Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) U.S. CORE DATA FOR INTEROPERABILITY TASK FORCE 2021 MEETING

July 20, 2021, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Leslie Kelly Hall	**Engaging Patient Strategy**	**Co-Chair**
Steven Lane	**Sutter Health**	**Co-Chair**
Ricky Bloomfield	Apple	Member
Hans Buitendijk	Cerner	Member
Grace Cordovano	Enlightening Results	Member
Jim Jirjis	HCA Healthcare	Member
Ken Kawamoto	University of Utah Health	Member
John Kilbourne	Department of Veterans Health Affairs	Member
Leslie Lenert	Medical University of South Carolina	Member
Clement McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Mark Savage	Savage Consulting	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Daniel Vreeman	RTI International	Member
Denise Webb	Indiana Hemophilia and Thrombosis Center	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	Staff Lead

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

Operator
All lines are now bridged.

Michael Berry
Great. Thank you very much. And good morning, everybody. I'm Mike Berry with ONC. And I'd like to welcome everybody back to the USCDI task force. We hope you've enjoyed your few weeks off for our task force members. We're glad to have you. Let's get started with roll call today. And I'll start with our co-chairs, Steven Lane.

Steven Lane
Good morning.

Michael Berry
Leslie Kelly Hall, our other co-chair, is taking the day off. And she will be back with us next time. Ricky Bloomfield. Hans Buitendijk.

Hans Buitendijk
Good morning.

Michael Berry
Grace Cordovano.

Grace Cordovano
Good morning.

Michael Berry
Jim Jirjis. Ken Kawamoto. John Kilbourne.

John Kilbourne
Good morning.

Michael Berry
Leslie Lenert.

Leslie Lenert
Good morning.

Michael Berry
Clem McDonald. Aaron Miri.

Aaron Miri
Good morning.

Michael Berry

Brett Oliver.

Brett Oliver
Good morning.

Michael Berry
Mark Savage.

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber. Abby Sears. Sasha TerMaat.

Sasha TerMaat
Good morning.

Michael Berry
Andrew Truscott. Sheryl Turney.

Sheryl Turney
Good morning.

Michael Berry
Daniel Vreeman. And Denise Webb.

Denise Webb
Good morning.

Michael Berry
Good morning to all. And thank you so much. And I'll now turn it over to our co-chair, Steven Lane, to get us started. Steven.

Past Meeting Notes & USCDI Version 2 (00:01:46)

Steven Lane
Thank you so much and thank you, everyone, for returning to the scene of the crime here for our task force meeting today. We have a number of members of the public with us on the line. And I want to welcome all of you as well and encourage you to participate in the online chat and public comments as well as taking advantage of our opportunity for public comment, which we open five minutes before the end of our allotted time. I apologize that, once again, my camera isn't working today despite reloading the app. So, we'll just have to go with audio. I don't know if anyone else is sharing cameras but if you are, I can't see you. So, I'm very excited to be here with you today to hear Al and perhaps others inform us about the process and outcomes related to the finalization and publication of USCDI Version 2, which came out on July 9. It came out just as I was going off the grid. But I was able to take a look at it and, subsequently, talk with Al about it.

So, I'm really excited to discuss that with all of you today as ONC, I think, really took apart a lot of the input that our task force provided through our Task 1 and Task 2 efforts. And I think that this will inform our work as we continue on with Task 3. Past meeting notes have, again, been posted to the web and should be there for all of your enjoyment. And what we're going to do primarily today is talk about Version 2, give Al a chance to talk about the process that ONC went through to review public and HITAC input, the final decision making, hopefully, give us a pretty clear sense of which of our recommendations were incorporated and which might have been passed over, and perhaps a little bit of why related to the latter if that's appropriate. And also, most of our recommendations regarding the On Deck process and how to best support a broad population of commenters and submitters, a lot of that work is yet to be done. But Al will share with us how the ONC is approaching that, which of those recommendations might be easier to implement, and which might take longer time dealing with the Paperwork Reduction Act, etc.

And then, as we have time available at the end, we can come back to our work towards our Task 3 efforts. And then, you will see I put a couple of additional meetings on the calendar. You should have received those meeting invites. Looking through the rest of our time together, finishing up our recommendations to the HITAC, which we'll be submitting in early September, our last set of those. So, the work time that we have together through the rest of this month and next. So, that's how we're going to be spending our time this morning. I see that I want to welcome Abby. And as others join, we will welcome them as well. Any questions or comments about the agenda before we dive in? I don't see any hands raise. So, Al, can we have the team pull up your slides and you can tell us a bit about Version 2?

Al Taylor

Thanks, Steven. And thanks for the opportunity to present. I think we're as excited as everyone else about being able to put out USCDI Version 2. It's been a long time coming and we had a lot of input, especially from this task force but a very large amount of public input into crafting this new Version 2. Next slide. One of the things that we wanted to clarify was just the general core principles. And we've gone over this before. But these are some things to keep in mind. The USCDI is really a core set. And we went back to this core set numerous times as we considered what are we going to add and what might we not be able to add. It is a core set of patient data. It's not an all inclusive set of health data but rather the core set. We established it as a consistent baseline and we did that so that even if the content of USCDI did not meet all of the particular users' needs, it at least set a bar at a certain point so that everybody knew what's in there. So, it's a consistent baseline, a consistent set that everybody knows as the reference.

And where there are additional needs, those can be addressed separately either by submitting those for addition in future versions or just meeting those additional data needs in other ways. We also felt like this process that we had been using is very important to set everybody's expectations about how USCDI is going to change over time. Hang on a second. I just lost my screen. We wanted to make sure that this process was very transparent and so everybody knew what happens, what's going to happen, and why so that everybody could participate in a meaningful way going forward. Next slide. This is it. This is USCDI Version 2. The little yellow stars indicate new data elements or new data classes. Compared to USCDI Version 1, it's not a big change. We added 22 new data elements across 3 new data classes. And technically, we removed four data elements by expanding the care team member into these five components that you see on the left.

And so, we can keep going back to this but this is just a high level intro to the changes that we made for USCDI Version 2. Next slide. To dig into the specific changes that we made, we made an effort to, specifically, address health equity concerns and how health data can address those things. And this is in line with the new administration's changes in priorities. The two major new changes that we added were sexual orientation and gender identity data elements to the demographics data class as well as we added four new data elements related to social determinants of health. Those being assessment goals, problems and health concerns, and interventions. And those are as identified by the Gravity Project's submissions for USCDI. Next slide. And then, by adding additional data classes and data elements other than those six in SOGI and SDOH, we felt like these new elements and data classes do support broader health data interoperability by defining a more complete set of data that needs to be exchanged. Next slide.

So, digging into the individual additions, these are the SOGI data elements we used for applicable vocabulary standards. We used the same ones that we used for our demographics criteria or the A5 criteria for certification. And so, this is the same value set that we used for that. And so, there is no change in the vocabulary that needs to be used for exchange compared to use and access of those data elements. And that's true for both sexual orientation and gender identity. Next slide. The new SDOH data elements, the original submission had SDOH as its separate data class. And as we pointed out on a couple of different occasions, those data elements were similar to data elements that were in other data classes. And so, we recognized that those are similar or the same using the same codes that are used for others. For example, SDOH goals uses the same set of codes as can be used for other generic patient goals. So, instead of adding them to a separate SDOH data class, we incorporated these data elements into their respective appropriate data classes as you see here.

And as you can see on the high level slide, those are now added to these existing data classes. We did not add it to a separate data class. And unlike for SDOH assessment and goals, ONC did not state an applicable standard for the baseline data elements. That is assessment and plan of treatment as well as goals. We don't have an applicable standard because there is so much flexibility or so much variability in how those are represented. For the SDOH data elements, however, because the Gravity Project has defined the applicable standards for use to represent those specific SDOH data elements, we did add these vocabulary sets as applicable vocabulary standards. Gravity is in the process of defining value sets that are subsets of these vocabulary sets. Those have yet to be published. But when they do, those will be there as guidance towards how to conform to each of these data elements. So, using a subset or a value set of LOINC and SNOMED codes to represent SDOH assessments, we can point to the value sets as a guide to how to conform to those codes required for that

And so, these are the applicable standards for these SDOH data elements. Next slide. So, care team members was an existing data class. We had a single generic data element for care team members. And what we ended up doing was removing that data element but replacing it with five different data elements that represent different components of the care team member. We had, as most recall, provider information was a new group of data elements that we wanted to add. And there was a lot of input in particular from the HITAC or the task force that the provider information should apply to all care team members and not just the credentialed medical provider for a particular patient. And so, we not only added additional provider data elements but we expanded the scope of those data elements to apply to all of the care team members. Care team member identifier is one where it might only be applicable for actual credentialed providers. But

we felt like where it was not appropriate to have a care team member identifier for somebody like a family member, a caregiver, a custodian then, an identifier wouldn't be needed for that particular one.

But the capability to capture an identifier of some sort as appropriate was one of the added ones. And so, we added name, identifier, role, location, and telecom to the care team members' data class.

Steven Lane
Al, this is Steven if I can just kind of jump in with a question here. So, for care team member role, there is really no applicable value set, correct? This is just meant to be a pre-text field or you could stick whatever value in there that you wanted but it's not specified beyond just naming it as a data element. Is that correct?

Al Taylor
Yes and no. It's not specified. For USCDI, the applicable vocabulary standard is not specified. And the reason we did that is we identified two different value sets that had yet to be reconciled. Those are value sets that apply to FHIR US Core provider role. And the CCDA, I forget the exact term, but the CCDA provider role value set is different. And that's well known that there are differences in those value sets. And because if we picked one of those two different value sets for USCDI, it would, basically, break conformance to the other value set used in the CCDA templates. And so, we removed the single value set. But in order to represent care team member or provider role in either US Core or CCDA that is the appropriate value set that needs to be used. So, consistent with our pattern of making sure that the bar is not higher in USCDI than it is for either or both of the exchange formats, we just removed the vocabulary standard.

Steven Lane
When we get there, it will be interesting to hear Sasha and Hans comment from EHR vendor perspective as to how difficult or easy it will be to manage that kind of flexibility. I had another question about location. Did you specify in the documentation that this is the physical location of the provider at the time of the encounter versus where they get their mail or what their usual office is? Certainly, a lot of providers move around. Or is this sort of left open ended at this point?

Al Taylor
We left it open ended because depending on how you're using that data element, you might need it to represent something different, like you said. At the time of care, business address, it could be a number of things. And that could apply both to providers as well as family members and custodians. They might have different locations depending on what the need is.

Steven Lane
Thank you. Sorry to interrupt.

Al Taylor
Thanks for the clarification because, actually, for a time, we were considering a particular value set for some of these and we did some research and realized that we needed to back off on some of these. Next slide, please. So, this is a new data class. It used to be called diagnostic studies and results, I think, was the term that was originally submitted. And we had a lot of discussion about what this ought to be and what it ought to represent. But as with its original name, it represents tests that are not imaging or lab tests. And that's kind of the short version of what clinical test represents. They gave some examples, not an exhaustive set

of examples, of different tests that don't qualify as imaging or lab tests and that are valuable pieces of information that previously didn't have representation in USCDI. But we felt like that was a significant gap in USCDI.

And so, following the pattern that we have for laboratory where we used laboratory tests and laboratory results, diagnostic imaging, which we'll talk about in a second, both the test and the result, we did the same thing for clinical test. And so, we have the name and the code for the test as well as the results. And as with the other exam or chest data elements, we wanted to make sure that that included both the structured where it's available and unstructured the narrative components as part of the results or report. Next slide. We also added diagnostic imaging as a data class and specified that the data class that we improved the definition of the data class to include all visual images. And then, we gave examples of what the reports on those images would result in. One of the comments, and this applies to laboratory, which we'll cover in a second, there were three clinical notes data elements that we proposed to move into these two diagnostic imaging and laboratory data classes.

And the feedback that we got pretty consistently, which we sort of expected, is that the content of the imaging narrative is often or almost always contained within the report itself, the report being, often times, entirely narrative, although there are some structured components to imaging reports that could be communicated in structured ways instead of narrative ways. So, aligned with the recommendations from the task force, we removed the data element imaging narrative and incorporated the content in the diagnostic imaging report to specify both structured and unstructured data would be included in that imaging report. Question from Grace.

Grace Cordovano
I just wanted to clarify. The diagnostic imaging doesn't include actual images from radiology or if there is digital pathology with the whole slide images.

Al Taylor
Correct. We did not add the images themselves. This has been an ongoing discussion about the feasibility of adding the requirement for images. But we have not added the image itself, Grace.

Grace Cordovano
Thank you.

Steven Lane
And when we do, Al, that will be a new data element within this data class or, potentially, within another data class, as Grace mentioned, pathology, correct?

Al Taylor
I would expect that, yeah. So, potentially, there could be the image file or image itself, yes.

Steven Lane
Right. And so, again, that's, obviously, something that, as you say, has been discussed by many people in many venues. And if our task force felt strongly that Version 3 was the time for including image files that would be something we'd want to talk about here over the next six weeks.

Al Taylor
Or at any time in the future, yeah, because we've already had a submission for image file itself but we have gotten some feedback that there is some interest in having the file. Clearly, there is a significant impact on adding that capability to USCDI or to EHR's, in general, whether it's by this or other criteria.

Steven Lane
Al, there is a question in the public comment from Patrice regarding whether we considered NUCC. Can you comment on that?

Al Taylor
Sure. We did consider NUCC as a taxonomy. But there some concerns raised by some of our technical experts that we consulted. But since we expanded the scope of provider identifier to include all care team members, and NUCC does not have non-clinical specialty elements, so custodian, family member, etc., are not represented by NUCC. And so, we removed that because we expanded the scope.

Steven Lane
Thank you.

Al Taylor
Clem has a question. Clem?

Clem McDonald
Yeah. Well, it's a question or a comment. Firstly, though FHIR does include images as sort of attachments, it's a fairly simple connection to imaging reports. But you've got applicable vocabulary standards and ISA includes all of them as one. And I don't know where the blanks come from. It looks like you pulled them out of ISA because that's the title they use, applicable vocabulary standards. The diagnostic imaging reports for clinical report, notes, and or the other diagnostic studies like EKG's and telemetry.

Al Taylor
Are you talking about the results codes?

Clem McDonald
Well, I'm talking about the code for the applicable vocabulary standards, which we've got a column for. So, you've got it for LOINC 3.70 and maybe I don't understand the difference now, I thought I did, between the test and the report.

Al Taylor
So, the difference is how to represent the test itself if the test performed without a result necessarily attached to it. So, there are LOINC codes for diagnostic imaging tests or panels. And the reports can sometimes be represented by LOINC, sometimes SNOMED and, in the case of labs, can be represented by labs and vital signs, for example, can be represented by LOINC as well as UCUM. So, there are a lot of different options about how to represent different reports.

Clem McDonald

Yeah. But you've got to clarify. UCUM doesn't represent the report or the test. It represents the units of the test in the record for the observation. And I think it would be a big problem if you randomly have different kinds of code systems identifying tests. People won't know which ones to look for and what names to search on.

Al Taylor
So, next slide, please. We added the new data class encounter information. I think that we had these first three as the data elements that we proposed for Draft V2 and we added, based on recommendations from the task force as well as others, these new data elements of location and disposition. There is a disposition code set but there were some concerns about how broadly applicable that particular code set was to both inpatient and outpatient systems. And so, we removed the applicable vocabulary standard from encounter disposition. But the other data elements, as seen here, are new data elements. One of the recommendations that the task force made was adding some clarity around encounter time. And so, we added the data element definition to really be more encompassing of different ways in which encounter time might need to be represented. So, both scheduled arrival and start and stop times are different options about how to represent time associated with an encounter.

And so, we added that and added some flexibility in the examples.

Steven Lane
Thank you. Hans's hand is up.

Hans Buitendijk
Thank you. A quick question here and it's, actually, a place for a good example. In the publication when you go to the page, there is also a link to the submission. And in this particular case, you see that encounter diagnosis does not have quite a definition to it but encounter time and the other ones do. So, that creates a question when you read it whether the definition is in accordance with the submission or not. And in some cases, there is also a submission listed and there is a definition. It would be very helpful that on the main page, there are, actually, definitions for everything as to what, actually, was adopted and that the submissions are great context and back drop. But it gets confusing as to when to go where with what definition to understand the scope.

Al Taylor
That's a good point, Hans. Sometimes, we identified some more breadth in the scope of what a particular data element ought to cover. And so, sometimes, we took the submission and made some changes to it to make it even more broadly or more narrowly applicable. And so, the context for the submissions and the submission information that's available on the website is there and all it really is is this is what was submitted. And we took that information, took feedback from the public and, in some cases, made some changes to it. So, we need to be trying to figure out a good way to manage that, especially when there are differences in the submitted definition or the submitted scope and what we ended up adopting. So, we'll definitely take that and see what we can do with it.

Hans Buitendijk
Thank you.

Al Taylor
Next slide, please.

Steven Lane
Actually, Al, before you go on, I just want to acknowledge that Dan, Clem, Jim, and Michelle all joined us. And I hope that after your presentation, we'll have a chance to hear from Michelle about how she and CMS feel about the additions that you made, some of which were clearly in response to their requests and submissions.

Al Taylor
Okay. So, the next data class is laboratory. We, actually, kept the two existing data elements tests and values and results, made a few changes to the definitions for both. In particular, the values and results data element we changed to make sure that it's clear that the narrative components are part of value and results allowing us to remove the laboratory report and path report narrative data elements because their content is incorporated into values and results exactly the same as with diagnostic imaging. So, we did that. Questions about that before we move on?

Clem McDonald
The word result is an ambiguous term. Many people think of it as being the whole observation record. It's the value of the test. So, I don't have a good suggestion but it needs something, maybe an example of what you mean by the two. I think what you mean is that if it's a DRVL test, reactive or nonreactive is one of the values. If it's a glucose test, 120 is the value. But in general, results doesn't really narrow the space very well.

Steven Lane
And I think, Clem, your point is well taken, this idea of asking for examples. I think we've heard that numerous times from commentators that examples are very helpful in clarifying the meaning.

Al Taylor
We definitely can look at that. I think that, in general, the particular category or particular data class of laboratory is less ambiguous about what do we mean when we say lab tests and lab results. That's my impression.

Clem McDonald
Well, the structures are exactly parallel in terms of V2 and FHIR whether it's an x-ray or an EKG or whatever. So, I think if you got some examples and they fit together, the same stuff fits. EKG results, they all fit the actual numeric results just like a lab does. I'm not saying it's a lab test but I don't think it's that ambiguous and examples would help.

Al Taylor
Okay. Thanks for that comment, Clem. Is there anybody else?

Steven Lane
Sasha comment that she also thinks examples are helpful.

Al Taylor
I guess my question back to Sasha and Clem is sort of some feedback on which exact terms are ambiguous that would benefit from examples. You don't have to answer the question now but we'd love to hear some feedback on where thoughts are where some of these terms might be ambiguous. I'm not sure that lab results is an ambiguous term. But if you feel like it is or others are, just please let us know.

Clem McDonald
It is because there are two pieces at least to a result. You've got to say what the test is and then, maybe what the problem **[inaudible] [00:37:00]** the test. And then, you've got to say what the result and the value are. The results are sometimes the whole report in many people's mind. You've got to say what the value of that measurement was or that test was. And that's why they say the test is like glucose and the value is 120. That would help a lot. Or the test is some categorical test and the value is reactive or present or not present. That would help a lot. But I'd be happy to go through this set of slides and make specific suggestions if that would be helpful.

Al Taylor
Sure. That would be great.

Steven Lane
Sasha, do you still have your hand up?

Sasha TerMaat
I was just going to say that, Al, the main place that I had been heavy relying on the examples and the certification test data was for assessment and plan, which I know we've talked about in this work group. I've been quite vague. And when I poll Epic users on what they consider the assessment and plan, I get a wide variety of answers. And so, it was useful to glean as much as was feasible from certification test data what types of data was ONC envisioning as the assessment and plan and how would that be different from parts of a product note or trying to understand, especially where we have a data element that is I might say ambiguous, you might say flexible. But in those cases, I think getting that insight into the intention is helpful.

Al Taylor
Okay. Thank you. So, we don't have to go all the way back but we did that for the SDOH assessment. We did provide some more specific examples. And that would be translated into the CCG, the certification guide, or other guidance that we provide for that. But your point about the more generic assessment and plan of treatment needing examples or benefiting from examples is a good one. So, thanks. So, let's move on to the next slide, please. There are a number of changes that we added to the problems data class. First of all, we added, as I think we talked about this in the original slide on SDOH, a couple of things starting from the top. We added ICD-10 as one of the applicable standards for representing problems. Lots of feedback and long term discussion about the appropriateness of doing this. And given the weight of all of the feedback, we did incorporate ICD-10 as an option for problems.

And so, we'll provide some clarity on exactly what implementation looks like of this. But systems will be required to represent either SNOMED or ICD-10 for problems. And I think that fits very well into longstanding, current practice for representing problems. The SDOH problems and health concerns, similarly, uses the same set of codes, although the Gravity Project is working on more narrow value sets

within SNOMED and ICD-10 to represent SDOH problems. And then, the two timing elements or problems of data diagnosis and data resolution are there. We added some what I think are clarifying definitions for these and added those data elements to problems.

Steven Lane
Al, I just want to comment as the original submitter of those particular data elements and participant in a number of fairly broad stakeholder discussions about how they needed clarification. I appreciate the work you guys did on clarifying the meaning of those terms. Obviously, people will quibble but it's good to have that there. There, again, I'll be interested perhaps when we get to more discussion to hear from vendor representatives as to how they feel about these and whether they feel that it's going to be particularly challenging to implement them.

Al Taylor
Next slide. This is a little bit more of a broad term. So, those are all of the new data elements, the removed data elements and the changed data elements. Part of USCDI V2, as expected, we updated the applicable standards to the most current versions of these vocabulary standards to these most current ones. Some of these like RX Norma and NDC Link or CVX are updated very frequently. And so, even at the time of publication, I'm pretty sure we have a new RX Norm since this. But systems are always able to update to more recent versions. But for USCDI, we set the bar at these data standard versions. Next slide. So, now that USCDI Version 2 is final, ONC will consider adding USCDI Version 2 as an approved standard version, which will allow developers to update systems for these new standards, the USCDI being one of them. There are others that are under consideration. And we are now in the open comment period for which standards versions ought to be considered for SVAP.

I think we're getting ready to publish a blog inviting people to not only submit USCDI Version 3 data elements for consideration as well as commenting on whether or not USCDI Version 2 ought to be incorporated into the SVAP process. Hans has his hand up.

Hans Buitendijk
Just one question here and you may not be able to answer that and it's just for awareness as we go into SVAP process. It's slightly outside of USCDI in a way. But USCDI is to be supported by FHIR, US Core, and CCDA. Is the direction of thought that the USCDI Version 2 would be introduced in SVAP and that it then would be used with existing versions in certification? Or that USCDI V2 would be coupled to newer versions that would accommodate some of the variances between Versions 1 and 2 that are in play and then, only it is applicable to new versions of US Core and CCDA? Again, it's likely a too early question but just to raise that that will be a likely question that will come up from a clarity perspective if USCDI V2 is mentioned separately in SVAP, what does that mean in context of using it with existing standards versions or with new standard versions.

Al Taylor
That's a really good question. There are a lot of moving parts to the question. I don't think I can answer all of them right now. But it's good to bring up. So, adopting updated systems of USCDI Version 2 could have some implications on what would US Core have to update to accommodate Version 2. And then, would you use the updated version of US Core to accommodate USCDI Version 2 and the same thing for CCDA, I think, is what your question is. And we expect that US Core and CCDA would make progress towards

updating to accommodate USCDI Version 2 where it needed. And so, for example, for SOGI and SDOH, we expect changes will be underway to accommodate that in updates to US Core. And so, we're not the ones that set the pace for that but we do say that so that, in order to implement USCDI Version 2, you would have to implement an updated US Core in order to be able to handle the new USCDI V2 data elements. Is that kind of answering your question, at least part of it?

Hans Buitendijk
Certainly, part of it. And I fully understand that this is too early right now but I just wanted to bring up that that's where USCDI V2 will have some impact on how it's being referenced.

Al Taylor
And we've been working with HL7 for their awareness to let them know where the puck is moving to if you like the hockey reference. So, they're aware that those changes would need to be made and work will begin or has begun on doing it. Next slide.

Clem McDonald
Could I just make a comment? I've got my hand up.

Al Taylor
Okay.

Clem McDonald
So, I'm just not clear. When you're talking about US Core, you're talking about the FHIR US Core?

Al Taylor
Yes.

Clem McDonald
The second thing is that I thought USCDI always applied through all of the three versions of HL7, CCDA, FHIR, and V2. Is that still a correct assumption?

Al Taylor
Well, for the cert criteria that require USCDI, there are some. There are, I think, seven criteria that, specifically, invoke USCDI. I'm not 100% sure if USCDI is invoked by V2. Actually, I think it is for public health reporting. But at least parts of USCDI. So, it apply updating one of those criteria to accommodate USCDI Version 2.

Clem McDonald
My last comment was that Core FHIR, actually, has anticipated some of these things. They're ahead of it in terms of the clinical stuff, I think, but I'll double check on that, too. Thank you.

Al Taylor
They're making changes sometimes in response to changes in USCDI, sometimes in response to other things. And so, I think that as Brett and Mark already described on this call a few months ago, sometimes,

it's a leap frog sort of thing where they're making advances. And sometimes, USCDI makes advances that they have to respond to.

Hans Buitendijk
It's a mix of both right now. In some areas, they're ahead. In a couple of areas, they're behind on the USCDI V2. And USCDI V1 is referenced in a number of places. But it's really only CCDA and US Core that you need to use to demonstrate the use of USCDI. And then, in public health, it is a case reporting requirement but there is no other standard attached to it in terms of V2 or anything else.

Al Taylor
Thank you. I appreciate it. That's sometimes hard to keep track of.

Hans Buitendijk
It's quite intricate here.

Al Taylor
So, let's move on to the Version 3 process. Steven, do you want to talk about V2 now and then, move on to the V3 process?

Steven Lane
Yeah. I think we should. I raised a couple of questions earlier, specifically, to our vendor representatives, both of whom have had a chance to speak but I didn't know if there was anything more that they wanted to offer, especially regarding data diagnosis, data resolution and then, also to Michelle for the CMS perspective on how V2 managed their request. So, I'd love to hear back. And then, Mark also has his hand up. Since Mark was so good to use the hand raising, do you want to go first, Mark?

Mark Savage
Thanks. I didn't jump in at the particular page and maybe I should have. But I just want to voice great appreciation for the inclusion of the SDOH data elements and sexual orientation and gender identity to advance health equity. I won't take the time on this call but those are huge additions. And I just want to say thank you.

Steven Lane
Thanks, Mark. I couldn't agree more. And then, Michelle, you were kind enough to raise your hand so maybe I'll let you go next.

Michelle Schreiber
Yes, thank you. And my comments are overall as well to express appreciation, not only to this group but, certainly, the ONC and their deliberations. We think that this new version, Version 2, has advanced a lot of very important aspects of what is needed, not only for beneficiaries to get important information but for many of our programs in healthcare to use these, in particular **[inaudible] [00:52:24]** that are included for equity that will shine a spotlight there as well as flexibility for having diagnostic information. So, we want to express appreciation. We're really very pleased with the direction and thank you greatly.

Steven Lane

Clem?

Clem McDonald
Well, I also want to thank everybody, especially for the additional clinical content. But I'm still a little bit not sure referring to V3. So, in the V2 presentation, we've mentioned other kinds of diagnostic studies and, specifically, tonometry was mentioned. That's one of my favorite things, as you know. So, now does that have to come back in V3 or are we done?

Steven Lane
You're asking, specifically, about tonometry because you can see that as an addition?

Clem McDonald
Is it incorporated in what we described as other diagnostic studies and, therefore, covered?

Steven Lane
Good question.

Clem McDonald
I would love that.

Steven Lane
Well, it's not imaging and it's not a lab. And it is a diagnostic study, right? So, Al, can you comment or do you need to take that back?

Al Taylor
I think this is something that we've been looking at a number, literally, in the hundreds of submitted data elements that might qualify as a subset of something else.

Clem McDonald
But as diagnostic studies?

Al Taylor
So, for example, yeah, for diagnostic studies, you could make an argument that something is a subset of a vital sign or other things like that. So, because the goal of USCDI is to serve many use cases, a vast majority or majority or large number of use cases, it's important to so many people. So, to add this clinical test or this category of "other" diagnostic tests definitely, I think that that container of clinical tests can include things like tonometry, table top tests that are done in clinic, even some sort of diagnostic procedures can be done, range of motion measurements, things like that. Those are things that, in that category, by saying only clinical tests and not tonometry and range of motion and specific things, it doesn't say that a system can't be capable of capturing something like tonometry. But it definitely is a container for it.

Clem McDonald
Well, I welcome that container because it would open the gates of lots of important clinical data, which is already being transmitted in many context, which already has codes to represent it and has places in V2

just like a lab test. But maybe a final clarification. Do we have to resubmit the individual things that would be in that container or just assume they're there? You can give an example of some of them.

Al Taylor

There are too many examples of things that could be contained by the clinical test data element. And I can't speak to how systems, generally, represent things like your example of it's ubiquitous to have system capturing tonometry values. I know **[inaudible] [00:56:37]** it would need to be. So, to request all clinical test data from a system like in the last six months from a system, would a system already be able to capture tonometry data and be able to transmit tonometry data now that there is a data element that requires its exchange? I don't know how systems currently are doing that. And maybe Hans or Sasha can comment on that to say whether or not these particular data elements that you're concerned with are already being captured and could be exchanged.

Hans Buitendijk

If I can react, different systems collect different sets more or less depending on the scope. So, there are systems that do it and other ones that may not do it as much or not. It's going to be much more about do the underlying standards, since we're focusing on Core data for interoperability, do we have consistency on interpretation. So, I think, overall, the USCDI progress is moving clearly in the right direction, as we have stated before. EHI should be the end goal, actually, a little bit beyond for other reasons. And we continue to believe that that it's not limited to a subset of that because it's important that for all data that there is guidance and clarity on what to do, whether it's variability in how the standards can manage it. And, certainly, there is variability opportunity using FHIR and other standards on how to do it if there is no guidance available.

So, I think the key, if we're looking at that area of how can HIT, not just EHR's but how can HIT support this, the next step is really going to be how can we ensure that the standards that are needed are up to date and that we can continue to grow it because we have not covered everything yet. So, to Clem's earlier statement after Version 3 are we done, I doubt it because there is still a long way to go to EHI where we need to have consistency of communication standards to ensure that we can, actually, consistently interoperate without special effort. So, there is still good work to be done. And I don't think we're done after Version 3. And this helps us take a big step forward in that direction but we have not resolved it yet, which is not USCDI itself because that's only a set of data elements with some vocabulary references. The hard part from many of those systems that need to be certified or needs to interoperate is the standards where we now need to make sure are we all in sync.

And there is still some work to be done. Some are well on the way, SDOH, and other areas require a little bit more work. Other ones seemingly would be able to be done by FHIR but are we all on the same page as to exactly which ones and what resources to use? So, I think we still have a bit of work to do. All good work, all necessary.

Clem McDonald

If I could join in, I would complain that all that does is delay it, what you just said. And tonometry is the name of a test. It's a number and a unit. It's just like a lab test. So, is the **[inaudible] [00:59:55]** and EKG. These don't need rocket scientists to get them captured. There are already places in both V2 and FHIR to do it. So, we should just claim that we've got a good, big opening in this new container and we use it.

Steven Lane
But I think to clarify, what I believe you're asking for, Clem, is a list of specific tests. So, we've got the test and the result. That's the container. I think what you're looking for is a list of examples, again, of specific tests and perhaps value sets as with tonometry that are expected to be exchangeable if, in fact, a system captures them. Tonometry, you keep bringing it back up because it's a great example. It's very straight forward. And Al, I guess the question to you is would ONC contemplate creating a list of those items that are expected to be transmissible or exchangeable if, in fact, they are captured in the system because that would allow greater clarity, I think, for vendors to both know that if these are there, they do need to send them and they do need to receive them if they have a place to put them.

Al Taylor
I think that that's I don't want to say an impossible task. But I think it's an extremely difficult task to be able to define all of the potential LOINC codes that represent clinical tests that might be needed by all different users in all scenarios. Even existing labs, I think there is no question that labs should be represented using LOINC codes. But even that value set is difficult to define. And LOINC defines a top 2,000. That's not anywhere near all inclusive representing lab test codes as a starter set. And that's how we reference it in the interoperability standards advisory is it's a starter set. And so, we haven't even been able to fully define the necessary value set for lab data let alone all the other clinical things that have a LOINC code associated with it. So, I think that it's not possible, not feasible to be able to define it because, first of all, all of the LOINC codes and the tests are ever expanding. And so, it's difficult or impossible to wrap your arms around all of the possible data elements that might need to be collected and exchanged.

Steven Lane
I really appreciate that response, Al. And I think that I'm just going to stick a pin in that and say that the 2022 task force, in the process of doing the V3 evaluation and providing commentary, may want to come back and discuss that. But why don't we use that as a segue, since all of the hands are down, to let you go on and discuss the V3 process?

Sheryl Turney
Steven, I'm sorry but my hand has been up.

Steven Lane
Oh, it was up and it came back down. I'm sorry, Sheryl. Thanks for jumping back in.

Sheryl Turney
So, just a couple of things. First, I wanted to say, again, pile on and say thank you about the SDOH data that was added. It's very important to payers. One of the questions I had was revolving around the conversation about adoption. So, USCDI Version 1 is, specifically, called out in the patient access API. I'm not as familiar because this is all new to payers, how would we then see this progress and the adoption to Version 2 applied to that landscape? Can someone help me understand that a little bit?

Al Taylor
Sheryl, I think the question is for me. And we set the certification criteria and we set the standard of USCDI V1, V2 and then, with a mind that we still mind require some additional implementation and guidance. And

we do intend to have, just like we do with all of the certification criteria, the certification companion guides that we publish for each of the criteria, including a reference document that we use for USCDI about how this is implemented. And we do plan on doing that. For the patient access API criteria, what does adoption of V2 look like? We plan on doing that. We are working on doing that.

Sheryl Turney
Okay. That will be helpful because I'm trying to figure out how do I gear up for this now so that we can all be ready. And no one is quite 100% sure since on our side, this is a new thing for us to deal with. So, I think that discussion would be really helpful. And it seems to generate a lot of discussion with no place to go in the trade group forums that have been part of it as well. So, it would be helpful to get some guidance on that. Thanks.

Al Taylor
Sure. Okay. I see no hands. Can we go to the next slide? This is a reminder about the timeline. Now that we've published USCDI V2, which will be now considered for SVAP and will go through that process the second half of this year and publish the approved standards, which, hopefully, will include USCDI V2 but will include all of the standard version updates that have happened over the last year. And we'll publish that and we'll publish the SVAP in January. We're now in a period between the final release and the period where USCDI V3 submissions are being accepted. We've, actually, been in that top, middle, yellow block since October of last year. But we are now looking for submissions and work on those submissions to progress through the end of September. Those submissions are due on September 30, which I think is a Friday. And so, once all of those submissions come in, we'll go back to the books and see which of those fit in some of the priorities that we set and come out with a new version of Draft V3 in January.

The work that ONC expects to do between now and September 30 is, not only evaluating submissions as they come in but continuing to engage in work with stakeholders on submissions or submissions that people are considering putting in. And we want to work with stakeholders on it. I note that Grace has already slogged her way through. She'd probably describe it as slogging her way through the On Deck system to submit about 10 data elements for consideration. We will continue to work with Grace and continue to work with other submitters on making sure that those submissions are complete. And once we get them published and, Grace, to one of your questions is we need to publish those data elements that at least are not duplicate data elements. We need to publish those data elements so that anybody can go in and review those data elements and make comments on them. Or maybe somebody else is working on some other component of that data element.

Maybe they have other testing going on a data element that's the same or similar so that they can collaborate and improve that submission to demonstrate more applicability or more implementation or more standardization or lower burdens to implementation. Any of those things are favorable to get something advanced into the next version of USCDI. And so, one of the questions is how do we connect people working on some of the same things and getting that information out in the USCDI onto the On Deck system is one of the key ways that we can do it. And then, making particular highlights on this task force meeting, in the HITAC meeting, in other public fora to say there is this thing that needs work. It's not quite mature enough but it needs work. Who wants in? There are a lot of different ways of advancing that connectivity to get some of these things considered for addition.

Steven Lane
Al, one of the things that we discussed in our recommendations was the idea of a routine review and releveling process for submitted data elements based on all of the available comments, etc. I don't believe that you have releveled anything since the beginning of this year. Is there a thought that that releveling process will occur as part of the review after the September deadline?

Al Taylor
I expect that review to happen before the September deadline and then, after the September deadline as well. So, yes. Especially given the fact, and this is a spoiler alert, we have also published some updated prioritization criteria, which may lead us to go back and look at some things that might have, actually, fallen into those prioritization criteria but we hadn't considered it before. So, we do expect and ongoing, I would say, baseline review process. Some of that is guided by particular stakeholder input. When they reach out to ONC either through On Deck or through direct contact to say we really think this warrants some additional work, we can work on that and consider releveling that based on ongoing work or new findings or new collaborations to go through and review those and get those bumped up to Level 2 for consideration for the next version.

Steven Lane
Got it. Mark has his hand up.

Mark Savage
Thanks. Al, building on a couple of comments that you just made, one of the recommendations from the task force and HITAC to the national coordinator was about identifying gaps, priorities where there is a need but the submissions aren't quite meeting ONC's identification of the need. And I'm wondering what ONC is planning to do around that particular area, that particular recommendation.

Al Taylor
I'm sorry. I was coughing and on mute. There are a couple of different things that we can do, Mark, to address those areas. The gaps are data elements that don't currently exist, didn't exist on the clinical set, didn't exist in USCDI Version 1 or now Version 2. They're looking at USCDI V2. It looks more complete. There is not as many clear gaps but there are people that would disagree. ONC can highlight some of those areas that we think warrant some additional development based on these new priorities we think ought to be worked on by the community. But the focus can be for self-driven, if you've submitted something that you think needs additional work or might fit into ONC's priorities then, that can be brought up in any number of different forms. I can't say, specifically, we're going to say this thing needs more work. Everybody get going on it. But that's one possible avenue for advancement.

Mark Savage
For me, when we talked about that recommendation that was one of the ways in which I was hoping ONC would provide some leadership was to, actually, name some of the things that were needed if they weren't already there. You mentioned the publication of prioritization. Are you referring to what I found at least in the standards bulletin towards the end?

Al Taylor
Yeah.

Mark Savage
So, just to comment then that those five priorities look pretty generic to me and similar to what we've already seen. So, additions, modest standards.

Al Taylor
We added a couple, Mark. I'm going to cover that in a second.

Mark Savage
Okay. Very good.

Steven Lane
Why don't you go ahead, Al?

Al Taylor
Next slide. The first part of this is the prioritization criteria that we used to come up in Version 2. And these will continue. We really feel like we can't, for the sake of implementation burden, developmental burden and then, also the burden on the providers, we would have to implement that and maybe be one of the responsible parties for collecting all of this information, we aren't likely to have massive changes in USCDI because the incremental work that is needed to do these updates, voluntary as they may be, is in many cases too difficult to do on a regular basis. And so, we are looking for data elements that do fill these gaps or have addressed specific data needs that are not part of USCDI V2. They have to be reasonable. And Hans keeps pressing on this issue. In some cases, there is a significant implementation to do work to advance the standards or implementation guidance that would be needed to adopt changes in USCDI Version any.

And then, looking at the total aggregate, all of these things are going to continue. Even though we are focusing on some specific areas, we still can't say we're looking to add like 100 new data elements that address one of these specific new criteria that we're likely to add. We have to operate under this constraint of reasonable incremental change. And so, those are going to continue. Because we have, as evidenced by our incorporation of SDOH and the SOGI data elements demonstrating our interest in improving data for the purposes of addressing equity in underserved stakeholders, we want to continue to do look where data can mitigate these inequities and disparities. I think that these two new groups of data address some underserved stakeholders. And then, we are also looking for specific data elements that aren't part of USCDI right now that would improve public health reporting, investigation, and emergency response. So, there are data elements out there that could advance some of these issues.

We feel like those are some specific areas that ought to be focused on. And we, certainly, can call some of these, specifically, out either through direct engagement with stakeholders or by various communication methods that we have. But what we're saying is that work in these areas will particularly pay attention to work in these particular prioritization areas where it works to improve USCDI for those purposes.

Steven Lane

Al, just a comment. You and the team got a lot of praise earlier for what's in V2. But I think similar praise is warranted for your calling out these priority areas. It's very much in line with our earlier suggestion. So, thank you for that.

Al Taylor
Yeah. Sure. So, I don't know if I have another slide.

Steven Lane
Yeah, one more.

Al Taylor
So, right now, we're in this V3 submission process. We're in the window. It's going to continue through September 30. We are looking for stakeholders to do one of a number of different things, not just go to On Deck and submit. In the context of these new and existing prioritization criteria, looking through the On Deck system as Grace has tried to do to look through for things that might already meet their needs, not part of USCDI that just need some additional work, collaboration, additional. And so, look at USCDI in its current form, see what might be missing, see what's already been worked on, and work to advance those particular data elements in the absence of those data elements that could warrant some additional work for collaboration and then, submitting new data elements through the On Deck, whether it's in response to their own particular needs, something that ONC has focused on, or some other stakeholders have submitted already.

And then, also, not just working with other stakeholders but also working with ONC like how do we make our submissions better? Or how do we make this other person's submissions better? And we expect for all of those things to be happening at a pretty good clip between now and the end of September. And I think that's it. We were going to just touch on it. I don't think we're going to get into the Phase 3 work because we're almost out of time. But those are some things that we hope will happen over the next couple of months. And we're looking forward to the work. There was a question that Peter Gunter had asked about finding data elements that didn't make it as part of USCDI V2. Peter and for everybody else, we have the USCDI home page. We have five different tabs across the top of that page. One is USCDI V1, which is the current existing regulatory version of USCDI, USCDI V2 as recently published, but also the Level 2, Level 1, and comment tabs are the content that was submitted but did not make it into USCDI Version 2.

Very shortly, literally, within the next couple of days, we're working to implement and improve search functions so that you can go ahead and type in a key word, even a misspelled key word, and find something that's already in USCDI that might meet your needs or might at least trigger your imagination.

Steven Lane
So, let's go to public comment now.

Public Comment (01:23:15)

Michael Berry
Operator, can we open up the line for public comment?

Operator

Yes. If you would like to make a public comment, please press Star 1 and a confirmation tone will indicate your line is in the cue. You may press Star 2 if you would like to remove your comment from the cue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. One moment as we poll for comments.

Michael Berry
While we're waiting, we do have a slide coming up that has our upcoming schedule of meetings. But just so one is aware, we are meeting next Tuesday, July 27 at 10:30 Eastern Time. Operator, do we have any comments?

Operator
There are no public comments.

Michael Berry
Thank you. Steven?

Steven Lane
Thank you so much. So, Al, I did want to come back to ask a question. We suggested a number of times that the task force will likely be re-chartered next year and, potentially, in future years to look at the additional versions. And in your Slide 21, there is, again, the red box clarifying that HITAC is going to be doing a review of Version 3. Is that a fair statement that there will almost certainly be a USCDI 2022 task force that will be engaged to do that work?

Al Taylor
I would guess that's the case because part of the structure of USCDI is to look for feedback. And we've, clearly, used HITAC regularly to get specific feedback on a lot of the things that we do. So, I do expect it. I can't promise it. But I would expect that we look for formal feedback from the HITAC going forward.

TF Schedule/Next Meeting (01:25:30)

Steven Lane
Great. Thank you. So, again, looking ahead to the remainder of our time together for this 2021 task force, if we can go on to the next slide or maybe it's going back, actually. Let's go back to Slide 24 here. So, just a reminder of where we've been and where we're going. We've been through our Tasks 1 and 2. We're working on our Task 3. We've started some of that work. And we have really until the end of August to get through this work. On the next slide, you see the meetings that we have on the calendar. These dates were selected to avoid major competing industry meetings that I think many people will be involved in and also to give us some time to get the work done in between meetings. But next week, as you've heard, we are going to come back and focus on SDOH and, specifically, meet with some of the leaders of the Gravity Project beyond Mark who we've had the pleasure of having with us all along.

And I think the idea there, Mark, just as you and your team prepped for that meeting, is really first to hear from Gravity their response to the changes that were included in V2 and then, talk really specifically about what priorities Gravity or other SDOH stakeholders may have related to V3 and future versions of USCDI because the whole purpose of this discussion is really to see if there is a need for our task force to weigh in with recommendations. And I would think that those recommendations should be informed by the people

who have been living and breathing this for the past couple of years. For the subsequent meetings, you'll recall that we have our Google Docs where we have captured topics for discussion from previous meetings. And we want to work our way through those. I have also made outreach to most of the FHIR accelerator teams beyond Gravity. And some of them have responded. I've scheduled some pre-meetings with some of those folks to see if there were issues that would benefit from discussion here at the task force.

Again, our number of remaining meetings is short but I invite others of you, if there are areas that you think are really important with regard to the three priorities that you believe we should discuss here, please let me and Leslie know so that we can discuss getting those on the agenda. So, we are at time. Again, I want to thank all of you for your participation today and look forward to meeting with everyone again next week to further dive into social determinants of health. Have a great day.

Adjourn (01:29:03)