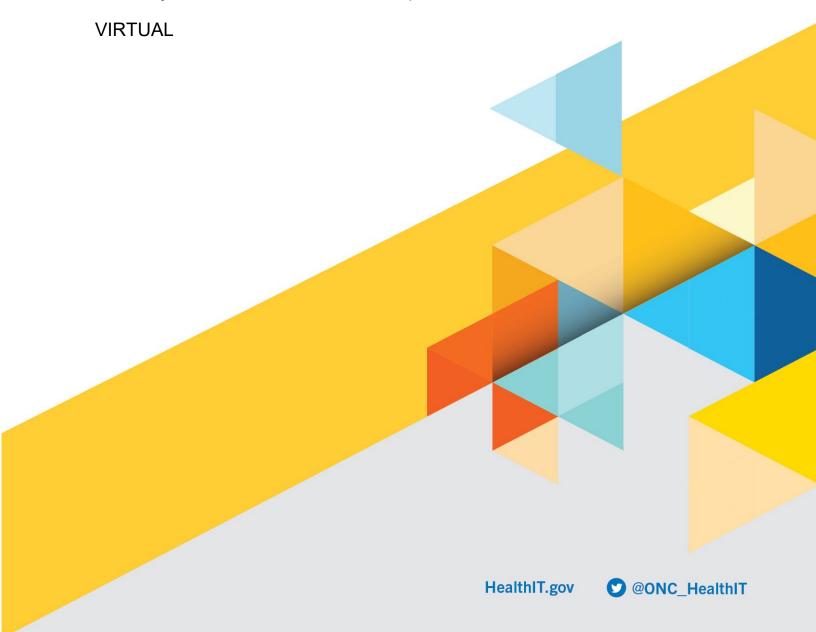
### **Transcript**

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

February 1, 2022, 10:30 a.m. – 12:00 p.m. ET



## **Speakers**

Name	Organization	Role
Steven Lane	Sutter Health	Co-Chair
Arien Malec	Change Healthcare	Co-Chair
Kelly Aldrich	Vanderbilt University School of	Member
	Nursing	
Hans Buitendijk	Cerner	Member
Thomas Cantilina	Department of Defense	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Steven Eichner	Texas Department of State	Member
	Health Services	
Rajesh Godavarthi	MCG Health, part of the Hearst	Member
	Health network	
Adi Gundlapalli	Centers for Disease Control and	Member
	Prevention	
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
Leslie Lenert	Medical University of South	Member
Lluma C. Luu	Carolina	Manahar
Hung S. Luu	Children's Health	Member
David McCallie	Individual	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	Baptist Health	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and	Member
	Medicaid Services	
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards	Member
Michael Dawn	and Technology	Designated Federal Officer
Michael Berry	Office of the National Coordinator for Health	Designated Federal Officer
	Information Technology	
Al Taylor	Office of the National	ONC Staff Lead
	Coordinator for Health	
	Information Technology	
Denise Joseph	Office of the National	ONC Staff Lead
	Coordinator for Health	
	Information Technology	

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

#### Mike Berry

And hello, everyone, and thank you for joining the Interoperability Standards Workgroup. I am Mike Berry with ONC, and we are very happy that you could be with us today. As a reminder, your feedback is always welcomed, which can be typed in the chat feature to everyone throughout the meeting or can be made verbally during the public comment period that is scheduled at approximately 11:55 Eastern Time this morning. So, let's begin rollcall of our workgroup members. So, when I call your name, please indicate that you are present. Let's start with our cochairs. Steven Lane?

#### Steven Lane

Good morning.

#### **Michael Berry**

Arien Malec?

#### **Arien Malec**

Good morning.

#### Michael Berry

Kelly Aldrich?

#### **Kelly Aldrich**

Hi, everyone.

#### **Michael Berry**

Hans Buitendijk?

#### Hans Buitendijk

Good morning.

#### **Michael Berry**

Thomas Cantilina? Christina Caraballo?

#### **Christina Caraballo**

Good morning.

#### **Michael Berry**

Grace Cordovano?

#### **Grace Cordovano**

Good morning.

#### **Michael Berry**

Steve Eichner?





#### Steven Eichner

Good morning and happy Tuesday.

#### Michael Berry

Adi Gundlapalli? Raj Godavarthi?

#### Rajesh Godavarthi

Good morning.

#### Michael Berry

Jim Jirjis? Ken Kawamoto?

#### Kensaku Kawamoto

Good morning. I generally have a conflict with this time, but I will join whenever I can. Thanks.

#### Michael Berry

Thank you, Ken. Leslie Lenert? Hung Luu?

#### Hung S. Luu

Good morning.

#### Michael Berry

David McCallie?

#### **David McCallie**

Hello.

#### Michael Berry

Clem McDonald? Aaron Miri is not able to join us today, but should be back next week. Mark Savage?

#### Mark Savage

Good morning from sunrise in California.

#### Michael Berry

Michelle Schreiber?

#### Michelle Schreiber

Good morning from getting 18 inches of snow in Michigan. That is for you, Mark.

#### **Michael Berry**

And, Abby Sears? Is Abby Sears with us today? All right, and I know Ram Sriram could not be with us today, but John Garguilo is serving as his alternate. John?

#### John Garguilo



I am here, good morning.

#### Jim Jirjis

Jim Jirjis is here.

#### **Michael Berry**

Thank you, Jim. All right, thank you, everyone, and now, please join me in welcoming Steven and Arien for their opening remarks.

#### **USCDI Process Review (00:02:30)**

#### Steven Lane

Well, thank you all for joining us again this morning. Most appreciated. Ken, you were not with us last time, I believe. Is that true?

#### Kensaku Kawamoto

That is right.

#### **Steven Lane**

Do you want to just introduce yourself briefly?

#### Kensaku Kawamoto

Sure. Ken Kawamoto, CMIO at University of Utah.

#### **Steven Lane**

Great. And, Michelle, were you here with us last week? I could not recall.

#### Michelle Schreiber

I was.

#### Steven Lane

You were? Okay, sorry. My bad. All right. And, I think we still have one or two members who have not made it yet, specifically Tom Cantilina, so we are looking forward to him being able to join us. Again, here is our agenda for today. At a number of people's requests, we are going to ask Al to continue to reorient us to the USCDI and where it fits in our ecosystem and rulemaking, etc., then we are going to dive into our work and try to focus in on our Charge 1A, looking at the new data classes and elements that have bene proposed in draft V.3. We will do public comment five minutes before the end.

Again, I want to welcome all the members of the public who are here. We have quite a number of public attendees today, which is wonderful, and I want to remind members of the public that we invite you to comment verbally at five minutes before the hour. We really do welcome your input in person, and you are also welcome to enter in the chat as well. And, I see we have some chats here. Adi is here, and Jim, we heard you, so, thank you, that is great. All right, Arien, do you want to add to that?

#### **Arien Malec**



HITAC

No, I think it is good that we are going to go over the USCDI process review because I think that has caused a fair amount of confusion, and I think knowing where we are is going to help us better get to the meat of this workgroup meeting, which is relate to Charge 1A.

#### Steven Eichner

Steven, this is Steve. I just wanted to add something very quickly.

#### **Steven Lane**

Sure.

#### **Steven Eichner**

Great. Just to differentiate, because we have two Steves or Stevens in the group, Steven and I decided that it might be easier to refer to me as Ike, coming off of my last name, Eichner, so I will make every attempt to remember to identify myself as Steve Ike when I speak, but just in case, to help us differentiate, please refer to Steve Eichner as Ike.

#### **Arien Malec**

Thank you, Ike. Very generous of you. Steven, why don't I lead us through the USCDI process review section, just because I was probably baseline most confused by the USCDI process review. All has prepared a ton of really useful content. I am just going to give a high-level perspective because I think there have been a couple of areas that have been the most confusing. No. 1 is there is a parallel initiative called USCDI Plus, and we are working on USCDI V.3. People have been trying to figure out where Plus sits in trying to get situated with Plus versus V.3. And then, I think there has been a fair amount of confusion about the role of certification, V.1, and the SVAP, and I will give a very brief description of both, and then, Al will give us the detailed deep dive.

With regard to USCDI Plus, I think the short version of this is that USCDI Plus is the blog posting that ONC published on this topic. It really outlines that the goal is for federal partners to help advance the future of USCDI by looking at areas of unmet need relating to, for example, public health, or disability determination, or quality measurement, but that initiative is a little too early for us to engage on, so we are going to focus on the V.3 portion.

And then, with regard to the V.1 and certification approach, Al is going to walk us through the state of play here. I think the summary that I have come to is the policy goal is to use the SVAP to advance standards. There is a little bit of gear teeth meshing with regard to the constraints that ONC has as a regulator to use the SVAP most effectively and have it mesh with the certification process, and we are right now in the middle of a process where the gears are trying to engage, and really smart legal minds who understand how the policy framework works for regulation is engaging to figure out how to best use the SVAP to engage with certification.

The general thrust of where ONC is going is in line with the commentary of the HIT policy committee and standards committee, and now, the HIT advisory committee, which is let's be mindful that certification, while it sets a floor that we want to raise the nation to, may also anchor or pin the nation to the floor. Let's use mechanisms like standards advancement to encourage organizations to go above the floor. I think from a policy perspective, that is right on, and we are just now figuring out how to make that mesh with some of



the regulatory arcana. But, I am going to turn it over to Al, who has a nice pictorial, walks us through in much more detail than I just covered the full state of play and landscape, and I think will help us get situated on V.3. At the conclusion of Al's portion, we will do a very short time for commentary because we want to get back to the main material, but Al, I will turn it over to you.

#### Al Taylor

Thanks, Arien. Next slide, please. So, like Arien said, we are going to go through some overall thoughts on USCDI and how it fits into the work that the workgroup is doing. So, the first question is why is USCDI important? First of all, USCDI, especially Version 1, was adopted in the ONC CURES Act final rule, which was early 2020. It is designed to set this foundation, or the floor, as Arien put it, for sharing electronic health information, and the areas of focus have been around patient care, the data that is needed for patient care, but also patients' access to their own data. USCDI is a required part of the new certification criteria, which is the CURES edition of the 2015 certification criteria.

In particular, USCDI is invoked or used as the data standard or the data set that is required for application programming interface access to data in a couple different criteria in the certification criteria, as well as replacing the common clinical data set, which has been used since 2015, for a number of other certification criteria that are listed here, and what that means is that all of these standardized documents and standardized exchange mechanisms must be able to handle the data elements and data classes that are part of USCDI, and that is a change. Previously, those documents and those standards required only the common clinical data set, so it is an expanded set of data that must be included or be able to be included in these exchange processes. Next slide.

We keep going back to this slide. It is really important to focus on the fact that USCDI is really a core set. It is a core set that replaces the common clinical data set, and it supports patient care and patient access to the data. It is meant to be a reliable baseline on which other data requirements can be built, but just like they did with the common clinical data set, when people refer to USCDI, it is a known quantity for reference when the needs exceed what is incorporated into USCDI. And, the other part to this, which is where HITAC and this workgroup are doing most of their work, is to inform the expansion process. This workgroup is part of the expansion process to make recommendations for adding to USCDI, not only Version 1, but also Version 2, which was published last year. Next slide?

I apologize for the busyness of this slide. This is how USCDI fits into other pieces of regulation. These are actually other parts of the CURES Act. Next slide. The first piece of this is where USCDI fits in. So, USCDI became available in April of last year so that systems could start updating to USCDI Version 1, compared to previously, when they were already certified to the common clinical data set in the 2015 certification criteria.

The other two things that happened in April of last year were that the information blocking provisions kicked in, and the very short version of information blocking is that data could not be withheld following a valid request for information for patient data, and the amount of information that could not be blocked without civil penalties is the amount of information that was contained within USCDI, and that amount of information that is subject to information-blocking provisions is what is defined as electronic health information, and so, currently, that amount of information is defined as what is in USCDI. Next slide.



There are two additional dates that are important, both of which happen later this year. Towards the end of this year in October, that amount of information that is subject to information blocking expands from just being what is in USCDI to all of the electronic health information that a system manages, and so, it becomes much more extensive than just what is in USCDI. Next slide. The last date that I wanted to focus on is the end of this year, when all of the criteria that required the CURES Act certification, including the new API requirements, the requirement for using USCDI V.1, all kick in, so everything has to be in place and certification must be complete and made available to health IT customers by the end of this year. Next slide.

This is meant to convey what the timelines are and w here we are at in the process. So, we are at the beginning of 2022. We just published the draft USCDI Version 3, and we are currently in the period where both the HITAC and the general public have an opportunity to comment and provide feedback on what was included in draft V.3. Last fall and last summer, lots of submissions came in, several hundred submissions came in that informed our decision about what should be included in USCDI draft V.3, and now, we are opening it up to the public to get information back from them, as well as from the HITAC and this workgroup, on what we got right, what people think ought to go in, possibly what ought to come out, so we are waiting for that input to be formed. That goes through the end of April.

At the end of April, ONC is going to take all of the feedback from the HITAC, from the recommendations that this workgroup provides, all of the public feedback that is coming in now and will continue to come in through the end of April. Then, we will take all of that input into consideration and make whatever changes we need to make to draft V.3 and publish the final version of USCDI Version 3 hopefully in July of this year. Once we publish the final USCDI V.3, that will be a new version of a standard, and there are many other standards that will be considered, but what that means is that ONC will consider whether or not USCDI Version 3 will be made available for updates to health IT.

So, an EHR could voluntarily update their system to either USCDI Version 2 or USCDI Version 3 in the future. The USCDI Version 2 that we published in July of last year will be under consideration for SVAP starting in... We anticipate that that will be a standard that will be available for update to the systems. And so, it is an annual cycle, and each new version of USCDI is under consideration for SVAP, which we will then make available for systems to be updated to. Next slide.

So, this is a little bit more information on the Standards Version Advancement Process. This allows certified health IT to update to newer versions of a variety of different standards that are part of the certification, the standards that must be used in the certification program, and that is the certification program that is based on the CURES edition of the 2015 certification. So, last year, we published the first approved standards list, and then, systems are then able to update to several different areas with several different certification criteria using the newer versions of the standards, and like I said, USCDI Version 2 is going to be one of those standards that will be under consideration for addition to this year's approved standards list. Next slide.

Our intention was to have an annual cycle, but we realized that once USCDI Version 2 comes out, which it did last summer, there are two key other standards that need to be updated to reflect the changes in USCDI Version 2. One of them is the HL7 FHIR US CORE implementation guide, and the other one is the consolidated clinical data architecture implementation guide. Both of those are HL7 products. Both of them are implicated by our certification criteria, and with the new version of USCDI, changes to the US CORE



and the C-CDA implementation guides have to be made to be able to carry the USCDI data elements and data classes during exchange or in pursuit of interoperability, and to give those implementation guides enough time to mature, to be validated and published, we extended that consideration period for SVAP through the end of May, by which time we expect updated versions of US CORE and C-CDA to be out, so that all of them can be made available for voluntary update by systems, starting in about August of this year. USCDI will be considered for SVAP, along with these other two implementation guides. Next slide.

#### Rajesh Godavarthi

Can I ask a question?

#### Al Taylor

Yeah, sure.

#### Rajesh Godavarthi

Steve is first. Do you want to go first?

#### **Steven Lane**

Why don't we let Al finish the presentation, and then we will drain the questions at the end? Thanks.

#### Rajesh Godavarthi

Sorry.

#### Al Taylor

Okay. And, this is a super busy slide, but it is an HL7 slide that just reflects that there is a lag time between the publication of a USCDI version and the incorporation of that new version into the FHIR US CORE release, and so, that is happening now. I believe that we are in the balloting process or about to enter the balloting process for the FHIR US CORE version that will incorporate USCDI Version 2, so that is a little bit of a lag for these implementation guides. Next slide.

We will talk a little bit about USCDI Plus. This goes back to some of the things that USCDI is and one of the things that USCDI is not. So, as a core set of consistent baselines, because it is both of those, a core set and a baseline, there are other things that might be needed, whether by a federal agency or some other system, that requires additional data that is not in USCDI, either Version 1 or even future versions. In response to that realization, ONC is establishing the USCDI Plus process. There is a blog about it. We have a small web presence right now, more to come on explaining more about this, but ONC is working with several federal agencies in order to define what those additional data needs are and how we can facilitate the dissemination of those additional data requirements and how best to get those implemented as part of this USCDI Plus program. Next slide. Or, is that?

#### **Arien Malec**

Thank you, Al, for that really masterful presentation through some complex terrain. We are going to do a brief session to entertain questions. As somebody who has attempted to dive deep into the arcana, and I see that we have a bunch of questions coming up, my request to the workgroup is let's trust that although there is some meshing of gears with regard to the Administrative Procedures Act, that ONC is going to figure out how to use the standards advancement process as the primary mechanism for working with



industry to update standards in production using certification primarily as the means to raise the floor for the EHR developers and other HIT developers who are not so advanced to be working at the level of the SVAP.

The second thing is that as tempting as it is to jump into USCDI Plus and have concerns related to variability for USCDI Plus, let's all recognize that project is a little to early for us to engage in. Finally, although we might want to give a bunch of opinion about how to use certification as a mechanism, again, if we are not experts in API and experts in certification, it is really out of our remit, so this is a time to just recognize the landscape and engage in the process which says hey, just trusting that the SVAP is the mechanism the industry is going to be using to adopt new core, broadly accessible definitions of health information, let's engage on V.3. But, with that, let's go through the five questions we have, starting with Steven. Go ahead.

#### **Steven Lane**

Now we are up to six. Mine are mostly comments more than questions, but I just wanted to get them in. One is to address a question that Grace raised out of band between the meetings. Just to clarify for everyone that USCDI becomes irrelevant to information sharing requirements come October. We are not looking to USCDI V.2, V.3, any of it. USCDI simply goes off the table as the October expansion to all EHI occurs, so I just wanted to make that clear unless, AI, you want to rephrase that in any way.

#### Al Taylor

I would just say that USCDI will still be a subset of the information covered in EHR, so it just expands beyond the scope, so we are just looking at additional data beyond USCDI. It does not mean that USCDI does not have to be exchanged after that point, it just means any amount beyond what is in USCDI.

#### Steven Lane

My next comment was for those who were not with us, we spent a lot of time last year dealing with this issue of wanting to add to the USCDI items where the implementation guides were not fully mature, and we had a lot of back and forth with HL7 and ONC, and we got this agreement that HL7 would accept our recommendations, do the work to get the IGs ready in time for this SVAP process, so that delay in the SVAP was really something that this or our predecessor taskforce requested. It is not like that that slipped, it was just modified to accommodate our request. And then, the third comment/question I would have is my understanding, AI, and correct me if I am wrong, is USCDI Plus is really plus. It is on top of USCDI. Clem was raising some comments in the chat. What if it goes in the direction or uses different standards? USCDI is the core, and USCDI Plus will define additional items on top of that to meet specific use cases. Do I have that right?

#### Al Taylor

Mostly. I would just say that the particular data requirements of our federal agency partners will include at least part of USCDI. It may not be all of USCDI plus something else; it could be part of USCDI plus something else. And so, I just wanted to make that clarification.

#### **Arien Malec**

That is right. We can decide that actually, rather than creating a new implementation guide for public health, most of the data is already there in USCDI, and there is maybe just a little bit more that needs to be contemplated, but again, just from a scope perspective, we firmly recognize that that work is just now kicking



off, and we do not have much in the way of anything for us to dig our teeth or comment on, and we have plenty of work to do for USCDI V.3. Raj?

#### Rajesh Godavarthi

So, I have a couple of questions. One is the dependency with the US FHIR CORE. So, who defines first? USCDI goes first, then tells the CORE that they need to follow that? What is the **[inaudible – crosstalk] [00:28:30]**?

#### **Arien Malec**

I will let Al comment, but my understanding is the mechanism that we are driving towards is one where we have additional data classes and elements considered in revisions to USCDI versions for the SVAP. Once they hit the SVAP, that is not the only mechanism that industry, HL7, and other SDOs have to engage, but that is the primary mechanism for industry and HL7 to engage and align on how to memorialize all of that in terms of updates to FHIR and consolidated CDA. That is a well-running process.

#### Al Taylor

Arien?

#### **Arien Malec**

Go ahead.

#### Al Taylor

I just wanted to clarify something you said. I may have misheard you. The publication of a final version of USCDI, which in this case is USCDI Version 2, is the event that triggers the updates to US CORE and C-CDA IG. You mentioned SVAP, and it is not SVAP. We want SVAP to adopt the new versions of US CORE and the C-CDA, which should already reflect USCDI Version 2.

#### **Arien Malec**

Thank you for that. So, just again, as a reminder, the policy landscape that we want industry to be engaging in is one where we have due consideration of mission and national priorities and needs. We have work like this consideration of USCDI V.3 that gets up and engaged. Once we have firmed up what, for example, USCDI V.3 looks like, we engage with SDOs and industry partners to figure out how to memorialize those data classes as actual interoperability specs, with particular focus on FHIR and consolidated CDA, and then, we should be pilot testing in concert, having that go through the usual cycles of DS2 and [inaudible – coughing] [00:30:59] etc. prior to national adoption. But again, a mature, standards-based framework has industry, business need, and mission driving work on the ground, which leads to fully formed and balloted standards that are informed by production use, and that is really the machinery that we are trying to get to. Ike?

#### Steven Eichner

Yes, thank you. Very high-level, Al, is there an expectation that USCDI Prime is going to potentially duplicate data fields or classes that are in USCDI, or is it expected to be completely different?

#### **Al Taylor**



Just a quick clarification on terminology. USCDI Plus is the program or initiative that ONC established to build on USCDI. I know that the term "USCDI Prime" has been used in the past, but just for clarity, I think it is best to reference USCDI, and whatever is contained within USCDI Plus can meet additional specific use cases. So, USCDI Plus will not duplicate USCDI, but will just simply build on it.

#### **Arien Malec**

Al, the way that I conceptualize this, and at some point, I think we just need to move on from USCDI Plus, is an ideal USCDI Plus outcome would be, for example, SSA to look at the disability determination use case and decide, "Hey, if we just use USCDI V.2, we can actually meet all of our disability determination adjudication, or we can meet 99% of our disability adjudication needs, but we need Extra Field Y." The ideal consideration would be one where we are determining that 99% of the data that is necessary for public health, or for disability determination, or for ECQMs is actually right there, and that the Plus could either be considerations for USCDI V.4 to expand the core or, in many cases, will be profiles on top of the core for specific needs, just from the same way that we might consider in the future profiles on top of core to address needs in oncology, or cardiology, or name your specialty that are not fully addressed by the core. Hans?

#### **Hans Buitendijk**

Thank you. I have three quick questions. One, just to indicate the question in the chat, and Steven already alluded to that as well, and it is for the process as we go through where and how, in these discussions, do we, or do we not, or how we assert that standard [inaudible] [00:34:23] vocabulary are or are not ready, therefore need to be paid attention to for later on. We spent a good amount of time in the last round on that, and based on that experience, is there another better way to deal with that? So, it is a process question that does not need to be addressed right now, but something to think about. The second question is a clarification, perhaps for Al. With the shift that happens in the timing from USCDI V.2 publication, then realizing that SVAP needs to be adjusted because of underlying standards, now we are sitting in the timeline of summerish, USCDI V.2 ready already, the underlying standards being [inaudible] [00:35:06]. Is that shift going to be the same way so that USCDI V.3, as we are thinking about it, would be in SVAP next year summerish, or is it going to be shifted back to January-ish?

#### **Al Taylor**

No, we anticipate that the annual cycle shifts to the summer on a summer cycle. So, to back up to the initiating event of the publication of a final version of USCDI, which then leads to a six- to nine-month prep time for those respective implementation guides, which then have to be available for consideration for SVAP. I do not want to call it a lag time because there is a lot of work to do, there is no lagging in updating those IGs, but it is because of that. So, the publication of the version of USCDI, followed by the updates to the IGs, followed by SVAP of all three.

#### Hans Buitendijk

That clarifies. That helps. The last question is a challenge I think we are going to be looking at. If I heard Al correctly, USCDI core, the basic one, could actually be subsetted in some context as well, and I think this overall landscape of USCDI versus USCDI Plus, whatever it is called, whenever it is going to be developed, is the stratification of the data to understand who is supposed to support what. The current state is that USCDI, with FHIR US CORE, which I will use as the underlying standard, and assume C-CDA, but you must support both fully as certified software.

So, as we are adding to the USCDI increasingly, the question is going to be is that truly something that everybody must support, or is this something that a smaller subset must support or should support. As we go through, that question will become increasingly larger and increase the complexity that we are dealing with to make sure that the combination of USCDI and USCDI Plus data sets and the underlying configuration of IGs works together. So, on one hand, I agree with Arien that the ESR focus is USCDI. Every time, the question will start to have to be asked increasingly if this is really core for everybody or is it better done in a USCDI Plus that we are currently not dealing with, but it needs to be addressed to ensure that not everybody needs to support everything?

#### Al Taylor

Let me just try and answer your question for a second, Hans, and if I do not, we can follow up. I know we need to move on. So, the USCDI is a requirement for certified IT, for certified EHR technology, No. 1, along with a lot of other certification criteria. There are some agencies that require the use of certified health IT, with all of the attendant capabilities in the certification criteria. There are other federal agencies that may or may not require certified health IT, but they do require a certain amount of information to be provided to them.

Using USCDI as the baseline, they can at least understand what they are going to get or they can get from certified EHRs if they say, "We want the information from your system," so we know that that system is capable of doing everything that is in USCDI by the means that are outlined in the exchange criteria. So, if they have additional, they can either shape their requirements around USCDI, or they can say, "At least we know what we are going to get from certified technology." And so, it is not about whether or not it is a subset of USCDI, it is just that as federal agencies consider requiring information, they can consider USCDI, like I said, as that reliable baseline.

#### Hans Buitendijk

That clarifies, because it sounded for a moment that we were going to carve inside USCDI, and that would effectively expand the number of USCDI [inaudible – crosstalk] [00:39:30].

#### **Al Taylor**

We are not. We are just trying to identify what the federal agency data requirements are and how USCDI might meet those.

#### **Arien Malec**

Right. As I said, a successful conclusion to that would say, "Hey, there is really nothing to do because we are actually pretty well covered through USCDI." That would be a good thing.

#### **Hans Buitendijk**

The second question is the harder one. Should something be put in USCDI, but is really a better candidate for a USCDI Plus data set? Where do we draw the line? So, I think, Arien, we still are going to be in that balancing act.

#### Arien Malec

That is right. Again, the intent of this whole session was to place the work of this workgroup in context, in focus. Our job is to consider for evaluation candidates to enter that hallowed set of interoperability elements



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that should be considered universal for the nation, and among the output of that set may be use of that universal exchange set for federal purposes, for providing clinical care, etc., but we have a really critical role to play in this workgroup by evaluating whether something that wants to enter that pretty significant set of things that we intend to have structured information exchange that intend to go into FHIR CORE and consolidated CDA revisions is appropriate for that consideration. Clem? And then, we will close out this chapter of this conversation and start engaging in the work. Go ahead, Clem.

#### **Clem McDonald**

I have a couple of questions/comments. One of them is that October thing where we are supposed to get all the data. As I recall, the regulation said that data can be sent any way the vendor wants, which, to me, says it is going to be pretty much unusable as a standard. Am I wrong?

#### **Arien Malec**

Clem, I made this comment as well. The intent of the USCDI is to form the floor for the information intended to be exchanged in a structured way. The intent of CURES is to enable information exchange for the complete record set. It is almost a consequence of that that some portion of the CURES exchange that is above the floor of USCDI core is going to be PDFs, notes, or other forms of unstructured information that does not have the same framework for computability that structured information has. That is absolutely correct.

#### Clem McDonald

To clarify a little bit, we have talked about this before, but the regulation for that part does say that vendors can send it any way they want. Am I wrong?

#### Al Taylor

No, Clem, you are not, but just with a slight modification, we are not looking for a vendor to actively convert some of their electronic information into some other form in particular, whether it is paper or some other form, but if it is electronic, it must be available for sharing. That is the bottom line.

#### **Arien Malec**

That is right. There is a feasibility. Again, this is not the time to dig into the information-blocking exceptions, but...

#### **Clem McDonald**

Please let me explain what my question is.

#### **Arien Malec**

Sure, go ahead.

#### Clem McDonald

If we do not label those things with at least a date and a who, how is it going to be usable? That is, I think we may be hopeful about something that is not going to be useful.

#### **Al Taylor**



HITAC

It is not to say that the information is not usable just because it does not have a particularly defined standard. The data is represented however it is represented in each EHR, and that information has to be exchanged on a valid request. So, it is not an assumption that it unusable, whether it be free text or structured.

#### Clem McDonald

Okay, I misunderstood. So, someone would request a particular [inaudible - crosstalk] [00:44:00].

#### **Arien Malec**

So, Clem, I would encourage you to look into the language, and it is pretty grody, but I would encourage you to look in the language for information blocking relating to feasibility of request, but the general mechanism is that requesters can request specific formats, and responders, to the extent that those format requests are feasible, should be able to respond in the requested format. So, in general, if something is available...

#### Clem McDonald

That answers it. I had one more little question, and that is regarding the Plus thing. So, in my life experience, everybody loves standards as long as it is their own, and no one wants to change. They all want to be free. There is this conflict between standards and freedom. So, the Plus gives an opportunity for groups to escape to freedom again because they are all thinking, "Oh, we are different, we do not have to use USCDI core." So, the question is do we have an opportunity to constrain that by maybe having them have to go back to USCDI central before they can rush ahead and make their own thing the way they want to?

#### Al Taylor

So, if you do not know him, Avinash is the Executive Director for the Office of Technology, under which I serve. Our information-blocking team from the Office of Policy is planning on addressing the February HITAC meeting on info blocking, and I spoke to them yesterday, and they said that they would be happy to have a follow-on conversation with the workgroup to answer questions until they drop on info blocking if the workgroup so chooses to have such meeting from them.

#### **Steven Lane**

I just think we are going to have to think as workgroup leadership as to whether we are going to have time for that, but it would be a lot of fun.

#### **Arien Malec**

I am going to limit debate at this point. We are going to declare cloture, to use the senate term. We are going to limit debate at this point, and then we are going to get back to the task at hand, which is now that we have appropriately situated ourselves in between the floor, which is defined by the SVAP and, eventually, some flavor of certification, and the ceiling, which is all the stuff that wants to be universal and all the federal actors' desires for additions and modifications, we are going to stay firmly grounded in the work of today, which is what of the candidate set that wants to enter the universal exchange defined by USCDI should we, in our wisdom, make recommendations to ONC about. So, with that, I am going to turn it back to Steven.



## Workgroup Work Planning & Charge 1a – Draft USCDI v3 New Data Classes and Elements (00:47:24)

#### Steven Lane

Thank you, Arien, and thank you, everyone, for that lively discussion and for the chat. We appreciate the fact that members of the public are joining the chat here a little bit. So, we are moving into our actual work here based on that clarification of where we stand, so let's go to the next slide. Again, just as a reminder, we have two charges. One is due in mid-April; one is due in mid-June. We are focusing initially on Charge No. 1, to evaluate the draft USCDI Version 3, and to provide recommendations. For this month, February, our hope is to focus on 1A, looking at the new data classes and elements that have been proposed within the draft Version 3, and then, once we have our way with that, we will focus in on 1B, which is looking at all of the other stuff that is in Level 2 that was judged by ONC to be technically and societally ready for inclusion in a version of USCDI, but was not included in draft Version 3.

And, I think last year, we did a lot of coloring outside the lines, which was a lot of fun and we learned a lot, but we are going to be laser focused on our charges, so as other good ideas come up, we will put them in a parking lot, but we are going to focus, over my dead body, on these tasks. And then, once we finish 1A and 1B, we are going to move on to 2, and if we have more work that we want to do this year, we will do that. ONC has been very good about supporting us in doing additional things outside the lines, as it were, and we have historically brought additional commentary back to the HITAC. So, any questions about the charge, our timeline, or where we are headed? All right, Arien and I are going to get you there, I promise you.

On the next slide, we are going to now start in our Charge 1A, so, go on one more. Again, just to be reiterative, here it is. We are going to look at the new classes and elements that have been proposed for inclusion in draft V.3, and our focus will be to get any commentary about whether these are appropriate to include, whether there are some that should not have been included, whether is detail that is needed to clarify those that have been included, whether there is room for improvement, as they say here, appropriate and meaningful data class, element names and definitions, did they get named right, and then, representative examples of value sets. And then, the third question here is are there significant barriers to development and implementation or use of any of these, and this goes back to our earlier conversation. It may be that there is an implementation guide that is still in flight that we need to assure gets completed or updated or something before one of these can be included in V.3.

Let's see. I just forwarded a document that I put together that I think would be helpful, if we could pull that up. Mike, is that going to work? What I did early this morning was I just went back to the website and I pulled up the picture, the graphic, of all of the new data classes and elements that have been included in V.3. It is the Word document that I sent you.

#### Al Taylor

Steven, we have the new data elements slide from last week's slide deck.

#### **Steven Lane**

But, what I did was I went a layer deeper in my document that I sent you, and I made a listing, and then I pulled out who proposed, who submitted. There we go, this is what I wanted. So, we have all seen the



graphic at the top before, but if you can zoom in a little bit to the text at the bottom, and hopefully we can figure out a way to share this through Google docs or something, it is very straightforward, but basically, these are the new elements, and these are the people who submitted them. So, I just wanted to point out the diversity, and I wanted to thank the people who did these submissions, some of whom are on this committee, some of whom are at CDC, etc. CMS, Da Vinci. All of our friends in the interoperability space put a lot of thought into these submissions, and I think it is important to realize that we are responding to those individuals as well as to the ONC staff that took the time to select these. So, that was the point I was trying to make. If we can figure out how to distribute this, I also pulled in the links to each of the individual submissions, which I think would be helpful for us.

So, what we want to do is work this list, to take the time to get people's feedback on these, and perhaps to go one chunk at a time, but again, we have February to focus on this Task 1A, and we want to get through it, but you all hopefully had a chance to do some thinking on this. We did not get a lot of people coming back to us with homework submissions. Mark Savage actually did send us some commentary, and we will invite Mark to speak to that here momentarily, but what I would like to propose is that we take the time that we have, which is not a lot, to at least start working this list and see how you all would like to provide your feedback. So, Mark, would you like to jump in first?

#### Mark Savage

Well, the things that I commented on were mostly just to indicate interest in helping out. I am happy to help on the sex and gender questions and the functional disability status. I have contacts in both of those spaces and have done work there myself. Also, I think it would be useful, perhaps, to pick one, two, three priority use cases from HITAC's recommendations and discuss what core data elements are missing from the USCDI, yet are integral to those use cases. So, I think that would be a more concrete way to answer the question that is being posed to the group and to use a real-world use case. One that occurred to me is shared care planning and patient-generated health data, but others may have other ideas as well. Maybe that is all you need to hear from me now, Steven, or did you want to cover any of the other things that I said?

#### **Steven Lane**

No, I think that is great, Mark, and thank you. Actually, it is a good reminder as a leadership team, we have already planned to have some focus in our next few meetings, so in our meeting next week, I believe, Al, we are going to have a focus on gender and biological sex at birth. Is that true? Are we getting the Gender Harmony group to come and speak to us next week?

#### **Al Taylor**

Well, not those terms, but yeah, those are the topics. You are already conflating a verity of different terms that we are going to be using. So, the two specific questions that ONC asked about, sex assigned at birth, gender identity, value set definitions, scope, and all of that, are going to be our primary topic, and we are going to have the lead or leads from the Gender Harmony Project present and field questions.

#### Steven Lane

Thank you. Similarly, the following week, I believe, February 15, we are hoping to have a focus on the address issues from Project USA.

#### **Al Taylor**

Yes, that is on the books, and Carmen Smiley from our Office of Technology, who is the lead from ONC on Project USA, will be presenting and also answer questions.

#### **Steven Lane**

And then, similarly, on February 22nd, we are hoping to have a session where we are going to focus in on disability and functional status, which I know there is a lot of interest in here, so I just wanted to lay out that roadmap for the month for those who had not heard that. So then, let's return to the hands up. Ike?

#### Steven Eichner

Yes. Just to drill down on disability status, I have been working the issue behind the scenes, trying to recruit a few people or identify a few folks that may be interested, including some people at the CDC and some of the disability rights organizations to provide it for the 22nd, if not before.

#### Steven Lane

That is great, and I think having subject matter experts, both those of you on the workgroup as well as others from outside, will be good. We are going to have to manage the time, but I think having a few people come and speak to that to inform our discussion would be very helpful. Hung?

#### Hung S. Luu

Yes. So, looking at the data elements for the laboratory, my concern is that there are some missing data elements that would help interpret the test results that are not currently included, such as the instrument and the test kit. I think public perception is that no matter where you go, your lab results will be the same, and that is not quite true. For certain tests, that is true, like if you get a complete blood count, that is not likely to vary from institution to institution, lab to lab. However, for certain tests, such as troponin, which is very important, the numerical value will change depending on where you got your testing.

And so, I think now, as patients are more mobile, and getting their care from multiple institutions, and also having the capability of having that interoperable in terms of having a longitudinal view of the entire history of the patient, having that information that includes instrument and test kit is essential because otherwise, there is going to be confusion about why values could be so different within a matter of days or something like that, and so, I think it might be too late for inclusion in this version, but I think in order for tests to be interoperable and understandable in the future, those two pieces of information need to be included.

#### **Steven Lane**

Thank you, Hung, and I want to thank AI for posting in the chat the link to the page on the USCDI site where the Level 2 laboratory data elements are listed. So, there is a long list there that includes test kit unique identifier. I do not see one there that is actually called "instrument," but it might be buried in one of those others. But, I think there are roughly nine additional Level 2 laboratory data elements, so as we move into this area and we look at items, this is our Task 2, which is items that are leveled as Level 2 that we believe should be included in Version 3. That is when that discussion should occur.

#### **Arien Malec**

I would also editorially comment that we are going to discuss SHIELD with regard to the ISA portion of our taskforce, which gives us another crack at effectively the same topic.



#### **Steven Lane**

Did you have anything else to say, Arien?

#### **Arien Malec**

I do. So, this sort of a grody question on tribal affiliation and expanding race/ethnicity code sets. So, let me just give you a view of the current world as it stands, which is that the vocabulary set for race/ethnicity that is currently in USCDI V.1 is any code from the CDC PHIN VADS code set, which, if you look through it, is incredibly detailed and expansive. And then, unfortunately, it is capped at a minimum at the OMB code set or vocabulary set, which is quite restrictive. And, again, if you look at the CDC code set, there is a large amount of specificity on tribal affiliation that is possible to express in the CDC code set.

So, I wonder whether the tribal affiliation proposed addition here really is a subset of a broader conversation on how we capture better and more detailed information on race and ethnicity and tribal affiliation within the context of a regulatory floor around the OMB conde set. So, the other examples might be what I think we saw in last year's wave of COVID, some significant targeting of outbreaks associated with, for example, Hispanic people in the Bay Area, and a better code set that allowed us to more finely distinguish race, ethnicity, cultural affiliation, and tribal affiliation would allow us to get faster at some of those areas. So, this is a placeholder for when we talk about some of those particular comments. I would like to have a conversation about the OMB code set, the broader CDC code set, and meaningful subsets that are related to capturing where the tribal affiliation conversation for USCDI V.3 sits with regard to that broader structuring. Thanks.

#### **Steven Lane**

Thank you, Arien. I want to be clear. Again, our task, which we are going to focusing in on during the homework, is going to be to collect workgroup members' input regarding whether any of these is inappropriate and should be stricken from V.3, as well as whether any of them need to be further clarified or modified before they are included in V.3. So, keep your comments focused in those two areas: Remove or modify, and if so, how. What I think we are going to be doing, AI, just to be clear, is putting up a Google doc that will give everybody the opportunity to submit their comments about remove or modify and how, and then it will invite you all to provide that input so that we can sort through it before next week and then go through it in a logical way.

#### Al Taylor

That is right, Steven. So, part of that "drop or modify" includes if there is a particular value set, so would the recommendation for tribal affiliation be the CDC's 900-plus race codes, or would it be some other set? HL7 weighs in on tribal affiliation and has a defined value set around that as well. So, do we align with that, do we align with the CDC, do we align with some other subset yet to be defined, do we move to actually constrain that to a particular one, do we develop and steward a value set around tribal affiliation? Those are some of the specific questions or answers that we would be looking to get.

#### Steven Lane

David?

#### **David McCallie**



Yeah, just a generic question on the value set axis. To what degree of value set specificity does the USCDI want us to achieve? I am just looking over the generic document over the weekend, and it will say things like, "The value set is LOINC 2.71," which, of course, is way too huge, or it might list half a dozen disability survey instruments, but it does not say which ones are included in USCDI and which ones are not. Is the expectation that it gets concrete enough to be implemented in code if somebody wanted to?

#### Al Taylor

It depends, David. We are pretty conservative about declaring what an appropriate value set would be. What we try to do is to constrain those recommendations on value sets to those where there is not unquestionable consensus on "This is the right value set." Occasionally, we have value sets that are encoded in regulation, and so, it is kind of a done deal. It has to be this set. Sometimes, it is a pretty clear delineation of what the best authoritative value set is, and sometimes it is up in the air, and sometimes there are differences between what one group uses as a value set and what other groups use as a value set.

And so, where there is widespread consensus, we typically will nail it down to a particular value set, but if there is another value set that we could use or should use, and an example from last year, where there were questions about what is meant by a clinical test, ONC actually defined its part there within the draft V.3 document. ONC actually wrote and stewards that value set to define at least a minimum set of terms that define the clinical test. So, where there are solid value sets, that would be the recommendation we are looking for.

#### **David McCallie**

But, I worry about the unintended consequences of "ors," where an implementer has to implement all possible value sets, even though you have not narrowed it down. So, by being vague, you increase the burden on interoperability, and is just too bad and we have to live with it, or could we try to narrow it down to a very specific value set when we can?

#### Al Taylor

Sure. That has benefit for implementers to be able to say, "Well, at least, what do we have to do at a minimum?" It does not mean that implementers cannot have a more expansive value set or have the capability of capturing the entire universe of LOINC codes or the entire universe of the CDC codes, but we have to test something. We have to test the abilities in systems to be able to do it, and by defining some sort of constrained value set, we can at least say we think that if you are doing the minimum value set, you are at least do something to meet that data standardization.

#### **Steven Lane**

And, let me clarify, David. I appreciate that you printed out and worked through the PDF document, but that does not have nearly the detail that we are going to want you to explore. At this point, you really need to go to the website and dig into each of these. What you will see on the first page when you select the data element is any value set applicable vocabulary standards that the ONC has included in their proposal. You can also then go to the submission itself, and the submission, which is in the words of the person who submitted it, has additional specification of applicable standards, et cetera. The ONC has added to those deeper pages their evaluation details and why they assessed it at the level that they did, but there is a little confusion, I think, still whether all of the supporting artifacts, if you will, or additional specifications or

applicable standards that were submitted by the submitter are also being embraced by ONC when they put it forward into a new version, and Al, I would actually ask you to clarify that. Can we assume that all of the specification in the submission is included in the inclusion in V.3, or not?

#### Al Taylor

So, the short answer is no, it is not a safe assumption. We evaluate the submission, including whatever standards were submitted, but we also have to aggregate that into the more common good, and sometimes, the value set associated with a particular use case may not serve enough of the community to be suitable for a USCDI data element, and so, we may need to dial the lens back, zoom out a little bit, and consider other things, whether it is other standards, like LOINC and SNOMED instead of just SNOMED, or instead of just one value set which only is applicable to the FHIR-based function to one that either includes the data required by C-CDA or just say there is a difference, so we are not going to say, we are going to let other people sort it out. So, no, it is not always according to the submission.

#### Steven Eichner

Al, this is lke. Just to interject really quickly, you raised a very good point, and my question is who are the consumers of the USCDI from a data element perspective or a data class perspective?

#### Al Taylor

Who are they? It is everybody who uses an EHR: Doctors, other providers, patients, consultants, sometimes payers, depending. Those are all the consumers of the data that is within USCDI, and actually, within the entire EHR system that is beyond USCDI.

#### Steven Eichner

Thanks.

#### Steven Lane

All right. I would like to get through the last two raised hands before public comment, so, Clem, you are up.

#### **Clem McDonald**

I have two things. In terms of the lab stuff, what has not been included is the interpretation code or the abnormal flag, which I think every physician looks at when they scan the reports to figure out which ones they have to concentrate on. It is way more important than really great deals about the specific instrument kit because most patients and users will not know what that is. I am not against the other one, but we ought to get that one on. And, the second thing, in regard to the answer to David, David always has good questions and issues, but I am not sure it is easier if you narrow it down. Personally, I think we really should get a single code for every survey because we can aggregate it better, but there is competition out there. I do not think that is going to happen in the next 10 years. Plus, if you say, "Here, pick what you have from this list," it may be easier than saying, "Do this." So, it is just a different perspective. But, I am glad the way USCDI is going because previously, we had, for example, no way to send specific tests or labs. Now, at least, we have something.

#### **David McCallie**

So, Clem, you want to have your cake and eat it too. Before, you were arguing we had too much diversity and that would impede interoperability, and now you are saying we should foster diversity.





No, no, I did not say to foster, I am recognizing we need to get people doing something so we get it done, and some of the stuff you have asked is very hard. There are probably 4,000 functional status instruments. I think we should work toward that, though. I am for you.

#### **David McCallie**

And, at some point, if US CORE is going to include the ability to pass this data through the API at some point when V.3 becomes part of the certification requirements, it is going to have to be specified in terms of specific value sets. It just has to be.

#### Steven Lane

So, to that point, David, and Hans, thank you for the private comment on this, one of the things we did last year as we worked through this process was we actually asked members of the task force to specify which of these data elements is already instantiated in C-CDA and/or US CORE, and Ricky Bloomfield, who is not with us this year, did a lot of work on that, as did Hans and, I believe, others, but we will try to do that again as we put together and evolve the docs that we will be presenting to you all to clarify which of these is already ready to go or needs more work done in US CORE and/or C-CDA because, as we have said, that may be part of the process, where we look back to HL7 and ask them to finish up implementation guides in time for the next SVAP version. Okay, Mark, you are up.

#### Mark Savage

Thanks. In light of Arien's comments about race and ethnicity, I wanted to quickly summarize a question that the Gravity Project is working on, which may be relevant to whether some of these V.3 elements need some modification. We are looking at race and ethnicity and whether we need to add to the value the source of the value and the method of collecting the value. There is a federal preference for self-reporting, and we have talked to people, we have found that sometimes those values get changed around. There is no indication if it is self-reported or not. Batch files can change them within the record.

So, we are exploring that with race and ethnicity, but we are also asking the broader question at the Gravity Project whether there are other data elements that that might be important to do with as well, such as sexual orientation/gender identity. So, ones in V.3 that might be relevant to that are some of the functional status, disability status, minimal function, and the health status element. Let me leave that as a summary since we are headed for public comment, but I just wanted to flag that in light of the comments about race and ethnicity. Thank you.

#### **Steven Lane**

You make a really important point, Mark. Our charge, again, just as a reminder, is to look at the items that have been included in draft V.3 and then look at other items from Level 2 that we might recommend be include in draft V.3. We have not been charged with going back or going beyond that to look at items that have already been included in USCDI and suggest adjustments to them or items that are leveled at Level 1 or comment and talking about those. We did some of that work last year, and I think it led us to some very interesting areas, but in terms of what we have been asked to do by and for the HITAC, it is very focused.



HITAC

But, it is a good reminder, Mark, that members of the public, including all of us, can go in and provide additional comment on items that are either already included in USCDI or are on the path towards potential future inclusion, and we can add that level of specificity or suggest changes to items that are already there, and those would also be considered by ONC, I believe, when they go to finalize Version 3 and to prepare for Version 4. Do I have that right, AI? Or, did I lose you?

#### Al Taylor

I am sorry, Steven, I missed your question.

#### **Steven Lane**

That is fine. Mark was talking about potential suggestions from Gravity for some of the demographic elements that are already included in Version 2, suggestions to upgrade or modify things that already exist. That is not the work of this workgroup, but it is something that any of our members could do as members of the public and submit those comments through the website, correct?

#### Al Taylor

Sure, absolutely. Anybody anytime can make comments about any of the previous elements, and the extent to which we can respond and maybe accept those recommendations is based on where that particular data element started. Some things we may be able to change; some things we may not be able to change.

#### Mark Savage

Steven, my point also was that may be a relevant question for some of the V.3 proposals under health status as well, and I will take a look at that, and others may have some thoughts about that as well. Thank you.

#### **Steven Lane**

Perfect. And again, I do not know if I could call on you, Grace. Last year, we considered some data elements that I submitted, and I ended up championing myself. You submitted one this year. Did you want to make any comment on the submission process or experience that you went through to get it to this point?

#### **Grace Cordovano**

So, it was a learning curve for me as someone new to the process, but Al was really wonderful and helpful, and the task force was very helpful in guiding me through it, going on through ONDEC, so, really taking a deeper dive into the USCDI website, looking and understanding what is at all of the different levels, Level 2, Level 1, comment, reading through the comments, absorbing what has been in the meetings, and then going through the ONDEC website, which also has a guide posted to help, step by step, walk the submitter through the process, submitting as much info as possible, and also, the ability to flag if you do need more support and try to connect with someone that may be able to help.

For example, I raised the fact that maybe a new person joining the group or wanting to submit may not know all of the different standards there, but to call that out in your submission, and maybe someone can follow up to patch that in, or at least to raise that flag, because I know as a newcomer, I had challenges in navigating ONDEC, and I did not want to leave things blank, but I also did not know where to look for the info. So, I think it has come to a great place, and I am pleased to see a lot of new submissions that will be really helpful to patients and their families included in here.





#### Steven Lane

That is wonderful. And, Michelle Schreiber, if I could call you out also, a number of these were submitted by folks at CMS, not by you individually, but can you say anything about the process that led CMS to make these proposals?

#### Michelle Schreiber

Thanks. We actually have an internal process to CMS to gather feedback from our stakeholders within the agency, but we also have an outreach where we talk among the federal partners, such as CDC, VA, and others, to see which are the areas that are most promoted, and we will be doing the same thing this year.

#### **Steven Lane**

And, Adi, same question to you regarding the CDC process. Obviously, CDC has brought a number of these items forward. Can you comment on the process of getting them here?

#### Adi Gundlapalli

Yes, absolutely. Thank you for the opportunity. So, we had an internal process where all our centers, which, as you know, we have 13 centers in Centers for Disease Control, were coordinated by my office and our supervisory office to look at these elements and then harmonize them, and then had a group of individuals go through these and try to help prioritize them. Obviously, everybody would have wanted everything to be prioritized, but we knew, and there were commonalities, so we were able to pick up those. And then, these are specifically for public health and those kinds of things. Thank you. Is that sufficient?

#### Steven Lane

That is great. I was just trying to provide the background so people understand all the work that goes into bringing these forward. It is pretty tremendous. Okay, I think this is a good time for us to transition to public comment, and again, I would strongly encourage any of you members of the public who are out there to raise your hand and be heard.

#### **Public Comment (01:22:23)**

#### Michael Berry

All right, thanks, Steven. If we could pull up the public comment slide, please. We are going to open up our meeting for public comments. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press \*9 to raise your hand, and when called upon, press \*6 to then unmute your line. Let's take a look and see if anyone has raised their hands. I do not see any raised hands, but we will monitor that over the next few minutes. In the meantime, I will turn it back to Steven and Arien.

#### Steven Lane

Wonderful. Arien, do you have any remarks you want to share as part of our closing?

#### **Arien Malec**

No, I am just glad that we appropriately situated the workgroup's work, and as you can see from the discussion, there is a lot of work to do, so we will dig into the juicy meat of USCDI in the weeks upcoming.

#### **Steven Lane**

Thank you. And, just as a reminder, we are going to have guests next week to talk about some of these items in particular from the Gender Harmony Project. That does not mean that we are going to be limited to that. We are going to try to keep that discussion contained within probably a half an hour of our 90 minutes together. And so, what we are going to strongly encourage you all to do is access the Google doc that we are hoping will get posted in the next day or so, which will give you the opportunity to focus on, as Al put it, drop or modify.

If there are any of these items that anybody feels should not be included in V.3, this is a great time to say that, and why, and modifications, and again, we encourage you to drill all the way in to each of these items, look at the submission, look at what was suggested by the submitter, as well as the evaluation that was made by the ONC team, which, again, is new, we have that this year, we asked for it, and we got it, as well as looking at the front page item to see which value sets ONC actually specified because as Al clarified, a lot may have been suggested by the submitter, but it is really at that front page for the individual data element that we see what ONC has specified for it. Al, do you have anything else you want to add?

#### Al Taylor

No. Thanks, Steven. I think you covered it all.

#### **Steven Lane**

Perfect. Grace?

#### **Grace Cordovano**

I just wanted to add I thought it was very interesting to hear that even the CDC and CMS have internal processes and groups to gather comments and feedback, and that is a very structured, well-supported format, and that patients, care partners, and general consumers may not have that level of support, so I want to encourage that we have our contact information available. I am not sure if there are ways to publicly post the emails of the workbook or if there is an email here to make that more forward-facing so if people do need support with submissions, they know exactly where to reach out to.

#### **Steven Lane**

Al, I think Grace is reflecting a lot of the feedback that we provided last year to ONC about how to make the process more accessible, more supported, especially for those who are not doing this for a living, and at some point, it might be nice to hear back from you what are the changes that have been made, that are being planned for the submission and review process. I am not saying we need to do that right away, but because there was a lot of feedback given on that last year.

#### **Al Taylor**

Sure. It sounds like probably a good spot for that would be right before or right after we issue USCDI V.3, which sort of kicks off the V.4 submission high season.

#### Steven Lane

That sounds great. Any other comments that we brought in from the public? No? Okay.

#### **Michael Berry**



I do not see any comments.

#### Steven Lane

Thank you, Mike. Anything else from workgroup members? Well, we will end a few seconds early. Again, I want to thank all of you for your time and attention today. Great discussion, and we really look forward to you doing your homework and us being able to leverage that input when we meet in another week.

#### **Arien Malec**

Thanks all.

#### **Steven Lane**

Bye-bye.

#### Al Taylor

Thanks so much. Bye.

Adjourn (01:26:54)