concentrate, but if we can open it up to Group 1 as well, we can point to where the update is for your reference separate from this meeting. There we go. I think it is about to be there. Yes. Now let us adjust the screen size here. Okay.

If you can open up the filter for just a moment, you will see on the righthand side as we go through and we have more information, we will begin to define what a recommendation would look like based on the discussion and the conversation that we have. If you have any comments put them in Column X next to it for additional suggestions. You will also see that the references are as we discussed, No. 1 is pointing to Column A, and that is just as we are sorting or otherwise that we can keep a correct link there. Keep that in mind, and we will start to do the same thing for others as well. Look out for those.

Group 2, if we go to the first one in that group, we started that conversation. We discussed the first three that you can see on the screen. On the first one, we specifically wanted to come back to that as Debi had a couple of thoughts and questions about CCD. We wanted to make sure that we captured that as well before we started to move on to other topics. Debi, can you clarify or provide the feedback that you were looking at?

Debi Willis

Sure, and thank you for this opportunity. We had a consumer-facing application that allows patients to pull in their data via FHIR, and we had been pulling in the CCDs with STU2, which are very handy for patients. We noticed that when we started pulling data in from the R4 endpoints, the first EHR that we started pulling in we weren't getting any CCDs.

So, we reached out to them, and we were told that CCDs were no longer required to be shared with patients. I do not know if that was an oversight or a misunderstanding of the standards, but the explanation I got was that everything was already being shared via FHIR, although particular elements. But the reality is that if a patient wants to share what happened at a particular encounter – maybe they went to an emergency room yesterday or they want to share their entire history – it is a lot easier to share it in a single document rather than search through different parts of their records to find out what happened at the latest encounter.

And so, I just wanted to bring that up to the committee to find out, has that requirement to share a CCD with patients been taken away, or is that a misunderstanding or an oversight? What is going on with that?

Hans Buitendijk

I guess there are probably two parts. We will look at the ONC as well, but the certification still requires support for CCD, so the certified software should have that. Now, the question is are they all exposed through FHIR APIs? That may need a little clarification on what kind of clinical notes are in there, but that is a little bit more outside the scope of this group to interpret whether a particular implementation is or is not supporting a particular capability according to a standard or a certification, whether that is accurate. So,



that part of the question I think we need to address separately from what we are focusing on in the task force where the question is whether a standard that's being used is still appropriate to be used.

Whether the implementation of this or other standards is done accurately needs to be addressed as a separate question outside of the task force. It is still a valid question to make sure that everybody is aligned with what is supposed to be there, but that is not the charge of the task force.

Debi Willis

That is fair. I was not quite sure. I did not know who to ask about this. I appreciate being able to have it identified and maybe understand who it is that needs to address that. That would be good.

Hans Buitendijk

Seth, is there somebody at ONC that you would suggest asking the question to? I know that several people on the call outside of the meeting would be helpful. I would be more than happy to see what the situation is, but the official answer needs to come from somewhere else.

Seth Pazinski

I am happy to take that one back and follow up.

Debi Willis

Thank you, Seth. Thank you, Hans.

Hans Buitendijk

You are welcome. Any other questions about the topic here? The first three we already went through, and we wanted to pick it up at Row 18, No. 16 there. As this is the second meeting that we're going through, I also want to give the opportunity if there is something else that somebody thought about on 13, 14, or 15 let us catch that, and then we will jump into the rest.

Steve, anything before we jump into 16 and 17 that you want to share, or are we ready to go?

Steven Eichner

I have nothing.

Hans Buitendijk

All right. The first one here is around the notation for national and international telephone numbers that is currently in place. When we look at the feedback that we see, many say there is still some work going on, "inconclusive," and "need more information." We will start with Alexis on the line, or if anybody else has additional questions or background that is needed on that standard. Effectively, it has the characteristics in some ways of a code system. On the other hand, it is about the format, so it is slightly in between.

The standard has not changed. Since it was published there is no known new version out there. At least for me, it was a reason to indicate maintain. There is nothing new that we know about. There is nothing else that we know about. So, perhaps this is one that we just keep on using it. It is still helpful. It still provides standardization of that aspect. There is no need to make any changes there. Is that something we can conclude from the feedback, or is there additional information that we need to have?



If not, then you can scroll to the right a little bit – no, it is showing. Now it should pop up. I guess for this one we are going to phrase something along the lines of "maintain."

Steven Eichner

This is Steve. I think they included a note that there was no alternative identified just to provide a little extra clarification.

Hans Buitendijk

I will phrase something around that. It sounds good. Then we have the next one, No. 17, International Public Telecommunicating Numbering Plan. You see very much the same kind of feedback, to maintain. There is also no known new standard. Maybe if somebody is aware of that, please let everybody know. As far as we know, there is no other one, no new version, no alternative, and it has been working.

Are there any other questions or concerns that would lead us to another conclusion than that we will maintain the same mark with no alternative identified?

Steven Eichner

Hans, this is Steve again. I think the same would apply, but it also occurs to me in looking at the report we are going to develop that one of the things that we probably should include or might consider including is a little bit of our methodology in looking at how we collected information about potential alternatives so that can be a resource when the next task force comes along in several years to do the same kind of thing. We can share the process we went through. Whether it is useful or not let the next task force determine, but at least we have established the methodology and shared that as a process, including where we have looked.

Hans Buitendijk

That seems to make perfect sense. Does anybody have additional comments on that? Then we can start to work on outlining that as well, summarizing that as we work on the other ones. I see reactions in the chat. Great.

Steven Eichner

To help build that out a little bit, if task force members can contribute where they may have looked for alternative standards, that would be great.

Hans Buitendijk

All right.

Vassil Peytchev

Although in this particular case, it is silly to look for telecommunication numbering standards outside of the ITU, right?

Hans Buitendijk

It would be self-defeating in a way, agreed. If there is something else it is fair game to consider, but I agree with your perspective there as well.





Steven Eichner

For these two particular items, it might not be a health-specific standard. There might be coming from a different domain or IT in general a standard that would apply.

Hans Buitendijk

Yes. Unless there are other comments, I think we are ready to go to the next one. More specific to healthcare, we have the Direct Project, No. 18. The ONC Applicability Statement was in Version 1.2. Since that time, Version 1.3 has been made available as well as has been put into assets. It is now permitted for an HIT that wants to be certified to that criterion that references it to use that more current standard. That is permitted. From that point forward, in the latest published there is nothing more current. This is very recent, last year. There may be work in progress, but not yet that I am aware of. There might be of some sort. Certainly, discussions are going on, but there is no known date of anything more current than that in flight.

If we then look at the reactions that are in here, you see a couple of "phase out" and "replace" because there is a more current version out there. There are a couple of "inconclusive," "need more information," and some are working on it. So, at this point, with that in mind, what additional information are we needing to help reach a conclusion?

I heard somebody speak up. No? Any additional information that somebody was particularly looking for to help inform their recommendation?

Vassil Peytchev

I can provide one piece of information. Version 1.3 is an actual ANSI standard compared to all the previous versions, which were consensus-based discussions without going through the ONC process with all the requirements that are attached to it. To me, that is a good indication that it makes sense to update to the latest version.

Hans Buitendijk

Do you think since we do not know when the next regulation may be proposed that this would be a statement along the lines of starting with, "Use a more current version," since that's available, plus add the additional comment, "Plus, it is now ANSI standard, which makes it a stronger standard"? Something along those lines, is that where you are heading?

Vassil Peytchev

Yes, that makes sense.

Hans Buitendijk

Okay. I will put that in as a note. Others? Does that make sense to everybody?

Deven McGraw

Yes, it does. I think I marked this as working because I was not sure what the status is of the use of Direct given migration to FHIR. I also do not have daily interaction with that standard, so I do not have a strong view on this, but I did not want to opine until I had heard more of the discussion. This was helpful.





Hans Buitendijk

Great. Thank you. Anybody else? Let me know what direction we need to head with phrasing this.

All right. Then we will go on to the next one. At any point in time if we go too quickly, pull us back.

Seth Pazinski

This is Seth. I just wanted to let folks know we did have an issue with the chat feature and the ability to send chats to everyone. We have gotten that corrected now. Apologies. I just wanted to make sure folks are aware you can now choose the "everyone" option if you want to send a chat out. Thank you.

Hans Buitendijk

Okay. I notice that I need to check my box there, too. Next one, ONC Implementation Guides for Direct Edge Protocols, Version 1.1. In the current certification, in the rules, there is no version listed in SVAP as a more current one, and there is no later published version for this standard. When you look at the feedback, there are also a couple of questions on more information and a couple "working." We see a difference in that there is one that indicates "maintain" and one that indicates "replace or phase out."

Vassil, not to put you on the spot, but which one are you looking at that could replace this or that would be a good reason to say, "Let us move on to something else," a new version or another standard?

Vassil Peytchev

Well, as part of the update to the previous standard, there is an ongoing update to a specification that was not named, which is the XDR/XDM for Direct Implementation Guide. However, part of the edge protocol specification will be moving into the XDR/XDM for Direct Implementation Guide because that is the logical place where that can be properly defined and more formally defined. The edge protocol is just about ready to be updated as well. Within the next few months, there will be a new version of the direct edge protocol which will reference the almost complete XDR/XDM for Direction Implementation Guide update.

So, if we are going to suggest having the latest version for Line 18, we have to have Line 19 up to the latest version. Otherwise, you have contradictory requirements since there are a lot of misunderstandings and mistypes corrected from that 2014 version.

Hans Buitendijk

Is it fair or appropriate to say that what is actually in the SVAP, because that is only 1.3 and not the corresponding edge protocol, is already causing challenges, or it is just a continuation of the challenge that already existed? Not that it necessarily matters for our recommendation, because this would effectively say, "Do the same on this one, and we are aware that something is coming out." So, it is fair to them to go to the newest version?

Vassil Peytchev

I think that the SVAP by itself does not contain issues. Not having the Line 19 requirement reflect what is in SVAP is an issue.

Hans Buitendijk

Okay. As part of our statement, should we indicate then that it is coming up in the next couple of months? It is a year or two out? Is it short-term or long-term? What is your assessment of that?

Vassil Peytchev

These will be ANSI standards as well, so they will go through the whole process. We are looking at half a year to a year.

Hans Buitendijk

Okay. There is a comment in the chat from Hung Luu. Do you want to clarify that or address that question?

<u>Hung Luu</u>

I am a little uncomfortable recommending replacement with something that is not fully ready yet. While we can comment on the recommendation that we are aware of versions that are being worked on and alternatives that are being worked on, the fact that they are not ready for primetime means I do not think we should be retiring something before a fully vetted alternative is available.

Hans Buitendijk

Is it a better phrasing that we may need to go back to other ones that we may consider? So, it is not a clear "maintain" as it is we do not know about anything else, but we know that there is a new one or there is about to be a new one, so you should consider it to move to the next one then.

<u>Hung Luu</u>

If the recommendation is to update to the latest at the time of whatever, our general comment should be to consider the then most currently published version. That will cover the case where the updated versions will be available, and they will be considered, right?

Hans Buitendijk

Correct. And at that point, if it is found that the then most current is not good enough, or there is something else, an alternative has come up in the meantime, that is still part of it. What we are indicating is that there is a high probability that there is something else coming. That is the reason why we can start to think about retiring what is there, but you cannot retire it until the next version of the regulations. It is not going to be taken out. Maybe that is a question to ask. Unless there is not a regulation that changes what is in the current one, it is still there.

Hung, does that address your question if we phrase it that way, or does that still raise a concern?

Hung Luu

That is fine. I thought the alternative I was hearing is that we are wanting to consider some of the edge protocols by the applicable statements for secure health transport versions. My understanding was that that was not yet complete, yet we were talking about actually retiring the edge protocols before the newer version or even the further work had been completely voted on and vetted. That is a problem. But if you are just saying that we used edge protocols, and we know that there is work out there and that it should be replaced when the newer alternatives are ready, then that is fine.

Hans Buitendijk

Okay. As part of our phrasing, I made a quick note that, "Until that is published it cannot be retired," shorthand for the moment that we address that in our phrasing to make sure that it cannot be interpreted as being removed. It might be a general comment, but none is supposed to be retired until such time that a new one is named where we feel that we can start to move along.

Steven Eichner

This is Steven. The fact of the matter is that it would not be likely that a standard would be adopted by rule and regulation and be required in place on the first day a regulation might be in effect. There is usually an implementation period or an adoption period unless it is more of a retroactive standard or retroactive regulation where everybody is already using a particular standard that has been around for quite some time and it is formalized in practice.

Hans Buitendijk

Correct. We need to be very careful how we phrase it so that we are not giving the impression here that we believe that it can already be replaced in the absence of something new. And if something new is not coming around then please do not replace it, because it is still needed.

Steven Eichner

The fact of the matter is there has to be sufficient time after a standard is published and adopted for implementation. Regardless, it would be difficult in an environment to say, "Here is a standard. It is the official standard as of today. You must comply with the existing standard as of today," especially when that standard was just published yesterday.

Hans Buitendijk

Right. A lot of that conversation can also happen once it has been proposed.

I also see a question from Samantha on whether this is about No. 18 and that it might go back without an update on 19. Vassil, I am curious whether you can clarify a little bit more what the dependency is now versus at a future point in time.

Vassil Peytchev

The dependency is one-way. You can use 18 without using 19, but you cannot use 19 without using 18. That is what it is. So, if at the time of the update the newest version of 18 is adopted but the new version of 19 is not adopted, and the previous version is maintained, the previous version will probably work to some extent, but it does not have the same formal strengths and same formal requirements that are present in the newer versions. That is all.

Hans Buitendijk

So, you can use Version 1.3 without 19, but you cannot use 19 until that is updated to properly work with 1.3 or thereabouts, correct?

Vassil Peytchev

That may be a little bit too strong of a statement because the new version is supposed to be backwardcompatible. As far as I know, they are not breaking anything except for properly formalizing things that before were not clearly defined so there were multiple ways to do things beyond what was intended to be





the right way. The newer version will have the one right way to do it. Validation tools for 19 for the old version I think will work just fine with the updated version of 19. It is just that they will not be updated to catch these special cases that were not correct before and were allowed. It is those types of details that are affected.

I do not think anything precludes 18 to be updated if the new versions of 19 are not adopted. It is just that the new versions of 19 will provide for better interpretability and lower the implementation costs because they will remove invalid variations.

Hans Buitendijk

Perhaps as we get to the next round of phrasing this stuff, Vassil, you can help make sure that we phrase that right to get that nuance clearer. Samantha, does that clarify your question? Great. That means that we have a draft for 18 and 19 on how to progress there, and we have some nuances that we want to make clear so that we do not reach an incorrect conclusion of standards being removed too soon. That gets us to No. 20 unless there are other questions around 19 or 18.

In 20, that is referencing several sections of the IT infrastructure or the ITI technical framework. There is nothing listed in SVAP, but when you look at it, there is the latest published version of the ITI overall that is as recent as June 2022. There are frequent updates to the ITI framework that are being applied all over the framework. When you go to the standard you notice that this goes back to early 2010-2012, in that range in Version 7. So, you could say that change has occurred. The question is how much change occurred in those sections since that point in time? That is where the question is coming up here. You see some indications of working on it, trying to understand that, to get more input on that. You also see some that need more information, and you see that there is a note that yes, we would phase out/replace, so that sounds like from Vassil's perspective enough news has happened to consider that.

Vassil, as you are probably more up to speed than others, you have a note in here. You indicate that it should also probably reference Volume 1, not just the transactions in Volume 2, so there is more to be done. Can you clarify that, whether it is a combination of improved references as well as updates, or is it just improved references that you are looking at?

Clem McDonald

This is Clem. What is this for, how much is it used, and how important is it?

Vassil Peytchev

Clem, all the Carequality network uses that, so you are looking at tens of millions of patient records being exchanged every month using those.

Clem McDonald

Well, this goes back a long time, but is this not something that HL7 should be doing?

Hans Buitendijk

Well, IHE defined the document exchange framework, which is part of the ITI, not HL7. HL7 defined the content, and IHE is defining profiles on some of that content. This is about document exchange and how to interact. These are really the fundamentals of how document exchange is to occur and whether it is part of





Carequality, HIEs, **[inaudible] [00:38:41]**, whatever. Everybody is using parts of the ITI technical framework to make that happen. These sections are an abbreviated version of the ITI that is explicitly referenced in the certification rules to do document exchange and participate in that. That is the intent and the focus of that standard, and that is why it is not HL7 in that regard. They are not operating in that particular space.

Vassil Peytchev

Well, thank you. Can I ask another question? Definitely update, because there is a lot of improvement in the documentation. The documentation is much clearer than what was in Version 7 or whatever in that area. The reason it only referenced Volume 2 is that it was the start of defining a new profile at that time that was not fully defined for the push transactions, and that is now fully defined. The update should be both to the current version and better references. Just pointing to a transaction that can be used by multiple profiles for multiple purposes – and different purposes have different requirements – you must frame it within the profile which defines those requirements. I can provide some great examples of the improvements and how the requirements are clarified, but I think you captured the essence.

Hans Buitendijk

I think for the arguments that we made for why it should not just be maintained this may be enough. An example or two might help, but we are not trying to come to a full list necessarily. That is part of the process of the next round of rule-making. That is where those considerations should be coming into play to say, "Is this enough to increase it to the next one?" Certainly, the indication here is that we should look at that.

Steven Eichner

Right. Not only is this out of the scope of this task force, but looking at what are the costs of implementation, and is there enough value in looking at changing to a different standard to warrant the adjustment, again, that is outside the scope of this task force. That is part of the whole regulation build and looking at justifications that would have to be considered by ONC in moving a regulation forward.

Vassil Peytchev

Just to be clear, this is not an alternative. Current implementations already follow an updated version to what is in Version 7. Certification tools have likely taken into account the newer version clarifications that are not present in the original references.

Hans Buitendijk

You could argue from that perspective that SVAP should probably have used them because they have not just errata. They are not necessarily very substantial there, but they are consequential. So, that would be perhaps **[inaudible] [00:42:59]**. Again, there will be a separate discussion around that. This seems to be enough to indicate that maintaining is not sufficient and that replacement with a more current version and references is appropriate to start considering. We can provide some examples to fill out that recommendation.

Is there anybody that has a concern with starting to flesh that out and move forward with that? If not, then we have come to the end of Group 2. We are then starting to look at Group 5. Is there anything on Group 2 that we may have to go back to, or are we all comfortable that we jump into Group 5? Okay.





This is going to be an interesting variety of a couple of them because we've started to look at different aspects. It is going to be an interesting mix of what is there. "Hodgepodge" came to mind. Let us work through that. The first one is an annex to FIPS that is about security. When we look at this, we have a couple of folks that are indicating needing more information. Some are working. To maintain is there a couple of times as well. There is a latest published version, but it does not seem that that current version is anything substantially new to this that would be material to consider. That is the reason why I did not put maintain. Vassil indicated "maintain" but wants to get a little bit more.

What information do we need on this standard before we can go and figure out a potential recommendation? Do we need additional information about this?

Clem McDonald

Is this used in healthcare heavily?

<u>Hans Buitendijk</u> Yes. We have to fully adhere to this to have proper security in place in several areas.

Clem McDonald

This is mostly security?

Hans Buitendijk

Yes.

Vassil Peytchev

If I put maintain I did not see that there is a new version. I would suggest that we need to update to the newest version given the essence of security. In terms of additional information, it would be helpful if we can get some federal feedback on whether the newest version would cause any issues being implemented. I do not expect a published specification to be too new to implement by most vendors, so I would suggest that we use our usual language of the latest version at the time of publication.

Steven Eichner

This is Steve. Even if there is no content change specific to the subject at hand, if the document is making changes in other domains it is still probably advantageous to modernize the standard so that there is consistency on the organization's part, that they are not playing by a different set of standards for their health information system as opposed to some other system within the organization. There is no cost to saying, "Yes, this is the current version that incorporates the same language as the old standard," if that makes sense.

Deven McGraw

I agree with these comments supporting the update to the new standard, although I do think it would be helpful to get some sense of how much it will cost. How big of a burden is it to ask people to migrate? Generally, in security I always think, given the state of the security environment and constantly evolving threats, we should always be pushing towards the most recent versions, mindful of course of what the different costs might be of that upgrade and needing to **[inaudible - crosstalk] [00:47:56]** to whatever time.





Steven Eichner

I am also thinking about regulatory impacts outside of ONC's specific components, looking at federal audits or things like that that may affect an organization where an audit finding is not compliant with the FIPS Standard 1A, but you are compliant with B, and you have an internal disconnect with auditors because there are two conflicting standards required.

Deven McGraw

Well, if you are required through some other mechanism to adhere to the latest federal standard there is nothing that stops you from migrating there, whether this is required as an ONC standard or not. We have had that discussion about being able to adopt more robust standards, but I just think for security, again, I agree with those that think migrating to the next version makes sense unless it is going to be significantly costly and we need to put it on a slower timeframe. Getting more information on that would be helpful.

Hans Buitendijk

It is also interesting to note that when you go to that standard, that link is always reflecting the most current version. You do not get to the 2014 version from that. You only get to the latest.

So, it sounds like there is gravitation towards using the same language, using the most current, whichever one that is. Reference that, and then move forward from that.

Steven Eichner

Administratively, we need to pick up whatever line is the time standard. We skipped it.

Hans Buitendijk

Liz just sent me a note as well slapping my hand on that. We will go back to 37. Any other things on 38? Are we good with that direction? Then we do need to go back to 37 since I accidentally skipped one extra line.

Steven Eichner

Time away from you.

Hans Buitendijk

All right. Let us see RFC 5905. I did not work according to the network time protocol, apparently. We fixed that. We are back in the right spot. There is no known current standard out there. I could not find the latest published unless somebody found it. The comments are mostly around maintaining and a couple of "information needed." This maintains the proper syncing of network time as needed for document exchange. There are others, but particularly that one. Any concerns that we keep this as a "maintain" because we just do not know about anything new? We do not expect that because of the nature of this type of standard.

Steven Eichner

I think we note "maintain" unless there is something we missed and potentially include something similar in the language of the recommendation.

Hans Buitendijk



So, the clarifying note, "We are not aware of any new ones that need to be evaluated."

Vassil Peytchev

There might be three other RFCs that update that one, and one of them is for message authentication.

Hans Buitendijk

Which ones are they, an update to RFC 5905?

Vassil Peytchev

Yes.

Hans Buitendijk

Well, then we need to check that out. Do you happen to have the actual -

Vassil Peytchev

One is 8573. Another is 9109.

Fillipe Southerland

I am looking at the Wikipedia page on this, and it says RFC 7822.

Vassil Peytchev

But 7822 is for extensions, and I do not think that any extensions are necessary. Again, out of the three, 7822, 8573, and 9109, 8573 is to get rid of MD-5 checks, I believe, and 9109 introduces port randomization, which I do not know if it is relevant. Out of the three, maybe 8573 is relevant, but I am not certain.

Hans Buitendijk

So, maybe a follow-up here is that we check it out respectively, and if you sense that the extensions in 7822 do not apply to what we are doing we would check that out then as well.

Vassil Peytchev

Right.

Steven Eichner

I think it is safe to say that there is consensus that understanding time between systems is an important consideration and those need to be a standardized approach, whatever it may be.

Hans Buitendijk

Okay. We will keep this as a follow-up. I am going to put that in a yellow color here so that we will catch that for sure to come back to. Any other comments here?

The next one is the ASTM Standard for Audit. We have a couple of different comments here, "working," "maintain," and a few of you need more information. There is a 2019 update that is accessible if you pay a fee. Some have not been able yet to check that out and see if there is anything in here that is substantially new, but there is an update out there. It is on the page that when you click on this there was a last-updated, etc. The name of the standards and otherwise look all the same. So, this might be in the same category



that we need to check it a little bit more unless somebody already had the chance and can provide some insight as to what happened between this version and 2019.

Steven Eichner

We know that the standards are about seven pages long.

Hans Buitendijk

And there are some critical components in that. We are still working on it, still checking it out and getting our hands on the version. I would suggest that we put this one on the side for a moment to check it out as well.

Deven McGraw

Hans, your comment about there being a cost to access the standard reminded me that Samantha has a comment in the chat regarding whether the cost of updates is something that we consider or whether it goes into regulation. Since I raised it with the last one, it would be good to get a clarification of whether that is in scope.

Hans Buitendijk

For us, it is not in scope. It would be a consideration in the next rule-making what the cost/benefits are. Here, since the primary focus is on what can be retired or replaced, it would fall in the category of "we should consider that." Therefore, that might be a good reason to replace it rather than maintaining it as-is or fully retiring. That is what we currently understand the charter of the question is, and we can go as far as some examples as to why but not necessarily go into a full analysis as to whether the cost/benefit functions, etc. are sufficient to make that happen.

Deven McGraw

Got it. Thank you.

Hans Buitendijk

And looking at Seth, just another on the ONC team to make sure we stay on track there because we do not want to stray too far. And the cost, by the way, is \$54.00 for the standards. That is less than whatever substantive changes it might have that we would have to develop against. It is just 15 minutes to open it up.

Steven Eichner

Just to reemphasize, Samantha, considering the cost of implementing standards is well outside the scope of the task force. It would take probably a very lengthy amount of time to look at a true benefit/cost analysis for any one of the standards we have discussed to this point, let alone all of the standards discussed across the entire health provider/health systems domain. That is just beyond our scope.

Hans Buitendijk

There was a question that came up in prepping for this as well. Since there is a cost with getting to the standard to review, whether it is substantive or not, most if not all are free. Question for ONC: is there a method by which this task force's members could get access to a version that could help assess what



recommendation to make, or are we then obligated to obtain those standards at the ASTF cost? Seth or somebody else, do you have a recommendation, or do we need to follow up on that?

Seth Pazinski

This is Seth. I am not sure I understood the question. Could you say it again?

Steven Eichner

Sure. The nature of the question is that this particular standard has a cost for acquisition of \$54.00 a copy, and it is difficult for the task force to evaluate whether the standard should be maintained or retired without understanding what the language of the standard is. So, is there a method by that we can get access to the language of the standard to evaluate and make a recommendation to ONC on whether it should be maintained or retired?

Seth Pazinski

Thank you for clarifying. Yes, we will follow up [inaudible - crosstalk] [00:59:06].

Steven Eichner

Basically, we can see the book and its cover, but we cannot see the contents.

Seth Pazinski

Got it. Yes, we will follow up.

Hans Buitendijk

Okay. We will check in on that. That gets us down to No. 40, Open ID Connect Core 1.0. And with the errata from Set 1, there is nothing published in SVAP. There is no known latest published for this one. This is currently what it looks like. We are not aware of more current versions, but I think Raj indicated – is Raj on the line? I did not hear him during the intro. No. He indicated a suggestion for either perhaps phase out or replace update, and we have a couple of other ones that are "maintain" or "inconclusive."

Is anybody else aware of any new version? We are not aware of any work that is going on that would indicate something relatively imminent. Any thoughts from anybody with additional insight? We may want to reach out to Raj to understand what is the reason for it potentially phasing out, no need for it at all. I am not sure whether that was his intended suggestion or whether there is an update there that he may be aware of. If not, then I am marking this one yellow for follow-up. Is there any concern if we mark open ID as a follow-up as well just to make sure whether Raj has some insight that we should consider? I do not hear a concern there.

We are going to go on to Secure Hash. It goes back to 2015. This is also from a security perspective. There are no known updates. Nothing was mentioned in SVAP. We see a couple of "maintain," a couple of "working." Does anybody have any additional information that we need before making a recommendation to maintain?

Steven Eichner

This is Steve. I think having additional information would probably be good. Again, looking at the date, 2015, and thinking about it from a security perspective, that feels like almost ancient history. I am wondering if



ONC might be able to help us identify a subject matter expert or two to either present some information on it or make a recommendation about a potential alternative or other things that are in development as potential substitutes.

Hans Buitendijk

I am also curious about adding to ONC. Not to put Ram on the spot, but NIST may have some insights on some of the development in security and how to improve upon that. I am wondering whether, Ram, we can ask you as well to see whether there is some insight there?

Ram Sriram

Yes, the security division is working on a number of documents. I can check that out.

Hans Buitendijk

That would be great.

Ram Sriram

Many of those documents are being adopted everywhere. This is all general stuff. It can apply to any domain, not only healthcare.

Steven Eichner

Looking at the data for 2015 and all the work going on in security on a daily basis, I think there is probably something at least in development, if not being released. It would be good if there is not something available today to keep our eyes on that ball.

Ram Sriram

I can send an email tomorrow.

Hans Buitendijk

That would be great. I suspect that it is going to be more of another approach versus that there is a version update because there are so many ways that you can generate a hash.

[Inaudible - crosstalk] [01:03:39]

Vassil Peytchev

The specification is specifically for SHA hashes, and the only thing that might have been updated is the removal from SHA-1 as a secure hash. So, there might be a relevant update somewhere.

Steven Eichner

Ram, I am also wondering – and I can reach out to Mariann Yeager from The Sequoia Project to see if there is some kind of hash conversation going on concerning TEFCA. That would be another place where I could see discussion around security and encryption going on today in the world of information exchange. There might be a linkage there.

Ram Sriram

Okay. I will check with my security division on this and let you know tomorrow.



Steven Eichner

Yes, not that Sequoia is developing a standard, but they may have had discussions about something going on in IHE or somewhere.

Hans Buitendijk

We have not heard anything yet on this finding, so we will come back to that one as well. On to the next, Content Accessibility. Currently, in the rules, it is 2.0. In SVAP it has been recognized through 2.1. When we look at the two rows they are going to be very similar in that regard. Some comments are indicating "replace," "out of date," and that sounds like in the direction of the then-most-current. We already went up to 2.1, so at least that seems a reasonable one to go to in the next recommendation.

There is nothing further published at this point, but these two seem to be the same type of recommendation of then-most-current since we already have something in SVAP and there might be more advances that come our way. Does that sound like that would be the appropriate direction for our drafting? Is there additional information needed? I will say "then-most-current."

Steven Eichner

Let me ask a question of our ONC colleagues. Is it worth questioning the Office of Civil Rights at the HHS for any guidance in that space so there is consistency within HHS on accessibility requirements?

Seth Pazinski

Certainly, we can reach out to our OCR colleagues on that one.

Steven Eichner

Thank you.

Hans Buitendijk

And is it reasonable to say that that is the same response to a recommendation direction for the next one, 43, the Web Content Accessibility Guidelines Level AA Conformance? There are in the guides different levels. Are we looking at that in the same fashion? Is there any reason to be different?

Steven Eichner

Hans, I think the note from OCR is looking not just at other developments but at consistency with other OCR-related activities.

Hans Buitendijk

I will add that. Thank you.

Steven Eichner

If there is an opportunity for internal consistency with OCR that might be a helpful thing for them.

Hans Buitendijk

I will add that to the other one as well. At the next meeting, we will have insights on that. Any other comments on either 42 or 43?





If not, then the last one in the group is USCDI. I am not sure whether it actually had a version number in it at that point, but certainly, there is a Version 2 that has been published in SVAP. We know that imminently – weeks, days, I am not sure – USCDI Version 3 is expected to come out, and that progression will continue. To move on, there is feedback that is indicating a variety of "maintain." That would indicate do not change USCDI Version 1, or at least that is how it could be interpreted. I am not sure whether it was intended. Other feedback says to go to the then most current, and another comment is "need more information."

Let us start with need more information. What should we find out more about before we can make a recommendation? Vassil, you made that one, but there might be others as well along those lines. You commented here around what are the implications for US Core and C-CDA Companion Guides? Vassil, do you want to clarify this?

Vassil Peytchev

Yes. I believe the latest version of the C-CDA Companion Guide was released specifically to address USCDI requirements, and US Core releases also are updated based on new USCDI requirements. I believe US Core 5 was published to address USCDI Version 2.

Hans Buitendijk

Correct.

Vassil Peytchev

And so, if we specify here that it is the latest, what is the impact on those downstream standards that are necessary to exchange the data that is in USCDI?

Hans Buitendijk

That is a great point because there is almost a year gap that Cadence has. I was talking with Brett Marquard as well on some topics. We went through the timeline, and clearly in Year 1 or Year N, there is USCDI Version N that comes out. Then there will be a catch-up by C-CDA and US Core specifically to address the increment. That means in year N+1, target somewhere in spring, that that would be available.

What we currently saw is that in July of last year USCDI Version 2 was published. In January, the US Core and C-CDA guides that were needed to support that were balloted. Ballot reconciliation occurred, and actually, SVAP review closed on April 15, if I have the correct date there, or it was May 15. After that day US Core and C-CDA were published, and then SVAP was published after that. That was the sequence, and it is starting to look like that is probably the cadence that we are on.

So, indeed, we would have to be very careful not to just say the most current version but the most current version that has US Core and C-CDA support for it.

Clem McDonald

You are going to get into a Catch-22 if we do not do this one because the other ones have not done it. I think we should support it and then encourage inclusion in the C-CDA and the other parts. because that is how it was supposed to be used.





Hans Buitendijk

That is a challenge. Hung Luu, do you have a question or comment? You have your hand up.

Hung Luu

Well, I agree that we should go with the most updated version, and I think that there is a surrounding process for doing that. I think we are probably overthinking it in terms of if we make a recommendation on this specific version that somehow we are going to get ahead of the process. I think that, hopefully, there is a well-thought-out process about how to onboard and implement a new version after it has been published. We have heard from ONC before that they have given a lot of thought not only to signal to the vendors that this is the direction that they are going but also to give them adequate time to adapt.

And so, I would just stick with the recommendation that we go with the most updated version that is ready and let the process work itself out rather than try and time it so that our recommendation fits with the process.

Hans Buitendijk

I see Jeff has his hand up.

Jeffrey Danford

Just to be contrary, I think I agree with you. We are in a situation where the USCDI definitions and the way that we implement it is going to be US Core and C-CDA. At least the way Brett has explained it to me, it sounds like we are going to be about six months to a year behind USCDI in all those cases. So, everything we are working on right now from SVAP for the current version of US Core is going to be supporting USCDI V2. If we go ahead and say, "Now we are going to immediately move to V3," the V3 version of US Core is not going to be ready until January or February of next year.

Hans Buitendijk

It is actually April or May of next year.

Jeffrey Danford

Okay.

Steven Eichner

Just to interject quickly, we need to be aware of comment times. We maintain the position where we kind of hybridized the approach. We recognize the need to adopt one standard but have the other standard, I am sorry to say, on deck if we are looking to build the next generation.

Hans Buitendijk

And looking at the time, in about a minute we need to go to the public comment. Maybe Vassil, you have the last comment, then we go to public comment. Depending on how much it is, we are going to come back with Clem, Jeff, and I am raising my hand as well.

Vassil, do you have a comment before the public comment?

Vassil Peytchev

Very quickly, my suggestion would be to specify instead of the most current published version for USCDI the most current published version that is supported by the published US Core and C-CDA Companion Guides. That way we do not get out of sync, and everything is up-to-date.

Hans Buitendijk

Okay. We will stop there for a moment and bounce it back to Seth to get us into public comment and go from there. We will come back if we have more time left.

Public Comment (01:16:24)

Seth Pazinski

Thank you. We are going to open the call up now for any public comments. If you are on Zoom and you want to make a public comment, please use the hand raise function. It is located on the Zoom toolbar at the bottom of your screen. If you are just on the phone, audio only, press *9 to raise your hand. Once called upon, press *6 to mute and unmute your line. We will open it up for public comment.

It looks like we have one comment. John Travis, go ahead. Just remember to push *6 to mute or unmute your line.

Hans Buitendijk

John, if you can unmute? Oh, it is only online. He put his note in the -

Steven Eichner

John, this is Steve Eichner. If you want to type your question, one of us can read it aloud. People can read it in the chat, but we can also read it aloud so people can hear it.

Hans Buitendijk

There is a new message coming in.

Seth Pazinski

While we wait for John's comment, do we have any comments just on the audio line? I think we just have the one public comment from John. Why don't we give him a second to type in his comment?

Hans Buitendijk

Otherwise - oh, there.

Seth Pazinski

The question or comment from John Travis is, "How does this process consider a current version of standards and current certification regulations as a question of retirement? USCDI Version 1 is a good example."

Hans Buitendijk

Generally, in this process, the way we would understand that is that the current rule has USCDI Version 1 in place, and there will be a more current version shortly. The recommendation that we could make is either to maintain it as there is no need to go up in the regulation to a more current version – we would have to give some rationale as to why – or we could say go to a more current version and indicate which one that

might be. Keep in mind that it is not the chore of the task force to fully define the recommendation, "It must be a particular version for these 10 reasons." At the point when that new regulation would start to be created there is going to be an opportunity to review whether that is the right version, the current one, a later one, whatever it might be. So, that is **[inaudible] [01:20:00]** more detailed comments and specific comments.

Rather, here we are looking at an argument that is sufficient to highlight why it need not be maintained in its current form. I think that what we are looking at right now is how we want to phrase looking at the more current version. I am getting the sense that we should move to something more current. The question now is how do we phrase that "more current" given that there is a dependency on being able to implement USCDI to have appropriate standards that could do that? For some programs that might be critical, and for other programs that might not be relevant.

And so, I think that is the reason why we have this. If we are looking at the reference to USCDI, it is referenced in regulations for certification, and it is referenced in regulation for information blocking until the end of October.

The other question, Seth, that I just see from John Travis is whether the reference is to one version maintained and one version recommended. Seth, you might have more insight into that. Again, this is not that we are trying to be very specific about it, but if we feel that there should be consideration of supporting more versions of that, I think we could hint at that. It is not necessarily that we are the ones that are making a firm recommendation on behalf of HITAC for that. That will be a future process. Seth, is that a proper representation there?

Seth Pazinski

Yes, I think that is correct. I would say there is an opportunity in the rationale and explanation section. If there is additional context to provide background for a recommendation, that would be the place to do that as well.

Steven Eichner

Seth, this is Steve Eichner. Is it also fair to say that until a regulation is changed potentially to reference a different standard, the current standard referenced in current regulations still applies?

Seth Pazinski

Yes. There is nothing binding coming from the HITAC recommendations. Any change as a result of that would be informed by the recommendations of the task force and ultimately HITAC. Any changes to the requirements would come through subsequent rule-making from ONC.

Steven Eichner

And would go through the regular rule-making process with a comment period, ONC or CMS processing the comments, then having an effective rule at some point down the line.

Seth Pazinski

Correct. Any changes would go through the full rule-making process.

Steven Eichner



Wonderful. Thank you for the clarification.

Hans Buitendijk

Seth, are there any other public comments that we need to address before the last couple of minutes when we go back to our raised hands?

Seth Pazinski

No, that is it for the public comments. You can go back to the panel discussion for the last few minutes.

Steven Eichner

Hans, I want to divert us for just about two seconds before we go back to the discussion. I want to do a quick closeout. It is my understanding that you will not be able to join us for next week's meeting, but we will be talking about public health-related standards. Is that correct?

Hans Buitendijk

That is the current plan, correct.

Steven Eichner

Okay. I just wanted people to be aware of that before they might have stepped off at the end of time. Let us go back to our earlier discussion.

Hans Buitendijk

Clem, you are in line next. Go ahead. You are on mute still. Clem, you are on mute.

Clem McDonald

I want to support Dr. Luu's position vigorously. We have been working on this for the last four to six months. Why would we not support it? Of course, it has got to work through other things, but if you keep waiting for the one to succeed, if we say, "If this one is not done then this is not done," we will be in a Catch-22. We should just support it and assume that it will work its way through.

Hans Buitendijk

Okay. Let us then go to the next comment, which is going to be somewhat different in that it is more aligned with Vassil's comment that from what we have seen in SVAP, SVAP was not including USCDI Version 2 until the FHIR, US Core, and C-CDA standards could be included as well. Otherwise, from a certification perspective, where these standards are being referenced could not be executed because you do not know what you have to adhere to. So, in this particular situation it is a little bit of a Catch-22 that yes, we need to go to the most current one, but if that current one at the time that the proposed rule is being written does not have and would not have in a reasonable time the right standards to implement it, then at that point it is not workable.

There is a difference between intent and desire versus what is practical and can work in the certification environment where you have to test against the specific standard, not necessarily USCDI, although there are some aspects to it. You need to have the standard that implements that. In this case, that is what happens. So, I would be very supportive of the other note to have a cautionary remark there to be careful. Do not put something in that you cannot work with. It is not that we do not want it there. It is that we would





like to have USCDI well beyond what is currently defined over time, but that is not the practical implementation of it.

We are within a minute. We can still get Fil in, and we know that we have to pick this up in the next session to reach a conclusion. We will not get there yet today. But Fil, if you have an opportunity, I will get this back on the agenda next time.

Fillipe Southerland

Thank you, Hans. Hopefully, this will be fast. I just had a loop-around on Lines 42 and 43 and a question on our process. It appears there is a WCAG 2.2 in draft form. I am wondering if we want to make note of that, that we are aware of that draft form for the next iteration of this committee that comes behind us.

Hans Buitendijk

Okay. Depending on the rule-making, that might then be the then most current. I am making that note in the notes that we have that awareness.

Fillipe Southerland

Thank you.

Hans Buitendijk

I think that brings us to the top of the hour. Steve, anything from your perspective that we need to wrap up with before we close the meeting and reconvene next week? Hung, then we will pick up with your comments on USCDI.

Next Steps (01:27:26)

Steven Eichner

I think that is a pretty good place to stop. We do need to have continued discussion about the approach to looking at interdependencies, but there is no more time this week. We will pick it up next week along with information about public health-related standards.

I want to thank all the task force members for their participation today and their valuable insights. Please do continue to look at the worksheets and provide updates. If there are any questions, please reach out to ONC, and we will address questions during the week by email.

Hans Buitendijk

All right. Thank you very much. We will be back next week.

Seth Pazinski

Thank you, everyone. I will just bring the meeting to a close here. Thanks, everyone.

Adjourn (01:28:33)

