Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

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

August 9, 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
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Liz Turi	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Scott Bohon	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Carmela Couderc	Office of the National Coordinator for Health Information Technology	Presenter
Caleb Wiedeman	TN Department of Health	Presenter

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

Mike Berry
Good morning, everyone. I am Mike Berry with ONC, and I would like to welcome you. Thank you for joining the Adopted Standards Task Force. As a reminder, your feedback is welcomed. It should be typed in the chat feature to everyone throughout the meeting or can be made verbally during the public comment period that is scheduled at about 11:50 Eastern Time this morning.

I am going to begin roll call now of our Task Force members. When I call your name, please indicate that you are here. I will start with our co-chairs. Hans Buitendijk?

Hans Buitendijk
Good morning.

Mike Berry
Steve Eichner?

Steven Eichner
Good morning.

Mike Berry
Jeff Danford? Raj Godavarthi? Jim Jirjis? John Kilbourne?

John Kilbourne
Good morning.

Mike Berry
Hung Luu?

Hung Luu
Good morning.

Mike Berry
Clem McDonald? Deven McGraw?

Deven McGraw
Good morning.

Mike Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Mike Berry
Vassil Peytchev? Samantha Pitts? Alexis Snyder

Alexis Snyder
Good morning.

Mike Berry
Fill Southerland?

Fillipe Southerland
Good morning.

Mike Berry
Ram Sriram is not with us today, but he should be back next week. Raymonde Uy?

Raymonde Uy
Good morning.

Mike Berry
And Debi Willis?

Debi Willis
Good morning.

Mike Berry
Good morning, and thank you, everyone. Now please join me in welcoming back Hans and Steve for their opening remarks.

Update on Draft Recommendations (00:01:40)

Hans Buitendijk
Steve, you may start. I just got back from PTO. I appreciate being back again, and I'm looking forward to the discussion.

Steven Eichner
This is Steve Eichner. We would certainly like to welcome Hans back as well as all of our Task Force members for another good day of discussion. We are going to be going through more of our charge, which is looking at the standards that are in regulation, providing some feedback for the HITAC's review, and then forwarding to ONC regarding whether the standards should be maintained, retired, or in some cases potentially updated. We have got some exciting things going on and some exciting discussions for today. Again, we would like to welcome you all.

Hans, the floor is yours.

Hans Buitendijk
All right. So, looking at the agenda, we are going to look at updates to the draft recommendation in a moment. Then we will have a couple of topics in the ONC Standards Review where we are looking at particular ones we will have some updates on. We hope to get to that shortly, then go from there. I think

where we are for the draft recommendation is – I am not sure whether we can easily share that – we are starting to shift, as I just learned, to move from a spreadsheet format into a Google Word Document. That is going to make it a little bit easier. We are going to be able to edit, review, and move forward on the drafts that we have so far. Change tracking will be a little bit easier opportunity to do that than right now in a spreadsheet. The spreadsheet was great to help get through old materials, then we will go from there.

I am not sure whether anybody has the link available. Steve?

Steven Eichner
We are sending it out to the Task Force members just after this meeting. We have created some potential draft text in the form of a draft recommendation for forwarding to HITAC. We created a loose frame document that includes each of the standards and in many cases some draft language about what a recommendation could look like. We have shifted from Google Sheets to Google Docs because Google Docs has better functionality for tracking changes. You can mark it with red lines, and we encourage you to use that as you are making suggestion changes in the text. That way it is easier to see what changes may exist. We are looking at using some of the toggle buttons to remove some of the edits so you can see what that final text looks like.

So, in the next week, please take a look at that. Help us refine some of that language that we need to provide an update to HITAC at their meeting in the next couple of weeks. It would be great to be able to report that we are really close, that we have finalized text on several standards, and are still working through just a few leftovers. That is where we are going after this. The worksheets are still available to you. Those links are still there and still live, but please make edits to the suggested text in the recommendations in that Google Doc document.

Hans Buitendijk
With that, if we get through all the topics listed under the ONC Standards Review section and get through Group 6 then next week we will start to begin fine-tuning the recommendations based on your comments and additional drafting that we are doing to get ready for that. The timing looks like we are on track and making good progress. Part of that will depend on how far we get today during the review topics that we have here.

Is there anything else, Steve, that we need to add to update the draft recommendations other than any questions that anybody may have?

Steven Eichner
If there are any questions, certainly we would like to entertain them and help make it as easy as possible for Task Force members to participate.

ONC Standards Review (00:06:45)

Hans Buitendijk
Are there any questions regarding that before we jump into the next part? If not, then let's jump into our list of topics, which starts with ASTM E2147. One of the questions that we had here is whether in 2019 or later an update was made that materially changed the ASTM standard that would lead us to believe that we

needed to suggest considering the new version, or whether the changes that were put in play were smaller points, and then from there.

Liz, you have your hand up. You may have some insight on this.

Liz Turi
Yes. We researched to figure out if there was an update in 2019. From everything we can see, and looking at what was published versus what is in regulation, this is the same standard that was published in recommendations. So, there is no change even though it says 2019 on the ASTM website.

Hans Buitendijk
All right. Thank you. That might imply that since there is no change, and in the discussion so far that we had there was no indication that there is an alternative that we may want to consider, perhaps for this one our draft recommendation is going in the direction of maintaining. It also seems that not having this information would not be helpful either. We will need to continue to support this capability. So, is there any concern or any alternatives to suggesting that our draft is, “Maintain the standard”? “Do not retire it, and there is no known replacement”? If so, we do not hear any concerns there.

I am updating the spreadsheet for now. I am not shifting to the Word document yet. We are going to go for a maintain. All right. That is the first one. In the second one, there were some questions on CDC Race and Ethnicity Code Set, differences between Version 1 and Version 1.2, and if everything is correct. Carmella, you are on the line to give some feedback on that.

Steven Eichner
And just as a reminder, there was some difficulty in easily determining what the difference is between Version 1 and Version 1.2, so we wanted to bring in a subject matter expert to help us better understand what differences exist between the versions.

Carmela Couderc
Good morning. My name is Carmela Couderc, and I am at ONC. I am the Branch Chief for Terminology and Content Delivery. I checked into the changes in this code system between 1.0 and 1.2, and I could not find what changed between 1.0 and 1.1. However, I can tell you that the only change between 1.1 and 1.2 was to fix a typo in the label for the ethnicity code for Israeli. There was an extra vowel in the 1.1 version. So, that is the only change that happened.

Hans Buitendijk
In that context, so far the vocabulary generally has been on a path of if a more current version is available somebody can start to use that. You are not locked into the one that is in regulation, and there is all that regular process. Is there any reason based on this that that would not be available to this one, or does the same hold true here if a new version is available and somebody can start using that for certification purposes?

Carmela Couderc
I’m sorry. It is the second. It was an “or.” It is the latter.

Hans Buitendijk
So, it can be used if you want to. That sounds like it can be treated in the same way as what we have done with others. There is no indication that something substantial is different, but where there is a new version of this it could fall under the same as the comments that we have made for all the other vocabulary. Go to the then-most current from a regulatory perspective, replace it as part of the regulation, but keep the rule in place that you can use a more current version. Is that for the Task Force an accurate and reasonable approach to that?

Alexis, go ahead. I see your hand up, but you are still on mute.

Alexis Snyder
Sorry. I do not know if I am misunderstanding what you are saying, Hans. Are you suggesting that we say that the 1.2 version which just had a spelling error update is the newest version that we should maintain? Last week we had a big discussion on how this is very old and outdated and needs to be replaced.

Hans Buitendijk
What would it be replaced by? Do we have a suggestion for that?

Alexis Snyder
No, but the recommendation is that it needs to be updated and replaced, not necessarily that there's something out there but that this should be looked into and updated. At the very least, I think we talked about making a recommendation that ensures that the language for race and ethnicity in this version or an updated version aligns with the current USCDI Version 3. It does not make sense to me to say, "Oh, there is a 1.2, and we should make sure that gets used," if it is just a spelling mistake.

Hans Buitendijk
The discussion was more about whether there is potentially a better version out there that should be considered, and it should be looked at.

Alexis Snyder
Well, it was about content. I do not know if it was a better version, but at least aligning with the USCDI Version 3 and making an updated version for this, taking a look at this and updating it because it is dated March 2000. It is old.

Hans Buitendijk
Does somebody know off the top of their head navigating to USCDI Version 3 whether those two are out of sync at the moment?

Carmela Couderc
We updated Version 3 to reference CDC Race and Ethnicity Code Set Version 1.2.

Hans Buitendijk
Okay. So, that would further reinforce that this one should be replaced with at least USCDI if not whatever the then-most current version is at the time that a new regulation is being considered, which could be a 1.4

perhaps already or another alternative. Alexis, that seems to fit with what you are indicating and what Raymonde indicated. Is that correct?

Steven Eichner
I think this is another opportunity to document that there should be alignment between whatever the standard is and what is referenced in the USCDI.

Alexis Snyder
Correct.

Hans Buitendijk
As well as that not knowing when the next regulation version comes out, if that is tomorrow let's say, then clearly, USCDI Version 3/Version 1.2 alignment that we want to consider more strongly. If it is a year from now or two years from now, hypothetically, then another version might have come out that both USCDI Version X and that regulation need to look at.

Steven Eichner
Right. Again, we are looking at the idea to float all boats at the same level so that if a particular standard is used independently and in the USCDI, they are both elevated consistently so we are not getting internal inconsistency that says to use an older version that is not in the USCDI but a more current version in the USCDI, or vice versa.

Hans Buitendijk
Right. The draft notes should be aligned with USCDI and the then-most current version of this code system. Is that reflective, and does it summarize the intent? Alexis or Raymonde?

Raymonde Uy
I agree with that.

Alexis Snyder
I think that makes sense.

Raymonde Uy
Yes, that makes sense to me.

Hans Buitendijk
Okay. I'm updating the spreadsheet. Was there anything else that was left on this topic that we should address?

Steven Eicher
I believe that was it.

Hans Buitendijk

Okay. It sounds like we can go to the next one, syndromic surveillance. We have Caleb Wiedeman of the Tennessee Department of Health on the line to provide a little bit more insight on this to help us. Steve, any additional backdrop from the last week's meeting?

Steven Eichner
We were still looking at understanding a little bit more about what the future of syndromic surveillance looks like and whether there are up-and-coming things that should be accommodated.

Hans Buitendijk
Okay. Caleb, are you on the line?

Caleb Wiedeman
Good morning. Yes, I am.

Hans Buitendijk
I see one hand raised. Oh, it just disappeared. Go ahead, Caleb.

Rosa Ergas
Sorry. I had my hand raised, but Caleb, please proceed. This is Rosa.

Caleb Wiedeman
I do not have any slides, but as far as what I prepared in making the recommendations that move to the newer standard, the newer standard updates and corrects a lot of errors and points of confusion that were in the 2015 guide. It would help as far as giving vendors clarity on what public health is expecting. Pages 13 and 14 of the newer 2019 guide detail the different changes and updates on legacy language and other things that are presented in the guide. That is all I had, but I would be happy to take questions or provide clarity on anything.

Rosa Ergas
This is Rosa Ergas from Massachusetts. I would just add that many of the updates are codifying interpretations that are already in place in terms of how the data are requested for the syndromic surveillance community. And so, it does add some nice clarification and does not substantively change any of the data process as I understand it.

Hans Buitendijk
It sounds like this has helped clarify one of the questions on the readiness of public health authorities and agencies to take that on. It sounds like this would have, from your perspective, wide support to adopt a more current version and therefore retire the older version to be more consistent along the line. That is a reasonable step to take. Is that a fair statement?

Rosa Ergas
That is my understanding, yes.

Hans Buitendijk

Does anybody align with that this one is a "replace and consider the then-most current version," which today is 2019? Is there any anticipation of an even more current version in the works that by the time the new regulation is being considered could be a candidate? Or is this the latest one that is out there, and there is no work in progress in that sense?

Caleb Wiedeman
I am not aware of one in progress right now, but it is open to the regular HL7 process for updating. So, updates would go through there as the formal mechanism for folks to provide input. It should be an open process as opposed to the older guide, which was a regular release with a smaller group of people.

Hans Buitendijk
So, it would be a "replace and consider the then-most-current version," which we think is the 2019 version. We will stay with that. Any concerns with that, or are we okay with that? I will mark that in our notes, and then we can flesh that out. Any other questions?

Anything else, Steve, on syndromic surveillance that we needed to address?

Steven Eichner
I do not think so.

Hans Buitendijk
Okay. Then we are moving nicely along to the next topic, which is USCDI where there were some questions on context. I understand, Carmela, you have an update on some of those questions and perspectives we can use to discuss it further.

Carmela Couderc
I do. I also sent in some slides if we want to go through those.

Hans Buitendijk
That would be great.

Carmela Couderc
All right. Let us hop to the next one. We wanted to give an overview of why USCDI matters – USCDI stands for the United States Core Data for Interoperability – and then give a quick overview of USCDI Version 3, which was just released in July, last month, and quickly go over some of the new data classes and elements and some new changes that occurred to existing data classes and elements. If that sounds like a good set of topics, we will just keep going.

As a reminder for those of you who know about USCDI or those of you who are new to it, USCDI is a core set of data needed to support patient care and facilitate patient access to their health data. It establishes a baseline of data for other healthcare use cases, and it expands over time via a predictable, transparent, and very public process. Next slide, please.

I mentioned at the beginning we are going to talk about USCDI Version 3, but USCDI Version 1 is referenced in the ONC Cures Act Final Rule from 2020. The data listed in USCDI Version 1 is required for

certification criteria, including a new one requiring API application programming **[inaudible] [00:22:52]** for access to patient data using the HL7 FHIR US Core implementation guide. As of now, USCDI also defines electronic health information for information blocking. We are going to look at a timeline in just a minute, but that is going to change in the near future. Next slide, please.

This is just a list of some of the certification criteria where USCDI comes into play. Right now, just a reminder, USCDI Version 1 is what is required in regulation. Hans, you had a slide that referenced USCDI Version 2, which just went through the Standards Version Advancement Process. So, we are not going to go into that here, but there was a Version 2 in between Version 1 and Version 3. Next slide.

This is just a quick look at the timeline that I have already referenced a little bit. Going across the top, when you think about why USCDI matters, it is USCDI Version 1 that is referenced in the Cures Rule, and it is available for certification. As of December 31, 2022, all the data elements in USCDI Version 1 must be available for exchange. And then, if we look at the bottom of the timelines, from April 2021 to October 5, 2022 – that is coming up pretty soon – USCDI Version 1, all the data elements there comprise the electronic health information that is subject to information blocking rules. In October, that switches the definition of electronic health information. Next slide.

Here is the snapshot of USCDI Version 3, and I will just go over the key here. If you see a gold-colored box with a single star, that means it is either a new data element or a new data class. Each one of these boxes is a data class, and the individual items below the heading are the data elements. If you see an arrow, as in let's go to the top center under Health Status and Assessments, that means that was an existing data element in USCDI Version 2, but it moved its home from one data class to another. And if you see a double gold box with a star in the middle, that means that was a data element or class that existed in Version 2, but it changed somehow.

So, I will just give you a couple of examples. On the bottom left, I will call out a data class called Health Insurance Information. That was brand new in USCDI Version 3. All the data elements within it are also brand new with USCDI Version 3. If we look just to the right of that, we see a data class named Medications. Oh, this is incorrect because there should not be a star or a little gold box next to the first data element which is just called Medications. But the four below it are new data elements, those units of measure, indication, and fill status. So, that is the pattern of how you interpret this diagram.

I will call out a changed data element. If we look on the bottom right under Vital Signs, at the second from the bottom there is a data element called Weight for Length Percentile. Underneath that, in parentheses, it says, "Birth to 24 months." Well, if you look in USCDI Version 2 that would say, "Birth to 36 months." The reason that was changed is that that age range overlapped with BMI percentile for 2 to 20 years. So, we made it clearer that the certification testing on the patient's age if it is from birth to 24 months will test for weight for length percentile, but once that child is 2 years old then it is BMI percentile.

Are there any questions about any of the information that is on this slide? I know it is a lot to look at, but sometimes your eyes can be drawn to those gold squares, and that tells you what changed. I see a question in the chat. Is it appropriate for me to take that now?

Hans Buitendijk

Sure.

Carmela Couderc
Okay. "In USCDI Version 3, it seems to note the data element and the code system are standard to use in some cases, but how do implementers know the actual codes to use for exchange?" That is a very good question. One of the changes we made in Version 3 is we removed reference to specific value sets; however, we reference code systems. And the reason for that is that terminology changes at a faster pace than the standards can, and what we count on are the implementation guides from HL7 to reference the specific value sets. So, that is how you know the actual codes to use for exchange.

Some of you might be familiar with the Interoperability Standards Advisory where we provide a compendium, a list of value sets or code systems, that can be used for the different data elements. But in the end, it is the implementation guides that define that. Good question. Thanks for putting that link on. Next slide, please.

I forgot to mention at the very beginning that Al Taylor prepared these slides, but he could not be here today. He is on vacation, so I am filling in for him. So, here are some questions we got ahead of time. "How do we operationalize the changes from USCDI Version 2 to Version 3?" Well, we do that through the HL7 implementation guides. In the case of C-CDA, we've been doing it through companion guide updates.

"Where do we sit in the regulatory process?" Well, as I mentioned, USCDI Version 1 is referenced in the Final Rule, and the data defined in USCDI Version 1 is required to be exchanged by the end of 2022. Also, it played a temporary role in the definition of electronic health information. I am going to skip over the next one because we were not sure what you were looking for there. And then, we have the comment to consider adoption of USCDI as a block, not as pieces. USCDI is a complete standard. Certified Health IT cannot decide to implement just a piece of it and not another piece.

If we want to talk about that third bullet, maybe you could help me out with what you were looking for.

Hans Buitendijk
Steve, do you have backup on the ONC management with SVAP for somebody who particularly raised that question?

Steven Eichner
Sure. That is looking at the SVAP process and how things are related between USCDI and standards that may be included in SVAP to maintain alignment between what is adopted through the USCDI and what may be promoted through SVAP in case there is a conflict.

Carmela Couderc
I see. USCDI, depending on the data element, may reference some sort of code system. For example, we added Occupation and Occupation Industry, and we referenced Occupational Data from Health. But a code system is not referenced in the SVAP process. Code system versions do not move through SVAP. The fact that USCDI itself is a standard that can be – this is not really a verb, but it can be SVAP-ed just like USCDI Version 2 just made it into SVAP, so it is available for Certified Health IT to implement and certify to that

version. So, the things that move through SVAP are standards that ONC regulates. They are not, say, code system versions. I have the sense that they are okay.

Hans Buitendijk
Carmela, you can ignore my comment. That is just for the chat.

Carmela Couderc
Oh, okay.

Steven Eichner
Just to interject, some of those standards in SVAP reference code sets and use code sets for implementing those standards. So, how does that resolve against the code sets that might be used for USCDI?

Carmela Couderc
Are you talking about the example where, say, USCDI references a release of SNOMED, and there is some other standard that is going through SVAP that also references a very specific release of SNOMED, and what if those are out of sync?

Steven Eichner
Correct.

Carmela Couderc
I do not know that we have that situation. I am thinking about the different implementation guides and how they bind to terminology. I would have to look, but I have the sense that in those implementation guides they may reference a value set that the binding strength is such that the terminology can move at a different pace than the implantation guide.

Hans Buitendijk
That is accurate. The implementation guides point normally to a value set that indeed has that binding. That binding can be very tight. You might say you can only use these five values, and it might be five out of a larger code system, and then the implementation guide would have to change to open it up. But there are also plenty of places where it is the exemplar, it is extendable, and it is something else you can add onto. And then, the full code system is available if that is appropriate. The code system can then have a new version based on the general rule that one can certify against a more current version of the code system. That allows you therefore to use more current values and pull them in at any point in time that a new code system version comes out.

That is not done through SVAP. That is done through the general rule. SVAP only deals with the implementation guides where the bindings are being referenced. So, that is the mechanism by which there is flexibility where it needs to be, and there is very tight control where you can only use these five because anything else would not make sense. That would have to be agreed to in the standards/implementation guide that that is appropriate. And there is always a balancing act going on to not make it too tight, but also not make it too loose either if that is going to cause problems. That is the ongoing debate in that area. And if Vassil is on the line or Jeff, they may also know for sure whether there is an exception to that rule. I am not aware of it.

Other questions? Does that clarify the SVAP component to that? Carmela, it might be helpful to also clarify that the SVAP reduction is voluntary.

Carmela Couderc
It is voluntary, yes.

Hans Buitendijk
Any other questions or clarifications on the USCDI and how do versions generally work?

Carmela Couderc
All right. That is my last slide.

Hans Buitendijk
Thank you. Any other questions or comments around that before we go back to the main question? Raymonde, you have your hand up?

Raymonde Uy
Yes. Thanks, Hans. I just have a quick question, Carmela. We were looking at the document published in reference to the USCDI site that has all of the new data classes and updates on the data elements. But to Lisa's point, it does not seem to reference any of the IGs, the specifications, value sets, or **[inaudible] [00:37:24]** on that document online. Do we have to rely on the tabs on the main site to look at the specifications and the IGs, or is there another, bigger document that references and comprehensively summarizes everything for developers?

Carmela Couderc
That is a really good question. USCDI is not going to declare specific implementation guides or anything like that. However, in the Interoperability Standards Advisory, SVAP, which is just a compendium of available standards, you will see a list of standards that are available, potentially code systems like SNOMED CT or CDC Race and Ethnicity. Also, there are references to implementation guides. However, ISA is a compendium. It says, "This is what is available." It also has an evaluation as to whether a certain item is required to be used. So, that is where you can get that information.

Raymonde Uy
On the document itself as well there is no reference to the ISA, so I think that is causing some confusion.

Hans Buitendijk
Maybe to clarify, purely from a developer perspective, the way we look at this and how we know what to do is that we do not look at ISA. We look at USCDI. We look at the certification edition that spells out the implementation guides that are required in full or in part, depending on how the certification criteria are written, that you must comply with and that you must attest to now support either the guide itself, and that is sufficient, or that by supporting that guide you support USCDI.

If you go to Carmela's slide, three or four back, where it said how are they substantiated in USCDI beyond the vocabulary, the C-CDA and the FHIR US Core implementation guides that, from a developer

perspective, if you are looking at HIT tell us what we are supposed to implement and how to implement it. It contains more data than USCDI declares because it needs to contain everything else that is needed to make it work. So, those are the two. By supporting FHIR US Core and C-CDA you support USCDI.

And then, there is a relationship between which version you need on the C-CDA side or the FHIR US Core side to support what version of the USCDI. You can get that by reading in reverse through the certification rules, but you cannot find it by going through USCDI. And if you go through ISA, you might end up in areas that are not material to what you are trying to do.

Raymonde Uy
Thanks, Hans. Thanks, Carmela. I appreciate the explanation.

Hans Buitendijk
All right. Any other questions? Carmela, any other things that you wanted to highlight?

Carmela Couderc
That is it for me. I think I went way beyond my allotted five minutes.

Hans Buitendijk
No worries. We needed to get through this to then go to the fundamental question for the Task Force. USCDI is a standard listed right now, Version 1. We know that there is now not only a Version 2 but also a Version 3 that is available. Version 2 is already referenced in SVAP. It is anticipated that once the standards have caught up with USCDI Version 3, the next SVAP, assuming no other regulations would happen, would pick up on that. So, our question is should we suggest that we hold on to USCDI Version 1 in the regulation as is? It sounds like, based on the discussion and conversation, that is probably not the recommendation we want to make. Rather, it is going in the direction of "replace it with the then-most current version whenever regulation is being considered." Do not stay with the old, but go to the next one.

There was also a discussion that we had before a little bit around if we look at whatever you put in a regulation, make sure that the necessary implementation guides that support it are in place as well. We had some other notes, and I see that Vassil is already raising his hand. Part of that conversation was around how do we make sure that there is some compatibility otherwise. I am going to pass it to Vassil. Do you have a comment?

Vassil Peytchev
Yes. Specifically, the USCDI, US Core, and CDA implementation guides have some new answers that are very important in terms of what the current latest version is at the time of regulation. There is a time consideration when something is released as to when it can be implemented. For example, if the time is now, and there is a USCDI Version 3 out, I think it would be impossible to specify USCDI Version 2 because most of the places have not even done USCDI Version 2. So, regarding the timing, saying simply "the latest" may not be very helpful in this situation. We need to be more descriptive in what we mean by the latest. A regulation that says, for example, that USCDI Version 3 will start to be used for certification in two years. That is something completely different from saying it will start right now.

Hans Buitendijk

Right. If we can bring up the spreadsheet then we will jump to Deven and Hung as well. In the spreadsheet, we had a couple of different options that we were thinking of considering where the concerns that Vassil raised are addressed in some but not in others, and we need to talk through that. Deven, go ahead.

Deven McGraw
I have a similar set of questions to the ones that Vassil just raised. Because the update of versions to USCDI seems to be moving pretty quickly – I mean, they are projecting that there will be a Version 4 out by January 2023. And the Standards Version Advancement Process allows for voluntary adoption, but requiring Version 4 at the next regulatory rulemaking, I think we have a genuine issue here about just how quickly one can begin to mandate these different versions. It is likely the uptake of different aspects of the various versions will be very different and will potentially lag for some aspects of it versus the entirety. And yet, you do not necessarily want to ossify Version 1 by not moving past it. So, I am struggling with how to word this because they should be migrating to the next version that has been sufficiently tested in the market that we need to move the regulation there, but that is a little hard to predict.

Hans Buitendijk
And we probably can put those considerations in there. I think there is a sense of general agreement that staying with Version 1 is not what we want. We want to move up. The question is, is it 3, 4, 5? Depending on where you are in the cycle, is it mature enough? Are there sufficient standards? Those kinds of questions will need to be considered. For the Task Force, it is not for us to say today, "Use 3 or 4." We do not know when that new regulation is going to come in.

So, our phrasing needs to be along the lines that we indicate to ONC what aspects you need to consider to do that, and then that process at that point can say, "If tomorrow they would come out and go forward…" If we keep it wide open it might be Version 3 they are going to consider. If we pull in some of the language that Vassil indicates, V3 would not be valid because you would have to go to V2 which has actual standards for it. If we can identify a couple of those parameters to consider that are important without getting too far, because that is not today's charge to get to a conclusion on what it is, that would be helpful. So, we have to get the three variants that we were talking about the last time.

Steve, do you want to jump in? And I think we have Hung as well.

Steven Eichner
I was just going to remind folks as well that the things that are in regulation would go through the NPRM process, which would include the feedback period as well, so it would not be implemented by an "if ever" rule that said, "Okay, the standard is being implemented. Put in print today, and everybody is supposed to use it tomorrow." There is that other element that is not in advance of that process. We may create some problems by just saying, "Use what is in the SVAP process." It could be incomplete compatibility between providers and looking at the ability to receive something that **[inaudible] [00:47:54]** in SVAP if everybody is not elevated at the same time and there is not that same NPRM process for something in SVAP.

Deven McGraw
That is right. SVAP is completely voluntary, so you do not start adopting it until you are ready to adopt it. There is nothing mandatory about it unless there is something that I am missing. There is a regulatory process for the comment to go through, but in terms of our task and what we would recommend, I guess I

liked where Hans was taking this. It would be difficult for us at this juncture to mandate a specific replacement for Version 1. It should be replaced, but there are a lot of dependencies to consider. There are the ones Hung has mentioned, and we are not going to say, "Go to Version 2, Version 3, Version 4," or even the latest version at this particular time.

Hans Buitendijk
Before we go to Hung, if you look at Cell X44, the third option, think about that one and see what else we want to add to clarify what needs to be considered. Is there something else? For maturity, do we need to pop in something else? Hung, go ahead.

Hung Luu
I agree with your recommendation, Hans, in terms of the language so that we follow the ONC process. It is really up to them to decide what version of USCDI to use for certification. As Deven said, we cannot ossify it so that we remain on Version 1 where there is no impetus for development or anything else. Remember, this work is only designated to meet every three years. We cannot be holding up progress where we decide on 1, then in three years we are still on 1, and then in three years, we go to 2. That is not the intent I think of the process. So, I feel very strongly that we should vote on the readiest version, but we cannot stay on 1.

Hans Buitendijk
I included the words with an underscore just to let it jump out, not that it should be there in the final text, "To ensure mature, interruptible support of the USCDI version." Do you think that something like this lasts, and I can remove that first part that that is not likely, that that is the direction we want to be heading and that is where we want to draft the recommendation? Deven, Hung, and Vassil in particular, does that fit with the comments that you made?

Deven McGraw
I think so, yes, for me.

Vassil Peytchev
Mature is good. I am wondering if there is something more specific like two years of SVAP availability, something like that that would put some concrete examples so you have a relationship with something that goes to SVAP. It is expected at some point that may become a regulatory requirement. Now you would have something that is even more specific saying, "Hey, if it has at least two years of SVAP availability, it is very likely to become a requirement." So, as things go into SVAP, people can start looking and saying, okay, I have two years to figure this out, and after that, I may have to scramble to catch up. That may be overreaching our goal, but something like that might be helpful and concrete.

Hans Buitendijk
I put in just two concepts of aspects of "mature." There might be a few more, but if I'm hearing you correctly, including those kinds of words would help from your perspective. Deven, others, would that be too strong or too specific?

We do not know exactly what the timeline is when we need to consider this, and we have Steve indicate the opportunity during NPRM to further indicate whether it is sufficiently mature. My definition of that might

not be the same as yours, and we need to work through that. So, would this help or hinder? Should we leave that in?

Hung Luu
My main thing is that the overall process should be in the hands of ONC, not in the hands of HL7. So, it cannot be that we hold up everything until HL7 decides that they are going to do the implementation guides and everything else. And so, there has to be the impetus that ONC decides what version to go with, and that then creates the priority for HL7, not the other way around.

Hans Buitendijk
All right. With the NPRM public comment process, it is always a back-and-forth discussion to align the reality of where we are and where we want to be at that point. Do we think that we can keep that widely deployed operational in there, or do I drop that and just leave it as "mature"? And then, that needs to be filled in along the way, but not for today because we are already indicating, "Do something more current." That is the essence: Do something more current. But we still might have a good debate as to what the most appropriate one is. We will figure that out when we get there.

Hung Luu
I prefer the "mature."

Hans Buitendijk
Vassil, are you going to be okay if we drop that for now? We still have the notes. We are going to have that conversation. Do we leave it along these lines?

Vassil Peytchev
I think it is fine, yes.

Hans Buitendijk
Okay. Anybody else? Alexis jumped in. You are comfortable as well? Then we will use this, and we will work out the draft, and we will have more opportunity to finetune and get some I's dotted and T's crossed around that. That is the direction then.

Okay. Steve or anybody else, do you see anything else that we missed on USCDI? I think we have the outline of a recommendation. That means that we can go to Group 6.

Steven Eichner
I think we are good.

Hans Buitendijk
All right.

Liz Turi
I believe we had on the agenda to look at the draft dispositions that were identified last week, and then Group 6.

Hans Buitendijk
Sorry about that. Is the best place for the draft dispositions in the spreadsheets?

Liz Turi
Yes. I copied them over to the spreadsheet, and there were only four that were highlighted for this week. That was the Secure Hash Standard, which I believe Vassil had drafted, and then Group 7 that Raj had drafted. I have that onscreen right now.

Hans Buitendijk
All right, we will start with Secure Hash. We did the last one. Any comments on Secure Hash? Can we be as strong as a "must include," or is it a "should include" given that we are indicating we need to do something, but –

Steven Eichner
Use the line that does not include it.

Vassil Peytchev
What is the current language? I am sorry.

Steven Eichner
The current language in the regulatory note is that SHA-1 is not included, so the language here is reflective of the current status.

Hans Buitendijk
So, it should be replaced with something that includes a note about SHA to recognize that is already not allowed and should continue not to.

Steven Eichner
Yes.

Hans Buitendijk
Okay. I can drop over to that one as well. Is there anything else on SHA? If not, then let us go to the next one listed. Those were the Group 7s. We did go to the CDC one, right? I believe we did that. We did not go yet through Value Sets for Administrative Gender and Null Flavor.

Liz Turi
We did that. We did all of these last week.

Hans Buitendijk
Okay. So, from that perspective, what was the result of the Value Sets for Administrative Gender to indicate that it is the same as Comment 1, "One can use the latest vocabulary unless otherwise indicated"?

Liz Turi
Number 1 was this verbiage.

Hans Buitendijk
Yes. So, everybody was okay with that. And Vassil, do you have any further concerns there? Would that be a good update and replacement? Anything else to add there?

Vassil Peytchev
I think we discussed that the current work of the Harmony Project concludes that there is no such thing as Administrative Gender. There is legal sex, there is sex assigned at birth, and there is gender identity. These Value Sets for Administer Gender and Null Flavor are a good enough representation of legal sex. Therefore, it should be maintained. If possible, it should reference legal sex and the Harmony Project in some way to lead into the future of when this type of data is represented, for example, in US Core where I believe if they are not leading, they are considering adopting all that information in some way.

Hans Buitendijk
So, Liz started to type that what we want to do there is recognize that it is efficient for legal sex purposes but that Gender Harmony should be referenced for a more comprehensive perspective on what is appropriate in that space to include in the next round.

Steven Eichner
And consistent with other discussions of gender such as the Harmony Project.

Hans Buitendijk
Yes, and that means then that second paragraph that starts with "recommend to ONC," in this particular case we do not need that because we are going to elaborate on that first paragraph to clarify that. We might pick up some elements of it, but the essence is there. Does that make sense for everybody? Is there agreement that that is how we are going to finalize it or work on it?

Vassil Peytchev
I agree with this, yes.

Hans Buitendijk
Alexis, you have your hand up?

Alexis Snyder
Yes. I would just change the wording from "good enough representation" to "currently represents" or – I just do not think that that language sounds good.

Hans Buitendijk
Okay. We will certainly have many editing opportunities to clean it up.

Steven Eichner
While we have got the group here, we can get "represents current approaches for describing legal sex."

Alexis Snyder
Yes.

Hans Buitendijk
And “should be maintained for that purpose.”

Alexis Snyder
How about “minimally should be maintained”? Because we are talking about later saying, “Align it with newer work with the Gender Harmony Project.”

Hans Buitendijk
Then we can work through any further edits. Anybody with objections can start to wordsmith that. Carmela, you have your hand up?

Carmela Couderc
I do. That last sentence that says, “Look to Gender Harmony for a more comprehensive view and consistent with SOGIE So, Gender Harmony only deals with the gender identity part of SOGIE. It does not deal with sexual orientation, so I do not know. I think you might want to say “sex and gender identity-related attributes.” It is not SOGIE. And the Gender Harmony model does not include a notion of legal sex, so I am not sure that we want to make some statement about that.

Hans Buitendijk
In that regard, I think we need to keep that distinction to indicate that the Value Set for Administrative Gender is currently being used for administrative legal purposes, and Gender Harmony is additional data and prospectus to be able to document. That starts to stray a little bit beyond because we all are looking at what is there, but we need to create this context to say for an additional prospectus that is where Gender Harmony can be considered on what value sets to use and how to represent that.

Steven Eichner
Yes. The language currently in place represents current legal descriptors. If there is a change in legal descriptors then the vocabulary set might need to change.

Hans Buitendijk
Okay. We can work through that in our drafting for that interjection, and then in our drafting between now and next week we can further refine that and work our way through it.

Steven Eichner
I was just looking for consensus on the concept, not necessarily the final language, so there was agreement in the thrust if not the specific words at the moment.

Vassil Peytchev
The Administrative Gender is the least common denominator among legal sex descriptors because different states have adopted different approaches. They can all be mapped with Administrative Gender because Administrative Gender has the other value, and everything that is not male or female can go into “other.” But it does not represent current approaches to describing legal sex unless we are thinking about the federal passport approach, which has M, F, and X currently, as far as I know. So, I think we are trying to be too specific in something that is just – it is a useful value set. It should be, “Maintain, and enhance if there are changes to legal sex descriptors,” or something to that extent.

Steven Eichner
You said it much better than I did, but that was my intent. You said it much clearer than I did. I appreciate it.

Hans Buitendijk
Any other comments? Go ahead, Vassil.

Vassil Peytchev
I cannot repeat what I said, but it is being recorded, so we have it.

Hans Buitendijk
We have a recording. If we need to, we can go back. And as we wordsmith, we can certainly look for that that is being made clearer.

Then we have the last one on the list there, Race and Ethnicity. We have an open question there. Where did we land, and what was the remaining open topic to resolve? Do we need to phrase something along similar lines here? We need to be aligned with USCDI. If there is a more current version, that should be considered in the same fashion as other code systems. Can we build it around that general paragraph that is currently copied in there as well, or is there anything further unique to this that we need to add or instead of?

Carmela Couderc
I would suggest that this one is a little different because this standard does not define a code system. Underlying it is the CDC Race and Ethnicity Code System, so the standard text does not align there.

Vassil Peytchev
Is that the value set that says white, not Hispanic, Hispanic?

Hans Buitendijk
Yes, it is the 5 and the 2.

Carmela Couderc
Yes, the 5 and the 2. Two is ethnicity groups.

Vassil Peytchev
That is a value set. It is a value set for a very specific purpose, but it is a value set.

Carmela Couderc
Well, but the name of that standard up there is not a value set in itself. That is what I was going on is that the standards reference is not the instantiation of a value set.

Hans Buitendijk
Correct. So, I think we need to make a general note here that we need to clarify the language to have the proper reference to the code system value set standard to make sure that there is no confusion around

that. But unless I missed it, I did not hear that the intent of what we are trying to say is still the same. Just the wording is not accurate based on what that thing is. Is that fair, Carmela?

Carmela Couderc
Yes, and I would just call out the first sentence in the stock language has a little bit of a grammar issue.

Hans Buitendijk
Yes, we will sort through that. Okay. That concludes the review of the dispositions topic, and then we can jump into Group 6. Steve, anything else before we do the jump?

Steven Eichner
I think we are good.

Hans Buitendijk
Okay. Then let us jump into 6 and see how far we can get. We have about eight or nine minutes for this discussion, then we need to jump to public comments.

Steven Eichner
I do want to remind Task Force members that they will have the ability to go in and make suggestive changes to the text in the Google Doc document. That will be available 24/7 for the next several weeks.

Hans Buitendijk
Let us look at 6. We will still use the spreadsheet for a moment because we can look at the various other comments that were made there. The first one, FHIR US Core Implementation Guide, currently in the rules is Version 3.1.1. We have 4.0.0 available, and it needs to be recognized that that can be used in support of USCDI Version 1 as well. Then we also have available 5.0.1, which can be used to support Version 2 of the USCDI. They are all available. There is nothing yet for USCDI Version 3. That work is just starting to make sure that any gaps are filled. That will probably take until the first half of next year when that will be done. The question is, is it April? Is it May? Is it March? Where will it fall to be published? If last year was guidance, it will be late May or sometime in June. But hopefully, it will not take that long this time. We will see.

Generally, this is also an area where if we are saying USCDI should meet a more current version, there are these dependencies on the standards there. This sounds like this would be in the same category of we should go to a more current version, but depending on where USCDI is at, depending on where everything else is at, maturity, etc., we are not sure which one it is, 6.0, 7.0, whatever the right one might be. With that in mind, should we model this close to the way that we are phrasing it with USCDI, but effectively on the flip side from that supporting standard perspective? Do we use that as our same premise? “More current,” “do not know yet which version,” “needs to fit with USCDI that goes in at that point in time,” and “needs to be sufficiently mature and used to ensure that it is easy to take on.” Effectively, the same element, just from a different context.

Is that what we want to do given the prior discussion, or is there something else that needs to be done, or is that not enough? Any thoughts there? If there are no further thoughts, we can keep on pondering. Unless there is a concern, let us use that as our starting point for the draft. Let me make that note here, “Similar to

USCDI but from US Core perspective," okay. Let me bold it so it is easier to find and go into the Word document.

The next one is FHIR Bulk. There is Version 1.0.0 in the regulation. There is a more current version of 2021 that is already in SVAP, so you have the opportunity to use something more current. And there is likely work in progress, and at some point, a more current version will come out. I am not sure when that might occur, but it is reasonable to expect that something will follow this one. Does that provide a sufficient backdrop to do a similar process? It would probably make sense to go to a more current version and consider which one it is at that time, whether it is the right one or it is too low, or maybe we are already on 4. Who knows? Any thoughts? I am not hearing any. Please stop me if I am going too fast. "The then-most current should be considered." Okay.

If we then go to the next one, this is the Base FHIR Standard. We currently have 4.0.1, and based on that one the various implementation guides. Particularly, US Core is built on that. There is work in flight on Version 5 that is not planned to have any new normative content. It is more capabilities, but nothing additional will go normative. That is anticipated not to happen until Version 6. Version 5 is expected to come out next year in the first half perhaps. The question is, should we already indicate, "Hey, consider that"? Keeping in mind, which is the big thing, that implementations are all based on Release 4 at this point. Implementation guides would have to be upgraded. So, after 5 is out then all the relevant implementation guides would have to be taken to 5.0 because it has some changes in there to accommodate that. There are all kinds of things that need to happen.

Here, the question is, is it premature to say, "Look at the most current version"? Perhaps you should always look at it, but if the timeline is going to be relatively short-term, 5 would not be a viable tenet for some time, for at least another year at the earliest, because all those guides need to be updated. What are some thoughts here as to how we want to couch that? "Readiness to go," "consider something new," or not with all the other caveats around NPRM, etc.?

Jeff, you have your hand up?

Jeffrey Danford
Just expanding on what you are saying, and I second it. This one is tough because there is so much built on top of it. Shifting this is going to require so many other pieces to move, but at the same time, you do not want to lock us into Version 4. I am not sure exactly what the path would be or how we could move this, but it needs to.

Hans Buitendijk
Go ahead, Vassil.

Vassil Peytchev
There is one piece that I think is important to move ahead with, which is the new subscription framework in FHIR. It is definitely in R5, but it is also in R4B. That is another piece that we should look at to see which one of those can be added to the requirements because it is a crucial functionality that would be enabled for the users of FHIR and I believe ONC. That is the goal of ONC, so we need to work on promoting that.

Hans Buitendijk
So, we need to couch this carefully because even with R4B, I do not think it is as big, but there are a couple of areas where IGs would have to be updated as well to make sure it works with that. I am typing something here that you cannot see yet because of the spreadsheet, but it is along the lines that we should suggest considering a new version because of new capabilities like the example that Vassil provided that would be valuable for new things to do. However, at the same time, we need to be very cautious that existing implementation guides are based on R4. They would also require a fair amount of work to potentially upgrade and support both R4 and a newer version. It has its challenges.

We need to go to public comment, so let us hold it here. I will complete typing, and then we will come back if we have time left with any final wrap-up on that before we adjourn. Mike, it is all yours.

Public Comment (01:19:36)

Mike Berry
All right. Thanks, Hans. We are going to open up our call for public comments. If you are on Zoom and would like to comment, please use the hand raise function which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon press *6 to mute and unmute your line. Let us see if anyone raises their hand.

I am not seeing any hands raised, Hans and Steve, so I will turn it back to you.

Hans Buitendijk
Okay. That did not give me a lot of time to type. It shows you how slow I am. But at least I got this far. If you can display the spreadsheet again, then we can spend two more minutes to maybe wrap this one up. Then we will wrap up the meeting with the steps for next week. Here it is, “Consider a newer version, for example, R4B or R5, for new capabilities such as subscription.” If you want, we can add a few more. That is certainly one that jumps out that will be valuable. While recognizing that any IGs referenced are based on FHIR R4, this would require upgrades to align, to be able to move everything consistently over to the next version. That is going to be a balancing act based on timing, where we are at, and how much time would be available to get this all done.

The challenge would be that when things are being proposed, do we already have those IGs or not? It is going to be a complex maze to go through, but the basic sentiment is that it makes sense at some point to move forward and not stay with Release 4 for a long period of time. Is that the basic essence that we are trying to articulate a little bit better? I see Jim agrees. Anybody else? Okay. We have some wordsmithing to do here.

Looking at the clock, I am not sure whether we can still get one row. We first ought to look at next steps, Steve, for next week, and we can address any questions around that. Do you want to take the next steps for next week?

Next Steps (01:22:39)

Steven Eichner

Sure. I am looking at the time to see if we can knock any more out, but I do not think we can. So, we will continue to work through the rest of Group 6 and do a quick review of comments that have been entered into the new Google document as a quick update, a quick general review of that. We will also talk a little bit about our report for the fall HITAC meeting. Are there other pieces that you want to cover, Hans?

Hans Buitendijk
I think you covered them all. The main focus will be on the recommendations that need to be in play. Also, as we talked about earlier, we need to have an introductory section to sum up the approach on how we went about it, etc. We will likely see an initial draft beginning to take shape as well so that we can begin that effort. We might not fully review that next week. It depends on how far we get. I see a note by Jeff. I am going to see when I can have an opportunity to copy that into the notes here.

Anything else, Steve? Any questions from anybody that we have?

Steven Eichner
Mike, are there pieces that we need to pick up administratively?

Mike Berry
I just wanted to mention that, for those of you that missed my comment at the beginning of the meeting, we will send a link out to this Google Doc that Liz displayed earlier so that you all can go in and start wordsmithing it so that we can finalize the disposition about any standards that are ready to be finalized. That will be coming out with the homework assignment hopefully later today or sometime tomorrow.

Steven Eichner
Wonderful. Thank you. I would like to take this opportunity to thank all the Task Force members for their input, and an extreme thank you to our support staff and presenters this morning. Thank you very much. Hans, the floor is yours.

Hans Buitendijk
Thank you. I am looking forward to wrapping up Group 6 next week and getting into the final stretch. It looks like we are still tracking very well, so I very much appreciate all of the feedback from everybody. I will talk to you again next week. Thank you.

Adjourn (01:25:17)