# Transcript

## HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS WORKGROUP MEETING

April 9, 2024, 10:00 – 11:30 AM ET

VIRTUAL

## MEMBERS IN ATTENDANCE

Sarah DeSilvey, Gravity Project, Co-Chair
Steven (Ike) Eichner, Texas Department of State Health Services, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Shila Blend, North Dakota Health Information Network
Ricky Bloomfield, Apple
Hans Buitendijk, Oracle Health
Raj Dash, College of American Pathologists
Steven Lane, Health Gorilla
Hung Luu, Children's Health
Katrina Miller Parrish, Humana Health Insurance
Rochelle Prosser, Orchid Healthcare Solutions
Mark Savage, Savage & Savage LLC
Shelly Spiro, Pharmacy Health Information Technology Collaborative
Naresh Sundar Rajan, CyncHealth

## MEMBERS NOT IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health
Keith Campbell, Food and Drug Administration
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Derek De Young, Epic
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, Centers for Disease Control and Prevention
Anna McCollister, Individual
Alex Mugge (absent), Joel Andress (alternate present), Centers for Medicare & Medicaid Services
Aaron Neinstein, Notable
Kikelomo Oshunkentan, Pegasystems
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian

## ONC STAFF

Seth Pazinski, Director, Strategic Planning & Coordination Division, ONC
Wendy Noboa, Designated Federal Officer, ONC
Al Taylor, Office of Technology, ONC

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

**Seth Pazinski**
Thank you, everyone. Good morning, and welcome to the Interoperability Standards Workgroup meeting. I am Seth Pazinski with the Office of the National Coordinator for Health IT (ONC), and I want to thank you for joining in today. I will be serving as the designated federal officer for today's call on behalf of Wendy Noboa. Just as a reminder, all workgroup meetings are open to the public, and public feedback is welcome throughout. Members of the public can type their comments throughout the meeting in the Zoom chat feature or make verbal comments during the public comment period, which is scheduled toward the end of our agenda today. To start our meeting, I am going to start with roll call of the workgroup members, so when I call your name, please indicate that you are present. I will start with the cochairs. Sarah DeSilvey?

**Sarah DeSilvey**
I am here. Good morning, everybody.

**Seth Pazinski**
Good morning. Steve Eichner?

**Steven Eichner**
Good morning.

**Seth Pazinski**
Pooja Babbrah?

**Pooja Babbrah**
Good morning.

**Seth Pazinski**
Shila Blend?

**Shila Blend**
Good morning.

**Seth Pazinski**
Ricky Bloomfield?

**Ricky Bloomfield**
Good morning, I am here.

**Seth Pazinski**
Medell Briggs-Malonson? Hans Buitendijk?

**Hans Buitendijk**
Good morning.

**Seth Pazinski**
Good morning. I did receive messages that Keith Campbell and Christina Caraballo will not be able to join us today, so, next is Grace Cordovano. Raj Dash?

**Raj Dash**
I am here. Good morning.

**Seth Pazinski**
Good morning. Derek De Young? Lee Fleisher? Hannah Galvin? Raj Godavarthi? Jim Jirjis? Steven Lane?

**Steven Lane**
Good morning. I am here.

**Seth Pazinski**
Hi, Steven. Hung Luu?

**Hung S. Luu**
Good morning.

**Seth Pazinski**
Good morning. Anna McCollister? Katrina Miller Parrish?

**Katrina Miller Parrish**
Good morning.

**Seth Pazinski**
Good morning. Aaron Neinstein? I got a message that Dayo Oshunkentan is not available to join us today. Rochelle Prosser?

**Rochelle Prosser**
Present, good morning.

**Seth Pazinski**
Good morning. Mark Savage?

**Mark Savage**
Good morning.

**Seth Pazinski**
Alex Mugge? Joel Andress?

**Joel Andress**
Good morning.

**Seth Pazinski**

Good morning. Fil Southerland? Shelly Spiro?

**Shelly Spiro**
Good morning.

**Seth Pazinski**
Good morning. Zeynep Sumer-King? Naresh Sundar Rajan?

**Naresh Sundar Rajan**
Good morning.

**Seth Pazinski**
Good morning. That completes our roll call. I want to thank everyone again, and I will turn it back to Sarah and Ike to get into our agenda.

## Opening Remarks (00:03:20)

**Sarah DeSilvey**
Hi, everybody. Thank you for coming to this meeting as we complete our charge to HITAC, and we look forward to seeing HITAC members on Thursday in person in DC. We have a lot to do today, so our focus is really on ensuring we review remaining Level 2 elements, agree on the text for the final recommendation in the transmittal letter, and address any questions ONC has or clarifications it requires in order to issue that transmittal letter to HITAC. Again, we are hoping to keep conversations efficient and swift because if we cannot achieve consensus here, we should save it until next year because we will be reconvening and we do need to make sure we get that recommendation transmittal letter out to HITAC after the call. Ike, anything else to note?

**Steven Eichner**
Just to add in, again, our gratitude towards workgroup members for their participation and their valuable insights, as well as to the support team for helping make all this happen. That being said, I think we need to get into the work of the day so that we can put together our transmittal letter.

## Level 2 Data Elements Recommendations (00:04:39)

**Sarah DeSilvey**
Wonderful. Thank you, Ike. Next slide. I am just going to remind everybody, because some of the comments on the text in our recommendations and transmittal letter relate to charge, just to ground ourselves fully on the charge that was given to us by HITAC, which was generally to provide review and recommendations on Draft United States Core Data for Interoperability (USCDI) v.5. This includes any new data classes and elements that should be considered for the final USCDI v.5, and then, to discuss as many Level 2 data elements and classes as possible that are elevated to significance by the members of this committee and that we feel should be part of Draft USCDI v.5. This is largely where we are focusing our efforts today, just to make sure that we review and agree upon those Level 2 elements in order to get it over to HITAC. Next slide.

Again, thank you to all of the work that has been going on. I will need the assistance of entities in IS WG to help elevate when there have been any significant changes in the previous wording of text on the final recommendations that are already reviewed because we are really going to lean into those Level 2 elements, so if there is something of note in a USCDI v.5 element that the committee needs to review, please let me know, but we are going to dive into Level 2 and some of the general recommendations that Hans elevated for the bulk of the meeting. Next slide.

We have a lot of work that was done, for which we are thankful, on the recommendation for health insurance information, and we are hoping to land that today. We had work done on the maternal social determinants of health (SDOH) note. Thank you for the clarification on the medication administration element, and again, thank you to everyone who worked on that. And then, in the Level 2 elements, you will see some comments throughout that the Level 2 element that was suggested is included in the recommendation above, and so, there is no need to focus on it specifically. Again, I want to thank the individuals who worked on the substance food recommendation. Next slide.

And then, we are going to be reviewing these Level 2 elements, really for the first time. Again, thank you to everyone who helped get recommendations for review across these, and a lot of them were from previous iterations of IS WG that rolled forward to this year. And then, I believe there is one more slide. So, this is the demographic information, and again, a lot of these elements were recommended by IS WG in 2023 and prior, so those recommendations that we sent over in previous years are pulled forward again, for example. So, I think we are ready now to actually go into the Share drive to start working on the Level 2 elements. Again, I promise to leave time to comment on the process elements, Hans, but I do want to review those Level 2 elements before we go any further. I will not neglect that this time, and I need you all to help me be accountable to that.

So, we are scrolling all the way down to the Level 2 elements. Again, if there is anything significant in a previous comment recommendation on a Draft USCDI v.5 element, please let me know, but we are going to really try to dive into Level 2 first to complete that element of the charge, again, skipping. On the care plan, I do not think there were any significant edits, if we go over to the recommendation, and I think I am correct that there were slight tweaks, but other than that, does ONC need any clarification on the final recommendation as it stands?

**Ricky Bloomfield**
From my perspective, I am good, and I made a note to Mark that since this was copied verbatim from this… There it is. There are three recommendations on this one line, eight, nine, and 10, so I think I have gotten everything, unless there is something in the text that I have here that is not right.

**Sarah DeSilvey**
Again, that was our responsibility to review prior to the meeting, so, barring any comments to that effect, I think we are good. The one thing I forgot to state heading into Thursday is that given the need to ensure that the charge of IS WG at direction of HITAC is completed in the public sphere, if there are any concerns with any of the comments that we have elevated or any of the Level 2 elements that we have raised that are not able to be addressed and timeboxed within the meeting itself, we need to bump them until next year because we cannot have post-HITAC addendums. We really have to make sure that we resolve and agree upon consensus in the meeting. Al?

**Al Taylor**
I just wanted to add something. We have added this in the past, but if individual members still feel strongly about the recommendation that we might not get to, they are still more than welcome to submit that comment as an individual, and as a reminder, the deadline for all comments on Draft v.5 is Monday the 15th at midnight.

**Sarah DeSilvey**
Thank you so much, Al. I am just clarifying that if, for some reason, we do not get it today in IS WG, each of us, of course, has the ability to comment in the public process. Mark?

**Mark Savage**
So, that means that you and Ike, as workgroup co-chairs, will make whatever decision you need to make on Thursday to excise some text. It does not necessarily mean that an entire recommendation is dropped. It is just whatever you need to excise to meet HITAC concerns so that we can go forward as much as possible. Is that correct?

**Sarah DeSilvey**
Yes. So, the next job is taking our recommendations from IS WG to HITAC, and the HITAC committee itself has an opportunity to say they do or do not accept recommendations or that they have comments on recommendations. Just from a point of process, if that recommendation can be resolved within the HITAC meeting, it gets bumped to next year.

**Mark Savage**
Sometimes the comment is just about a particular word, and only the word needs to be dropped.

**Sarah DeSilvey**
Yes, and those kinds of edits are very easy to do in real time, Mark. If there is anything more substantial, I just want to note that we are bound by our charge within IS WG and HITAC to resolve things in public spheres and public spaces. I am just making sure that everyone is aware, as there are lots of new members. Okay, care plan. Good job. Next? I am trying to keep it going. I believe we are good on the recommendation for health literacy. Thank you so much for all the comment we had. Again, given that we have already discussed these things, I am really trying to lean into the things we have not, and we have all had time to review, so I think we are good. Al, if you need additional things, you can stop us, but I want to keep on going.

**Al Taylor**
Thanks, Sarah. For this one in particular, because there was an original recommendation that was edited last week, I just wanted to make sure that I got the right edits in the new text under Recommendation No. 11.

**Sarah DeSilvey**
I absolutely read it, and it looks aligned with what we agreed upon in the committee last week. As you can tell, because of timing, what we are having to do is ensure that the content and the transmittal letter that we are all responsible for and that Ike and I have to assist with meets with your intent, Al, as we are going

through things in the meeting, so the timeline is definitely contracted. This is why I am making sure Al has what he needs. I think we are good on specimen collection date and time, correct?

**Al Taylor**
I think so.

**Sarah DeSilvey**
Yes? So, again, I am going to ask you to raise your hand, and Katrina, thank you for drafting this, and again, all of you were significant in helping with this. If it is okay, given that there is a lot of content change in the substance food recommendation, I want to lean into that one next. I hope you all had a chance to review the recommendation. It is very straightforward. Many of our pharmacy friends have given the rationale for why this Level 2 element would need to be elevated. And then, we have Recommendations 13 and 14. Do members of IS WG approve of the text in the recommendation letter as our colleagues drafted it? Great. Mark?

**Mark Savage**
I have one question that has come up in various elements. At the applicable standard, should it say something like "SNOMED CT, among others"? As I understand it, we are not constraining a particular code. If it is fine as is, let's go forward. It is just a question.

**Sarah DeSilvey**
Al?

**Al Taylor**
Yes, Mark, it is fine. Every time we cite an applicable standard, systems would be required to represent the data element with at least SNOMED CT or whatever, so that is fine.

**Sarah DeSilvey**
Thank you so much. Okay, great. So, now we are moving on. Again, thank you for all the work that happened there. Going over to family health history, I believe there were both general and specific elements there. Again, thank you for pulling forward. I hope that this captures it, again, expecting everyone to read this prior to the meeting, and I am sorry to be so firm, given the timeline, but I am hoping that we can approve this as drafted so that Al can put it in the transmittal letter. Mark?

**Mark Savage**
The one addition is to mention the data class. It is as it was in Level 2, recommending that the data element be added to a family health history data class. That is new since the last meeting.

**Sarah DeSilvey**
Where did the rationale come from?

**Mark Savage**
It needs to have a data class…

**Sarah DeSilvey**

Yes, I just want to make sure that you bring people along.

**Mark Savage**
Right. So, in looking at the various options, I have talked to some folks who said that, at the exchange level, family health history as a data element really functions more like a data class in Fast Healthcare Interoperability Resources (FHIR), and for now, it makes the most sense to leave it as ONC has, at Level 2 in a family health history data class, and if there needs to be any tweaking in the future, IS WG can do that.

**Sarah DeSilvey**
Any objections to the recommendation of a data class to support the addition of a family health history data element? Going once, going twice… Okay, moving on. Again, I want to thank everyone for all of that work and for trying to keep the ball rolling. Thank you for the work that was done to refine the suggestions for the health insurance elements. I believe this recommendation really adequately contains the conversation that we had, both in what we are able to support now in recommendations for future standards development and clarity. To whoever is hovering on the hyperlink, can you move? Okay, is that what you wanted to do, Katrina? I hope that is what you meant.

**Katrina Miller Parrish**
Yes, thanks.

**Sarah DeSilvey**
Okay. Any concerns with the recommendation as drafted? I do not think the text box is long enough to look at the recommendation letter text. Al, is that correct? I think it is hidden. Is that true? There we go. I just want to make sure everyone can see the recommendations. Can we scroll up in the box?

**Al Taylor**
I am trying to make it visible. This might work. Oh, there we go.

**Sarah DeSilvey**
There we go. Awesome, thank you. I just want to make sure people see the text. So, the recommendation was drafted by members of the workgroup. Thank you so much. I want folks to see the text from the recommendation letter and how that is transmitted because that is in the transmittal letter. Hans?

**Hans Buitendijk**
I have a small note. I think the indents and the bullets might be off, so if it was intended to be literally going into the letter, then the usage note needs to come back out to the left.

**Al Taylor**
Do not worry about format, Hans. This is copied from the Word document into this, and the content is there. Do not worry about the bullets, spacing, and all that.

**Hans Buitendijk**
Sounds good.

**Sarah DeSilvey**
Albert is a bullet master. The format is amazing. Thanks, Al. And again, I want to thank ONC for supporting a very condensed timeline in delivering this transmittal letter. It was a busy week and weekend, so, thank you so much. Any concerns with the text as drafted? I do not see any. Again, thank you for the work of the committee that came to that agreement. We are very appreciative. All right, again, thank you for the tidy recommendation statement for the maternal social determinants of health data element. On to the clinical notes data class. Again, thank you for refining the note from the conversation that we had last week. Any concerns with the text of the recommendation as drafted? Thank you so much. Moving on. Again, I expect hands to be raised if there are concerns. I just want to make sure.

All right, again, I want to thank everyone who worked on the synthesis of our recommendations within medications. There was a lot of work in there, again, with comments from our colleagues in CMS and the extensive work of our pharmacy experts, so I just want to note that what we have here is a very robust and helpful recommendation, Recommendation 20. Are there any concerns with the recommendation, which is recommending that ONC revise specific medication administration event data elements? Any concerns with the text as drafted here and already in the transmittal letter? Oh, "for recordkeeping, could members state…" Al is asking that if you are writing "approved," you should actually say "Rec 20." I can also do something more formal with the hand-raising if you would like, Al.

**Al Taylor**
No, this is fine. I think it would help the chat become a better record of everybody, especially if there is an objection of some sort.

**Sarah DeSilvey**
Each of the recommendations obviously has a number, so if you can say "approve Rec 20" for the sake of Al's tracking, that would be great. Thanks, Hans. Moving along to the next element, this is the recommendation for portable medical orders. The text of the recommendation **[inaudible]**… Steven, I think you are not on mute. There we go. He is off again. Any concerns with the addition of Recommendation 16, which is the portable medical order data element under orders data class?

**Hans Buitendijk**
I am good with it, so do not worry.

**Sarah DeSilvey**
Awesome, thanks, Hans. Thank you again to all IS WG members who supported this recommendation and the drafting. It is very, very helpful. Again, thank you so much to our colleagues at CMS for reviewing, integrating, and blending their recommendations into existing elements. The next element was elevated and discussed by CMS, but again, thank you for noting that it is already covered, so the advance directives element was covered by additional recommendation above, and there is no need to focus on it. I want to now call out an element that has been discussed in previous IS WG meetings as really critical from a Centers for Disease Control and Prevention (CDC) and CMS perspective, and this is the recommendation that ONC add facility address data element to complement other facility information data elements such as facility name, facility identifier, and facility type.

Any comments or discussion on this? Again, this has been part of a suite of requests that CMS and CDC have made from a surveillance and monitoring perspective. Any concerns with this recommendation? All right, moving on. Again, the medication administration element that CMS elevated to Level 2… I feel like I am not really here right now. But, for the medication administration element that was recommended, CMS notes that it was addressed above. Again, thank you. And then, if we go over to the next one, Al, for this one, can we look at the recommendation first?

**Al Taylor**
For which one?

**Sarah DeSilvey**
Scroll back. So, there was the medication prescribed code suggestion, and then, Shelly and IS WG members convened and recommended to not add it. If we are recommending to not add it, it is just "do not add," and there is no comment required. Shelly, can you help give context for this in how their approach was integrated into your other recommendations? Thanks, Shelly.

**Shelly Spiro**
Yes. No. 1, it was a Level 0, and I did not convene with anyone, but I could not find why we would need this because it is asking for a prescription code, and it is asking for RxNorm or National Drug Codes (NDC), I believe, if I am not mistaken. That is already covered in medication, so when you are saying the medication, you are already putting the code in. That would not be a different code. I did not understand why it was needed.

**Sarah DeSilvey**
I am going to go to Hans, and then, can a representative from CDC or CMS help us? Again, if we cannot achieve consensus in this meeting, we can come back next year and get it, but we do have a lot to cover, so if there are enough concerns and it is clear that people do not want us to do this, it might be that this is not moved forward. Hans?

**Hans Buitendijk**
I support Shelly's comment. Plus, in the implementation in FHIR and Consolidated Clinical Document Architecture (C-CDA), there actually is the focus on the medication request, and in the medication request in combination with the medication data elements, those codes are already covered as to what was ordered. I would agree. I am not sure what the new aspect would be for this Level 0, and therefore it should be removed from ONC New Data Element and Class (ONDEC) altogether, though I guess it is already there.

**Sarah DeSilvey**
Al, do you want to lean in before I go to CMS?

**Al Taylor**
To highlight Hans's point, this is one of the data elements that was submitted a while back. It felt like the code was different than the name, but in fact, the data element represents both the name and the code for medication. This is a data element that should have been designated as a duplicate of medication, and we are in the process of rectifying that and other similar duplicate data elements that have slipped through. So, I agree with everything Shelly and Hans said.

**Sarah DeSilvey**
And now, I am going to lean on our CMS friends who are on the call. Given that there is no comment in the final recommendation column except to counter Shelly's recommendation of "do not add," are we okay with not adding it, as it seems to be a duplicate and covered elsewhere. Hi, Joel. I am sorry to call you out.

**Joel Andress**
No, it is fine. I think I am the sole representative from CMS here. We are okay with designating this as a duplicate code. We will take a look and see if there is a need for it. Given the discussion here, we are fine with pulling this back, and even if we did retain it, it would simply be a request to move it to Level 1, not to include it within Version 5. So, given all of that, we are fine with considering this a duplicate code.

**Sarah DeSilvey**
Thank you so much. All right, moving on to the recommendation, if we can go over it again and look at the element and the request, there is a question within the medical device data class to add an element, device to use. If you scroll over, you can see the recommendation as drafted in Column M. And then, you can see that Traci documented the initial draft, and then, Al has put for us the recommendation that would be in the transmittal letter. Recommendation 22: Recommend that ONC add device used data element to the medical device data class, and then, the applicable vocabulary standard is Logical Observation Identifiers Names and Codes (LOINC), and then, there are examples for example elements. Al?

**Al Taylor**
We have considered other device-related data elements and recommendations around those in the past and currently. I just wanted to highlight and make sure that the intent of this recommendation is to convey that when we say "device used," to me, the LOINC codes that are used to represent these devices as examples point to categories of devices rather than a device that is identified by Unique Device Identification (UDI), which is only one brand, one lot number, etc., and so, to ONC, this comes across as a device category, and I just wanted to make sure that that aligns with the way that CMS sees this data element. I understand the reason why it needs to be categorized like this, but it represents more of a category than a specific device.

**Joel Andress**
Yes, I think that is exactly what we are aiming for here. We are not looking to delineate between brands or anything like that.

**Al Taylor**
Okay, cool, thank you.

**Sarah DeSilvey**
Hans?

**Hans Buitendijk**
I appreciate that clarification because I was going to ask a question about UDI. Would there be expectations that if it is in the medical device data class, that these would be able to carry UDI as well? For some, that might be available, and for others, it certainly would not, at least not typically, so it is helpful if it is intended

to be more of a category question at that point in time. I am not sure that this is being captured in this way in a variety of systems that would be of interest, so I am not sure whether it is fully ready to understand what systems really would capture that at this level of granularity or coarseness. So, that is where I would have a concern. Is it truly ready to be used, or not? That is my concern at this point in time.

**Al Taylor**
Joel, I do not know if you wanted to weigh in, but my impression from a health IT standpoint is that these codes are already in use to capture elements of quality measurement for reporting. That is the way I understand it. These LOINC codes are already used in value sets supporting quality measurement.

**Joel Andress**
Yes, that is correct. I cannot speak to other use cases for that purpose, but I can say for quality measurement, we are currently trying to get this level of data for the measures.I would say I do not necessarily see a reason why would object to incorporating the UDI within the data class, or even within the data element, and getting that greater specificity. I can see where that would potentially be useful. It is just not part of the use case that we have identified internally here.

**Hans Buitendijk**
If the intent is to categorize, then UDI would not come into play until you get to the individual item that is actually being used and you want to record that. For some, that might be reasonable and appropriate, along the lines of implantable devices, and for other ones, that is not necessarily going to be as easily available to collect today, or does not even exist yet. The related question on the quality measures is if those measures already exist because I am trying to trace back how that data is being obtained, whether it is actually literally entered at the category level, or it is derived from data that is otherwise in there and categorized in there, which are two different things that would not necessarily be captured, and there is only certain HIT that would do it. I am concerned with it at this point in time, so I would not be in favor of it yet, although I understand the direction it is heading, and we could look at it a little bit deeper to understand if it is reasonable for all HIT that wants to be certified to do it at this level of coarseness.

**Sarah DeSilvey**
Thank you, Hans. Shelly, do you have thoughts on this?

**Shelly Spiro**
Yes. I think it is just the name of it. If you use “device used,” it is kind of confusing because then you would want the UDI, but if you look at it as a medical device order, then it can be a category because you are not actually dispensing or giving the product that is actually being used, which would be the actual device/product’s UDI, but if you look at it in terms of an order of somebody ordering who would know which particular device was to be used, then it would make more sense as a category that could then be used as a measure. So, I think the problem is the name of it, “device used.” For quality, maybe we should just change it to “device ordered.”

**Al Taylor**
Shelly, I think it represents both because after the fact, something like “Did you use pneumatic compression stockings?” would have a LOINC code associated with it.

**Shelly Spiro**
Correct.

**Al Taylor**
"Did you use pneumatic compression stockings?" is obviously a key safety quality issue for reporting.

**Shelly Spiro**
I do not have a problem with doing this. I think it is appropriate. I just think it is confusing because of the way it is named.

**Sarah DeSilvey**
So, Hans has concerns. Joel, can you help me understand the intent of the quality measure that is capturing this information? I am wondering if this data exists most easily in this category or in the actual item abstracted up to this category. I think that is kind of what Hans was saying as well.

**Joel Andress**
It is a fair question. I am not sure that I would be able to comment on that specifically. I can tell you that where the measure itself is being used, it is being used in the context of functional assessments and identifying whether or not assistive devices are being used in conjunction with the assessment or whether or not they are typically being used to complete certain daily tasks within the assessment.

**Sarah DeSilvey**
Wouldn't that go in health status assessments if it is actually a LOINC question/answer set to establish dependency on devices? I hate to say that question.

**Joel Andress**
Unfortunately, I think that is probably a question that would be better answered by our political action committee (PAC) team, and they were not able to join us today, as they are at the quality conference. I do not know if I can give you an informed response on that.

**Sarah DeSilvey**
That makes sense. Ricky, do you have any questions? As an assessment maker/user, I think I can understand how this would be utilized in understanding context for specific clients in a PAC situation. I do not know if Fil is on the call from a Long Term Services & Supports (LTSS) perspective. Ricky?

**Ricky Bloomfield**
I just had a comment about the structure of the recommendation here. It was not clear to me if the proposal was to include these exact codes because the way it is written says "including," which almost implies that this is just an example of the types of things that should be here versus proposing a specific value set, so if we did move forward with it, I think it would need more specificity in terms of what is meant by the text.

**Sarah DeSilvey**
I am going to make a recommendation, and I hope this is okay. Again, I do not want to put too much pressure on Joel to do an element that is not directly aligning. What I am wondering is whether this is a good element to hold onto, develop deeper understanding of, and revisit next year, given that understanding

use is pretty important to understanding how to implement it as a standard. Again, I hate to say something so bold, but that might be a path forward. If it is an assessment by an entity of an individual categorizing and documenting what medical device was used in order to complete a functional task, that makes a lot of sense to me why it would be LOINC and why it would be able to be category and not something more specific, but then I wonder where it would go. Again, I do not want to be so bold, but I was thinking about how this is the final hour. Does anyone else have questions? If people feel comfortable going forward with it as it is, that is fine, but I am wondering whether we need to figure out what class it belongs in and understand use more before we advance it.

**Joel Andress**
I think you referred to it potentially going under the health assessment data class.

**Sarah DeSilvey**
It could go under medical devices, but I think understanding the use is really important. What I hear you saying is this is something that is being documented observationally on behalf of an entity assessing a person, right?

**Joel Andress**
Right.

**Sarah DeSilvey**
Like "They are using this device. I, the physical therapist, assess that they are using this device." So, it is a LOINC question/answer.

**Joel Andress**
Just to follow, as I am taking notes for this and I want to go back and talk to my folks, when we are talking about improving upon this, I think you want clarification on its use and the potential for that use being more appropriate within the context of the health assessment.

**Sarah DeSilvey**
I think it is more the first one. I think I need to understand use more. Does anyone else have thoughts? I am not sure why it would still belong in medical devices, but the use element and how we get to these data element is really important for me to understand personally. Rochelle, and then Hans, and then we need to move on if we are not comfortable with coming to consensus. Rochelle?

**Rochelle Prosser**
Looking under the functional assessment, it is definitely different than a health assessment. Someone could be immobile, but still have great health, so it is different to say, "How do we get this person moving? What kind of transportation do they need?" It has a whole bunch of connotations on how a person would move through the healthcare system and navigate to and from the healthcare system, so I do think that it is important. My suggestion is to say we can clarify later, as we do with other processes that meet that little element of clarification, but functional assessment is very important whether somebody is disabled or not.

**Steven Eichner**

This is Steve Eichner. The fact of the matter is that many of those values, from a person's or patient's perspective, really are not comprehensive enough, nor do they represent reality. Speaking for myself as an example, I use a power wheelchair. I cannot take a step without a rollator or a walker. I personally cannot stand unassisted. None of the things that we are looking at in this set of elements come anywhere close to addressing that basic mobility. Again, I am not trying to expand it, I am just saying that, from a recommendation standpoint, this could be an initial list, additional work is necessary, and we should reach out to the patient community and other communities to refine it.

**Sarah DeSilvey**
I think Joel and I have talked a little bit more about use and how this is derived. This is an assessment of device used. I think we can go forward with it as it is if people are comfortable, but we need to get there quickly because we do need to move forward in the meeting. Hans?

**Hans Buitendijk**
Picking up on the comments from Ike and Al, these codes are much more category at a certain level of coarseness or granularity, but with the questions that are being raised, is it in the context of what is being ordered? Possibly, you will have to go into more detail when ordering when you are using it, it might be appropriate, and if you look back, you are not necessarily tying it back to an order that you do or do not know about. I think there are a number of things. Is it best done in medical devices or in functional assessment? But then, if you do it there, what else is needed?

To me, it sounds like we are not quite sure yet what this is, and it needs a little bit more work. The individual data elements or the values in LOINC or otherwise are defined, but the context in which we are asking that it be applied and implemented in USCDI is not totally clear. Is it functional assessment? Is it an order for a manual wheelchair? What is it? We have some of that in lab and medication as well. We have data classes that you could interpret to cover either the order, the report, the test results, or the medication administered. So, that is why I am worried. This is close, but it is not sufficiently clear yet as to what would be asked if we put anything like this in USCDI. I am not sure what is asked to be implemented. It requires a fair bit more discussion to say what the intent of it really is. That should be part of the definition, and it is not there yet.

**Sarah DeSilvey**
Joel has added context on use, and again, I think this is helpful. I was just reviewing the Level 2 element submission, and I think it is helpful for further clarity. Let's hear from Al, and then just get to a show of hands on whether we feel comfortable so we can move on because we do need to keep going.

**Al Taylor**
Really quickly, from ONC's perspective, from my perspective, going back to the Level 2 submission, the potential use for this data element is much clearer than the simple text in this recommendation. From ONC's standpoint, I do not have a problem with this recommendation coming across as used, and Hans, yes, either "used" or "ordered" would be appropriate to identify this category of device used or ordered, for whatever purpose, whether it is for frailty, quality measurement, VT, prophylaxis, or whatever other use you use a device for. To me, the additional information in the submission makes this much clearer than just what is in its recommendation. From ONC's perspective, we would combine a recommendation with a submission and come up with a solution.

**Sarah DeSilvey**
I agree. I feel like the observational nature of the information that is contained in the submission itself is helpful. I had to go there myself right now to remind myself. So, given that this is our final meeting, we have clarified the use a little bit, and again, I would caution against "ordered," though I do not know if I actually see that. As an ordering clinician, I think "device used" in this submission makes a lot more sense to me. We can add that clarity in the recommendation letter. Can I have a show of hands from individuals who feel like this conversation has been sufficient?

**Steven Eichner**
This is Ike. I do want to insert one thing. I would feel a lot more comfortable if there were also text inserted that this is an initial level and more work needs to be done, because there does need to be more patient impact because there are communities that are not represented well here in looking at this list of elements. There are lots of places to grow. I am not trying to grow them here and now, but I do think we need to recognize that there are gaps.

**Sarah DeSilvey**
The value sets included in the submission are much more extensive than these recommendations, so that is comforting, Ike, and I hear what you are saying. So, can we have a show of hands from individuals who feel like moving forward? Rochelle, I believe this addresses your question as well. Medical device used, now that we understand the use. I am going to raise my hand myself because I think going into submission grounded me, and Joel, thank you for your patience. We have one, two, three, four, five, six, seven. Steven Lane, you are not raising your hand, but we have… Okay, I believe that is the majority of us. Can I have a show of hands from those of us who are against moving forward with this recommendation at this time, just so I can have clarity? Ike, I am assuming you are going to take your hand down.

So, Hans is not recommending. Hans and Ricky have concerns. Are we comfortable moving forward, then, understanding that our technical friends…? It seems like we have definitely achieved consensus, and Ricky and Hans, hopefully this is a first step, and thank you for supporting conversation and holding us accountable. These are examples, Ricky. The full value sets are in the submission. It was very helpful for me to go there. There are representative value sets in the Level 2 submission of reference.

**Ricky Bloomfield**
Got it. Yes, that is helpful. I am assuming that is going to be clarified when this is put forward, then.

**Sarah DeSilvey**
Al, I do feel like we can integrate some of the use case and the examples from the submission into the final transmittal letter, which really are why we had this conversation today, just to understand that. Are individuals on the call comfortable with us doing that? It seems like it. Go, team! Hans, do you have a final thought before we go?

**Hans Buitendijk**
Oh, I still have my hand up.

**Sarah DeSilvey**

Again, thank you for the conversation. Joel, thank you for representing CMS on this one. Again, that conversation really helped me. Moving forward, we have a conversation to advance to Level 1, which is, again, very low risk, the provenance signature data element. This is just to move the dial along. This is not going into USCDI v.5. This is just moving this element to Level 1. Any concerns with this? Again, it is very straightforward, very low-risk. It is just CDC and CMS trying to advance elements they feel are critical along the standards development evolution process. All right, no concerns there. I am going to skip the next one. There are a couple rollovers from previous IS WG recommendations of elements within the Gender Harmony data set that were not included in Draft USCDI v.5, and so, we have a recommendation. I think it is helpful to look at the data class and data element, Al, if you go back over, just because we cannot see it. Thank you so much for your patience.

So, with inpatient demographic sex, this is a recommendation to change, and again, thank you, CMS friends, so now, we can go to the recommendation. This is recommending that ONC change the name and definition of sex to being an example of recorded sex. This would allow the capture and exchange of more nuanced information, which is essential for proper care, and aligns with the elements from Gender Harmony. Any concerns with this recommendation as it stands? This is just changing the base element from sex to be more aligned with current…

**Mark Savage**
Sarah, it is Mark. Can I just ask for confirmation that the language that is there is the same language that was indeed there without edits from two years ago?

**Sarah DeSilvey**
Grace is not here to attest to that, but we can make sure that that is the case.

**Mark Savage**
If it is the same language, I do not have any concerns.

**Sarah DeSilvey**
We have that table. Al, can you confirm that the recommendation is the same text from previous years?

**Al Taylor**
I will look it up. Do not wait for me, but I will look it up right now.

**Sarah DeSilvey**
I just want to note that there is this one, and then, there is also gender identity, so there are two elements there which were intended to be carryovers from previous IS WG recommendations that were not included in the Draft USCDI v.5 recommendation and are therefore in Level 2, asking for advancement. This is for this one here, which is recorded sex, and further down is gender identity, again, aligning with Gender Harmony. Mark?

**Mark Savage**
I will just note that I did not go back and check to see whether Gender Harmony Project's thinking has evolved since this language. I know it has some of the ones that we have already considered and approved, but I have not done that here. This looks like a low enough level that it probably does not do any harm, but

I am just saying they have continued to think over the past several years about evolving the landscape. Thank you.

**Sarah DeSilvey**
I am pretty sure that we can look at the example value sets. Any concerns? Hans?

**Hans Buitendijk**
Following Mark's comment, Gender Harmony has defined a variety of different aspects that are relevant to be captured distinctly, and if we have a data element in USCDI that is more general and overarching where it becomes examples of which one is part of that data element, that can work, as long as we recognize that what is in USCDI is not necessarily mapped one for one with what you see in FHIR US Core, C-CDA, and others, where it may need to be teased out into the respective aspects on that. So, if that is the case and we are comfortable that USCDI is more general, then I would agree with Mark.

It would not do much harm just as an example in some places, but if the intent is for USCDI to be consistent in language with or close to the underlying standards that Gender Harmony is given, then I think this is going to add confusion and ambiguity because there are a variety of different concepts and terms being used when you look at the Gender Harmony analysis and other terms. What we need to be capturing, when and where, and in what context that really means is critically important, and we are hiding that a little bit in USCDI, which might be okay, but we need to recognize that if we are more general in USCDI, there will be more specific things that need to be recognize when you actually manage the data itself.

**Sarah DeSilvey**
Mark, I just put the recommendations into the chat, and it looks like they directly align with the recommendations from last year and current Gender Harmony value sets of reference. Hans, thank you for your comment on usage. Given that we have recommended this last year and that the delta is not significant, are there any concerns with moving forward on the recommendation to include recorded sex or gender and gender identity elements as critical elements in USCDI v.5? I see no concerns, so we are okay. Again, this is just a recommendation we had before. CMS re-elevated it, and thank you for doing so. Okay, wonderful. Now, again, team, thanks so much for moving along.

The next two elements, including assessment and plan of treatment, are actually all extraneous, so then, we are going forward into the last two elements, which were recommendations for vaccination with an immunization data class vaccination event record type, and the text is there, if we can go over to that recommendation. This is the text in the recommendation letter. Any concerns with adding vaccination event record type into the immunization data class? Shelly?

**Shelly Spiro**
Yeah, I had somewhat of a problem with this because it is very similar to what Hans is going to talk about, that we need some talk about status and timing. That is where I was coming from with this recommendation. It is very difficult to put it in the way we have it, and I think there is some thought that has to go back, and I think we need to hear from Hans in what we came up with when we were talking about medication administration. Both of these immunization categories were a little difficult for me in coming up with a recommendation.

**Sarah DeSilvey**
I support that, and again, this is partly a situation where we iterate on things if we are not comfortable. Any other comments on this one, again, really respecting Shelly and the concern she has?

**Shelly Spiro**
We had the same problem with labs. When we are talking about the status, what is the status? Was it given? Was it prepared? Was it administered? Thes are the things that are subcategories under what we are talking about as status. That is the problem that I had. Can you just categorize the definition of status? Is it taken or not taken? Is it prepared?

**Joel Andress**
In this case, for the use cases for CMS, though I do not want to speak for CDC, though they are in agreement with us on this because they use it for quality measurement as well as public health surveillance, "status" here is referring to whether you have received the full course of vaccination, whatever that definition is in this case. So, first, it is really just asking if you are vaccinated or not, second of all, if you were vaccinated, are you vaccinated today at the encounter where you are recording the vaccination, or is this something that was reported historically, as in the patient having said that they have received vaccination or there is historical record of them having received vaccination?

**Sarah DeSilvey**
We do this often, for instance, in primary care, trying to make sure we have the elements with pharmacies administering vaccinations, but it is not coming electronically in a way that is sufficient, so we have to hand-enter the presence of the vaccination from a fax.

**Joel Andress**
For the quality measure use case, it is actually pretty straightforward. We are just trying to tell whether or not a patient has received a vaccination at the event associated with the particular encounter that is being recorded or if they are recording that that vaccination had previously occurred, and therefore, they are not providing them with additional vaccination now. From a quality perspective, that is fine, because they are already covered.

**Sarah DeSilvey**
Exactly. So, the childhood immunization status measure is a good example of how this is an important element. It exists, but it did not happen then. Are there any concerns with this? Again, we do not have a ton of time, so if we have people who do not feel comfortable, we can always bring this back next year. Can I see a show of hands of individuals who feel comfortable with the recommendation as it stands? Have we captured everybody? So, by a show of hands, we only have five individuals, and the sixth is me, in favor of advancing this. Who is concerned with this? Oh, Pooja, I am so sorry.

**Pooja Babbrah**
Sorry, I just raised it.

**Sarah DeSilvey**
So, we have one, two, three, four, five, six, seven. And then, who is concerned and wants to hold up until next year? I am assuming hands need to come down.

**Mark Savage**
Sarah, my hand is down. I have connectivity issues.

**Sarah DeSilvey**
That is fine. I do not see any hands for holding it. Okay, if we had an incomplete vote in favor but no hands on holding it, are we okay with moving forward as it stands? It seems like we must be.

**Steven Eichner**
Sarah, this is Steve. I just have one minor text correction. It should be "vaccine information" rather than "submitting the vaccine," just for clarity. I made the note in the chat.

**Sarah DeSilvey**
Okay, thank you so much. Al, is that clear to you from a final recommendation standpoint?

**Steven Eichner**
At the base of the first line, "facilities submitting the vaccine" should be "facilities submitting the vaccine information" because they are obviously not submitting the vaccine.

**Al Taylor**
Sorry, I was responding in the affirmative. I am good with that change. So, "submitting vaccine information." I am going to write it. So, Steve, the recommendation that Traci wrote is not exactly the same text as in the recommendation letter. Does the text in the recommendation letter as it is right now take care of that issue of "vaccine" versus "vaccine information submission"?

**Sarah DeSilvey**
It seems to. Ike, are you okay with that?

**Steven Eichner**
Sure. I was just making sure we said what we intended to say.

**Sarah DeSilvey**
Awesome. Thank you, friend. So, moving on to our final Level 2 element, focusing on the text in the recommendation letter and not Traci's comment, if we can go over to the goals and preferences healthcare agent data element, this is a request to…add the recommendation?

**Al Taylor**
I do not have the number. I realized that what I wrote in the cells was the same.

**Shelly Spiro**
It is No. 26.

**Al Taylor**
Thank you. I figured that, but I wanted to acknowledge that the numbering was not currently correct.

**Sarah DeSilvey**
The recommendation is that ONC add healthcare agent data element to the advance directive, and this has changed a little bit because it is now adding to the new advance healthcare directive data class, and not goals and preferences. As submitted, designating a healthcare agent is a valuable part of advance care planning that should be captured in the advance directives data class if applicable. Any concerns with this addition? No concerns. All right, I am going to switch it slightly. If there are no concerns, I am assuming we are in favor of adding healthcare agent to the newly recommended advance healthcare directive data class, if that is what we named it. Does that sound good? Fantastic, okay.

So, I am going to move now, Hans, to the discussion on process to make sure we can get to those, and then we are going to close out with any resolutions on final recommendations that ONC needs in order to craft the transmittal letter. We are almost there, friends. Hans, I think you have had these general process statements here since the first meeting. If you could help us briefly walk through them before we transition to any final edits or requirements for the transmittal letter, that would be fantastic.

**Hans Buitendijk**
Okeydoke. So, there are two topics, and they have come up in different ways in the prior HITAC discussions on USCDI as well. I am navigating to the text on my screen so that I have it readable. It is about two challenges, and I think we are seeing a couple more potential examples today, that when we have USCDI and it is defined initially and then published, when you go through the next round, which takes place roughly between June or July and May of the next year, when the FHIR US Core and C-CDA guides come out, there is a fair amount of discussion going on that clarifies intent, perspectives, etc., that are then accepted into the standard, and the standard that is used by health IT that wants to be certified to certain criteria is based on what they actually test against and what the right test receives.

Now, the challenge is that in a number of areas, there is just a small variation, though most of it is actually fairly clear, but there are areas where it is not clear that you can interpret the USCDI scope differently than in the standard, and that is being worked out through that discussion, balloting, etc., and then we end up there, but it is not coming back into USCDI in a recognizable form for those that are not familiar and are not going to dive into the standards that they have the same understanding of what is in the scope that is going to be looked at. I have a couple examples in here, like the medication administration that we talked about. Are we talking about lab orders, or are we just talking about the lab results and tests? You can interpret it a couple different ways in USCDI. So, these are examples of where this happens and some concerns that come up.

Where the suggestion is from a process perspective, it would be reasonable and appropriate to ask and say that as there are these differences in interpretation and intent that are being clarified but that you could not quite read out of USCDI, there is an update process of sorts that can reflect that. So, today, that would mean there are some variances that go back to USCDI Version 3 or 4, and we have discussed a couple of them that have a potential opportunity in Version 5 to have the same kind of challenge where what we defined is not necessarily what we did.

The example today is of devices used. Are we truly going to look at used or ordered? The current text would allow you to interpret it both ways. Assume for a moment that it goes in as proposed. We would not know exactly what it is, and we likely are going to end up with one of the two, though not necessarily both. So,

the suggestion and recommendation is that as we run into those and highlight where that distinct difference is too big, at that point in time, can we have an update to the version that was already published to clarify that so that there is no difference in interpretation by those that just read USCDI and those that start to really work with the software that supposedly supports that? So, that is the first one.

**Sarah DeSilvey**
Hans, I am going to ask you to simplify that in a way that we can put in a transmittal letter because if we scroll over to the final recommendation… Sorry, this is just because I have to take responsibility for drafting everything in approving the transmittal letter. How do we succinctly translate that into a recommendation to HITAC and ONC?

**Hans Buitendijk**
So, in Column J, the draft that is in there actually does indicate that the recommendation synchronize v.5, and prior versions as well, with the final FHIR US Core and C-CDA specification to ensure that the scope is fully aligned, enabling consistent interpretation of what is in and what is out, and we can tune that a little bit. And then, specifically, it is looking at these ones, where that distinction is substantial enough that such an update would be appropriate. So, we can tweak these words, but that is exactly saying that the intent is to synchronize v.5, and then to go back in some wording or otherwise that it is clear that it is applicable for some of those back to v.3. So, those are the specifics.

**Sarah DeSilvey**
Okay, great, thank you. This is still all the way back into the group.

**Hans Buitendijk**
Not a problem.

**Sarah DeSilvey**
And then, can you just quickly highlight, because again, we have a very short period of time to address your concerns, the second comment? That also needs to be translated and drafted into something that can be IS WG recommendation relevant. I think it is very straightforward, but then we can move to having workgroup conversation on both of the process elements in toto.

**Hans Buitendijk**
Yes. So, the second one suggests to lift a copy from prior HITAC recommendations, as we have done in a couple other areas as well. The underlying concern that is highlighted is that the intent of USCDI as we understand it is to inform the standards that are being used in certification, and certification is used for any health IT that wishes to be certified. There are a couple of criteria in that, and I will pick on the one for C-CDA, though it is the same for FHIR US Core, that for certain criteria, of which G-10 is the exact one, you are actually going to have to certify against all the capabilities that are listed in FHIR US Core that support all of USCDI. It continues that certain specialty Electronic Health Records (EHRs) are not necessarily collecting or managing all the data. They may get a document that contains it that they can view, but they do not necessarily have a need to take all that data out that is applicable for them.

And then, there is other health IT beyond EHRs that might be interested in certifying as well, or you could consider some of those specialty EHRs, or a very focused one, but effectively, they should not have to

support everything in USCDI. So, I think the continued concern is if there are ways where we can organize USCDI in combination with the certification program to better manage that not every health IT needs to certify against everything. EHRs are expected to certify against everything, but even specialty EHRs frequently do not support everything that is in USCDI, and USCDI is where it starts, so that is why this is the process question. How can we make it clearer from the start, and then throughout, that one need not support everything always?

**Sarah DeSilvey**
Thank you. Again, we have to figure out how to translate that into a final recommendation comment. We do not have a ton of time before public comment, so we are going to have a general conversation, and then clarity on whether individuals agree that these are process questions. Again, thank you, everybody, for the herculean work to come to this point, and I am glad that we are at a point where ONC has what they need for the transmittal letter. Let's go. Mark?

**Mark Savage**
I tend to think of USCDI as being data elements that are available across use cases and workflows not really constrained by anything, both present use cases and workflows, but also the future ones that we are not yet envisioning. And so, I **[inaudible] [01:15:13]** broadly of how USCDI would work, and it raises concern for me about whether we are constricting things, both in the present and in the future, in ways that might not be helpful. Thank you.

**Sarah DeSilvey**
Thank you so much, Mark. Again, there are a couple more comments, and then we have to decide whether or not we as IS WG approve of these two comments being part of the transmittal letter. Rochelle?

**Rochelle Prosser**
I think I agree with Mark. He says it a little bit more eloquently. I think we have done a lot of work on trying to clarify or to say where we can add specificity for future elements where it is not clear, but to move forward on them, and I understand what Hans's concerns are, but if we go too far down the procedure or process part, we may lose the spirit of what we are trying to capture.

**Sarah DeSilvey**
Thank you, Rochelle. Ricky?

**Ricky Bloomfield**
In general, as the others have said, these are all valid and important concerns. My question about the first one of these is more technical, which is what exactly does "synchronize" mean? Are we proposing an additional step in the annual process where there is some sort of reconciliation between what has been drafted in US Core and C-CDA to what was proposed, or something else? Maybe that would need to be fleshed out a little bit more in terms of what that means, who is going to be doing that, and what the outcome is. And then, on the second one, I agree with the other comments. This seems really important. I think how it is implemented could be lots of different ways, and so, I think it would warrant more discussion to figure out what the best way is to meet the needs of the health IT vendors for whom this may not be relevant, but yet make sure that it is also not used in a way to limit the data that may be accessible by patients and providers.

**Sarah DeSilvey**
Excellent. All right, we have a teeny bit of time. Let's start with the intention of the first process element, if we can go to the full text. Hans, you were saying that the text as stated, even with Ricky's comment on what synchronize means here, could be transferred into a comment in the transmittal letter. Hung, do you want to comment before we do that?

**Hung S. Luu**
Yes. I am actually a little uncomfortable with the language. What do we mean by "synchronize USCDI Version 5 with FHIR US Core"? Does that mean that if things are not present in both, they should not be considered? Because there is a time and a place, and sometimes, USCDI needs to prod US Core and the other standards to say, "This is something you need to work out." And so, to me, this kind of neuters and abrogates our responsibility to be thought leaders and to be able to suggest things that are not currently available in the standards, and that is a function of the USCDI, which is to set the standard, not to conform to what is already out there.

**Sarah DeSilvey**
Thank you. Al?

**Al Taylor**
This concern has been raised over several years, and I just wanted to reframe the question of what synchronize means. I wanted to pose a question that may reframe synchronize into a recommendation, and I understand that this concern may be to go back and change USCDI Version 5 after US Core is published. If that is the question, that should be the recommendation. I believe that that is the question or the recommendation, but that question may help clarify what the recommendation ends up being.

**Sarah DeSilvey**
Again, we do not have a ton of time, so Hans, if you have a brief comment, go ahead, please, but I need to move us to a formal vote about whether people are comfortable with the content, and I hear enough people not being comfortable that I want to make sure we get to that discussion. Hans?

**Hans Buitendijk**
I have a suggestion in place of synchronize, that there is an amendment clarification update to the version that the standards are intending to support to clarify these variations so that there is clarity to the reader, not having to totally go back and republish a prior version, but to have an explanation to indicate, and these are things that are currently not implemented in FHIR US Core, and it is agreed to that they are not there so that conformance to the certification and conformance to USCDI can then be measured to say, "Yes, we are conforming to USCDI as intended." So, it is to have an amendment to identify those areas and clarify, from a USCDI perspective, what aspects were really meant to go into the standards. That is what was meant by synchronize.

**Sarah DeSilvey**
Sorry, we are at public comment time, so I need to move us to a vote. I am so sorry.

**Steven Eichner**

The last part is that USCDI is intended to look forward in some fashion, but the question is, at times, the additions that are being made are more than it turns out that the standards are then able to actually implement, so that harmonizes with this. That is not to say that USCDI can only include what is already included, although that would actually be much clearer, but because it is going ahead and the two are used together, which is something we need to recognize, USCDI v.5 is going to be supported by FHIR US Core 8 as the particular, and you want to be reasonably aligned on expectations, hence the amendment that addresses any variations that have occurred that are too big to leave open.

**Sarah DeSilvey**
I am so sorry. I hear enough concerns on the recommendations as drafted that I am going to make a recommendation that pulls forward a suggestion from Mark, which is first of all to acknowledge the rightful concerns that are raised in these two elements and to make that observation, and Mark has elegantly said that it could be a suggestion to ONC to reflect on ways to respond to it, and then we can come back next year, but I am going to make a recommendation not to move forward with the recommendations as drafted because I hear enough significant concerns about that that we do not have time to address, and we are already moving into public comment.

So, that is my proposal, trying to synthesize where we are. All in favor of that, please raise your hand. All right, is anyone not raising their hand that needs to? Okay, we have agreement from Steven Lane in the comments, and Hung is in there. Okay, that is definitely a majority. Thank you so much. Hans, thank you for your critical perspective, especially representing EHRs. We really appreciate it. I think elevating the observation of note is really important, and I believe the charge is addressed. Seth, we can go to public comment. Thank you. So sorry that we are late going into public comment.

## Public Comment (01:24:11)

**Seth Pazinski**
Thanks, Sarah. Accel, could we open the line for public comment, please? If you would like to make a public comment and are on Zoom, you can use the raise hand function that is located in the Zoom toolbar at the bottom of your screen. If you are on the phone only today, you can press *9 to raise your hand, and once called upon, please press *6 to mute and unmute your line. We will give folks about 30 seconds here to queue up if we have any public comments. Okay, we have no comments on the line, and I am not seeing any hands raised in the Zoom, so I will turn it back to Sarah and Ike to close us out.

**Sarah DeSilvey**
It is hard to say anything else, other than thank you, friend, for the always extensive, brilliant, thoughtful, representative work of this committee. It blew me away last year, and it blows me away again today. It is an honor to facilitate and assist in all of your wisdom. Thank you for helping us complete our charge. We have a fair bit of work to do before April 11th, when we will present this to HITAC, and we are incredibly grateful for all of you. Ike?

**Steven Eichner**
I would like to extend my gratitude to everybody as well. It has been a real pleasure working with everybody on the IS WG this year, and I think we have put some great recommendations together. Thank you again for all your efforts.

**Sarah DeSilvey**
I see a comment. Al, just note that there is a comment on how we are going to draft the recommendations. I will work with Al and Ike to make sure the recommendations on the process elements are correctly included in the transmittal letter. Friends, thank you. Happy spring. I hope to see all of you on April 11th at the HITAC in-person meeting in public representation or at HITAC itself. Hopefully, I will see you next year, too. Thank you.

**Mark Savage**
Bye.

### Adjourn (01:26:47)

## QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
No comments were received during public comment.

## QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Rochelle Prosser: I approve

Pooja Babbrah: yes

Rochelle Prosser: NOPE

Rochelle Prosser: great job!

Rochelle Prosser: No Objection

Rochelle Prosser: Approve

Hans Buitendijk: All up to #20 - Approved.

Rochelle Prosser: I approved the Maternal Health.

Pooja Babbrah: Agree - all up to #20 approved

Rochelle Prosser: Approved req 20

Hans Buitendijk: I hope the recommendations were in sequence... :)

Rochelle Prosser: I approve Portable medical orders

Rochelle Prosser: I approve req#21

Hans Buitendijk: OK on #21

Rochelle Prosser: Hans +1, TA +1

Rochelle Prosser: Concur this is a duplicate

Shelly Spiro: @Al agree 22 as a medical device category and not the actual device product.

Steven Lane: I think that device ordered and device actually used should be kept as separate data elements.

Rochelle Prosser: Is this for patient Safety or looking for Ambulation?  AHh yse for ambulation safety

Hans Buitendijk: +1 Steve Lane.

Rochelle Prosser: Health Assessment is different from Functional Assessment

Rochelle Prosser: A person can have health and not be mobile

Rochelle Prosser: Can we add further clarification later?

Rochelle Prosser: Functional safety is important. Can we improve on it with clarification later?

Rochelle Prosser: Al +1

Rochelle Prosser: AL +1

Hans Buitendijk: Those perspectives would require more distinction, similar where, e.g., "Laboratory" or "Medications" focus on the ordering aspect, scheduling aspect, or result/administration/actual event perspective.

Steven Eichner: It is important that the information reflect the patient perspective and that patients with demonstrable needs are not left behind.

Rochelle Prosser: walker is missing from this list I concur. but we can add or clarify after for the individual

Rochelle Prosser: Hans +1

Steven Lane: Agree with moving forward Medical Device Used.

Hans Buitendijk: To capture it in FHIR context it would have to consider DeviceUse, which is not very mature/adopted.

Steven Eichner: with the caveat mentioned

Mark Savage: Comfortable.

Rochelle Prosser: Comfortable

Ricky Bloomfield: It’s not clear to me whether this recommendation is proposing this exact list or whether these are examples.

Hans Buitendijk: Needed becomes Plan, Used becomes DeviceUse, two different concepts, which is not clear from the definition, and would have to be part of the definition, not part of a submission as the scope may not encompass everything in the submission.

Rochelle Prosser: No Concerns on req 23

Albert Taylor: S-WG-2023_ Recommendation – 20 – Recommend that ONC change the name and definition of Sex to become an example of a Recorded Sex or Gender, e.g., recorded at birth.

Albert Taylor: The supplemental comment is new, but the text of the recommendation is the same

Mark Savage: Thanks so much, Al.

Rochelle Prosser: No Concerns on req 23

Rochelle Prosser: Is there a significance on why we need to know when the vaccination occurred? Or are we just stating a vaccination has occurred?

Rochelle Prosser: I support the prior speaker before Sarah

Ricky Bloomfield: US Core manages this today via the “reportOrigin” element.

Ricky Bloomfield: Value set includes: provider, record, recall, and school

Albert Taylor: @rochelle, this data element distinguishes between a "reported" or "historical" vaccine or an "administered" vaccine, like on the day of encounter.

Rochelle Prosser: thank - you Ricky for this clarification.

Rochelle Prosser: Thank - you AL

Rochelle Prosser: AHH okay

Rochelle Prosser: So received within the reporting year verses given now.

Rochelle Prosser: okay

Steven Eichner: Three's a minor grammar correction- submitting vaccination information, not submitting vaccine.

Rochelle Prosser: Thank you everyone for this discussion.

Rochelle Prosser: I approve #25

Rochelle Prosser: NO caoncerns

Rochelle Prosser: on 26

Steven Lane: Agree with adding health care agent.

Rochelle Prosser: Approve # 26

Rochelle Prosser: Hung +1

Steven Lane: +2 Hung

Mark Savage: SUGGESTION: Thinking that we're not ready for a recommendation per se without further time. But might be appropriate now to raise as an observation and suggest that ONC reflect on the issue and way(s) to respond to it.

Steven Lane: Agree

Pooja Babbrah: Can the vote include Mark's suggestion above?

Rochelle Prosser: Pecialty pharmacy should be brought into scope within a newer version of USCDI for transparenct. the variation will allow for this to happen.

Rochelle Prosser: Specialty +

Hans Buitendijk: I'm comfortable with raising the issue that needs to then be worked on.

Rochelle Prosser: Thank - you Hans. it just needs more time

Mark Savage: It's been real!

Steven Lane: Amazing work by two wonderful co-chairs + members and ONC staff. 🙏

Pooja Babbrah: Thank you Sarah and Steve for your help in getting us coordinated and organized!!

Ricky Bloomfield: Thank you for facilitating - wonderful job! Great work!

Rochelle Prosser: Appreciate the inclusion to this momentous work!

Katrina Miller Parrish: You leads and all this group - YOU ARE AMAZING!

Shelly Spiro: Thank you Sarah and Ike and ONC team.

Mark Savage: Thank you ALL!

Rochelle Prosser: See you Thursday

## QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

## RESOURCES

IS WG Webpage
IS WG - April 9, 2024, Meeting Webpage

Transcript reviewed and approved by Wendy Noboa, HITAC DFO, 4/16/2024