



Transcript

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

May 25, 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

Thank you very much, and good morning, everybody, and welcome back to the USCDI Task Force. Our task force members and co-chairs have been super busy again over the past week. Anyways, we thank you for joining us today. I am going to open up the meeting with roll call, and I will start with our co-chairs. Steven Lane?

Steven Lane

Good morning.

Michael Berry

Leslie Kelly Hall?

Leslie Kelly Hall

Good morning.

Michael Berry

Ricky Bloomfield?

Ricky Bloomfield

Good morning.

Michael Berry

Hans Buitendijk?

Hans Buitendijk

Good morning.

Michael Berry

Grace Cordovano?

Grace Cordovano

Good morning.

Michael Berry

Jim Jirjis?

Jim Jirjis

Good morning.

Michael Berry





Ken Kawamoto? John Kilbourne?

John Kilbourne

Good morning.

Michael Berry

Les Lenert? Clem McDonald? Aaron Miri? Brett Oliver?

Brett Oliver

Good morning.

Michael Berry

Mark Savage?

Mark Savage

Good morning.

Michael Berry

Michelle Schreiber?

Michelle Schreiber

Good morning.

Michael Berry

Abby Sears? Sasha TerMaat?

Abby Sears

Good morning. Sorry about that.

Michael Berry

Good morning. Sasha TerMaat?

Sasha TerMaat

This is Sasha. Hello.

Michael Berry

Hello. Andrew Truscott? Sheryl Turney?

Sheryl Turney

Good morning.

Michael Berry

Dan Vreeman?

Steven Lane





Sheryl is here twice.

Michael Berry

Oh, sorry. Dan Vreeman? And, Denise Webb?

Denise Webb

Good morning.

Michael Berry

Good morning, Denise. Thank you very much, and I will turn it over to our co-chairs, Steven and Leslie.

Past Meeting Notes (00:01:42)

Steven Lane

Thank you so much, Mike, and thank you, everyone, for all of the great work that you have been doing providing input in the documents, emails, and conversations. I was actually out of pocket about half of last week. I excitedly got to go watch my daughter graduate from medical school, which was really wonderful, and Leslie and others really carried the water, and Leslie and I burned a little midnight oil last night and tried to pull everything together.

So, we went through our Google doc and resolved the vast majority of the comments that people put in there and incorporating that, and our goal today is to go through and see if we can come to some consensus about the recommendations and some of the commentary that we have captured there in anticipation of preparing our comments for the next HITAC meeting. We have also gone through the notes in the last two meetings, and I think AI is doing a final polishing of those before those get posted. I anticipate those to be posted later today. Leslie, do you have anything else you want to add by way of intro?

Leslie Kelly Hall

No, I think we have a lot of work to do, so let's get going.

Finalize 2a, 2b, 2c Recommendations (00:03:06)

Steven Lane

Terrific, okay. So, just as a reminder, we have this week, and potentially next week if we need it, to finalize our recommendations with regard to Task 2 to then transmit to the HITAC. This is the Task 2 that is before us: Reviewing the ONDEC submission system and the suggested improvements, reviewing the evaluation criteria and process used to assign submissions to levels within the ONDEC system, and then, the prioritization process used to select new data items for draft of the next version, and of course, we have sort of expanded the scope of 2C to talk about prioritization within all of the levels or each of the levels to identify items of highest priority.

And then, once we finalize our recommendations to HITAC for June 9, I think we can take a little bit of a break. We will look at the calendar because we have, then, until the end of the summer or the end of August to put together our recommendations around Version 3 priorities. So, any question about why we are here or what we are up to? Hearing none and seeing no hands raised, we will power on.





So, I would suggest, if we can, AI, to go ahead and bring up the Google doc just to reorient people. The doc has been cleaned up a bit. I want to back up just a little bit, AI, so that we can see all four columns. This doc has four columns. The first one focuses on our Task 2A and the recommendations for improvement to the ONDEC system. We went through those pretty thoroughly last meeting, I think finalizing and approving the ones that we had there, and then, AI has started to draft our recommendations document for the HITAC, and he put little check marks next to the ones that he had captured. Leslie and I did not hear about any further suggestions or changes to those, so I think those are pretty well mailed at this point.

There was one comment, which I think came from Mark, that... I lost the comment...which is because I incorporated it. That is why. Mark suggested that submitters could potentially sign up for email alerts when comments were received on their submission. I actually get email alerts when things are done to my submission, but I do not think it is so much when comments are submitted as when ONC has issues with it. I cannot remember. AI, can you comment on the email functionality within ONDEC and how it alerts submitters to comments and/or changes?

AI Taylor

Sure. Not only do you get the emails around your submission itself, but when comments are put on that page that is then published, if you have put in a submission, and we publish it, and somebody comes in on that particular data element and comments on it, you do get an email notification. If somebody were... So, take Mark's example with the SDOH submissions from Gravity. A lot of the comments that came in came in on the USCDI main page and not on his individual submission pages, and so, he may not have gotten all of the notifications, but the system is designed to notify you of comments or additional information posted to that particular submitted data element.

Steven Lane

Actually, now, I did find Mark's comment. It was resolved. You have to scroll down to the bottom of this to see it. It was a comment on our recommendation to allow a submitter to easily see when others have submitted the same or similar element.

AI Taylor

Which column? Are we talking about Column A?

Steven Lane

Column 1, down near the bottom, in the section called "Data class elements," and Mark's comment was "Could this include signing up for email alerts?" So, email alerts for when a submitter submits a same or similar element. So, if nobody objects, I will add Mark's suggestion here, and I will put it in bold, AI, so that you can find it to incorporate it into the recommendation.

AI Taylor

I have it on the screen. Are you guys seeing that?

Steven Lane

Yeah, you do. You absolutely do.

Leslie Kelly Hall





And then, Steven, up above in this column, we also have a bold comment from last time.

Steven Lane

Yeah, we will go back to that. I wanted to cover this one first.

Leslie Kelly Hall

Okay.

Steven Lane

So, just in terms of Mark's comment here, does anybody have any objection to these changes I am suggesting in bold? Go down a little bit, AI. Go back down to where we were, to the data class element section. There it is, okay. So, just adding that based on Mark's suggestion. All good? Thumbs up? Terrific, thank you. All right, then. Let's scroll back up.

There is another bold comment. This actually came from a comment. I forget whose it was, sorry, but it was a suggestion that as part of the periodic review of ONDEC, ONC should identify gaps in the current USCDI and encourage or support submissions by stakeholders to close them, and I think this is an acknowledgement of the fact that ONC does this and has identified gaps, at least in our first cycle, but poor AI had to submissions for closing those gaps, or he asked me, in the case of my submissions, to do one more because they had identified a gap. So, in general, I think this is a good practice, and in general, I think it would be better to have community stakeholders make the submissions as opposed to ONC making them themselves, so, I am proposing this as an add to our Task 1A. Any objections? Are you good with that, AI?

AI Taylor

Sure.

Steven Lane

Okay, good. And then, at the very bottom of this same column, AI added some clarification in yellow text about the link embedding, and I think we talked about that last time. So, I think Column 1, which is our Task 2A recommendations, is done, and I am hoping we will leave that there and move on, all right? Any objections?

AI Taylor

Steven, before we do, I just wanted to ask. The reason I put this comment in there is to suggest we consider not advancing that particular recommendation because it is part of...

Steven Lane

Ah, because it is not needed.

AI Taylor

Yeah.

Steven Lane

Okay. Do you mean the "embedded links" piece, not the "patient stories" piece?





Al Taylor

Yeah.

Steven Lane

Good. I am good with that. Let's get rid of that text right there about the embedded links. Going, going, gone. Okay. Thank you, Al. So, back to the top of the spreadsheet, reminding everyone that we have four columns: Three for our Tasks 2A, B, and C, and one for Task 3. We did move some things over into the rightmost column for Task 3, figuring that we would have plenty of time to address that. I think our goal in trying to get Task 2 done and in early was primarily to be able to impact the publication that Al and the team are preparing for July, when they actually publish the final Version 2 as well as the guidance for the Version 3 submission cycle, which will include an articulation of any changes to the evaluation and prioritization criteria, and they may or may not have time to instantiate our Task 2A recommendations. Some of these are process changes, but I think that getting these recommendations in now is a good thing.

So, in the absence of comments or hands raised, we will move on to Column 2, Task 2B, and try to get through that. Leslie and I made a number of minor changes, which are in bold for our attention, and what I would like to do is go through Column 2 and see if we can reach consensus on all this. We made a first pass at this last time, but again, some changes.

So, at the top, really diving right into the meat of the matter here, we have been talking a lot about majority versus minority use cases, and Al clarified for us that ONC's intention in their previously published leveling criteria was really to keep USCDI focused on use cases that apply to the majority of patients and the majority of users of systems, the thought being that the USCDI, of course, is something that we point to, it goes into SVAP, and then into the certification process, so every certified health IT system needs to be able to manage this data, and if we require every small certified EHR to manage data related to rare or specialized use cases, we run the risk of slowing down EHR development, distracting developers, and forcing them to build things that are not what their users are asking for.

If you are providing an EHR to a small office practice, having detailed data fields to support transplant use cases is probably not what you need, and if we create those in USCDI and move them on to SVAP and certification, that potentially does a disservice to our industry and the users of health IT products, and yet, we are very interested in supporting the disenfranchised and supporting minority use cases when and where we can.

So, this is how Leslie and I propose to tackle this idea. "ONC should support minority use cases where possible. When considering minority use cases, evaluation should include identification of where the use case can be supported within existing or compatible mature data elements and classes and provide direction to stakeholders to support implementation and use. For example, specifying what note type should be used for exchanging coroner's reports, organ transplant harvest reports, et cetera."

So, the idea here is not to completely ignore minority uses or minority stakeholders, but rather to identify and highlight their needs and see if we can provide guidance to developers, implementers, and users that would help them to be able to use the tools that are appropriately in USCDI to support their needs. I know it is a small gesture, perhaps, and not the same as saying USCDI is going to be a whole new thing, but I





think it is a way to get at what I think a lot of us have been struggling with. So, I want to throw that open to discussion.

Leslie Kelly Hall

I think the big point that this came from was Clem pushing us to say, “Wait a minute, there is some low-hanging fruit, and where it is appropriate to repurpose, especially for minority use cases, let’s look at that.” So, this gives a mechanism to make sure that those on the fringe are not going to be forever on the fringe. Sasha has her hand up. Sasha?

Sasha TerMaat

Thanks. So, it was really helpful, Steven, when you outlined some of the commentary or concepts behind this recommendation. I did not glean that from reading over it, and in fact, I have some of the concerns that I think your commentary [inaudible] [00:16:32] around how it would be handled in certification [inaudible] that were not intended for that use case. Could we put some of the commentary and background into this or below it for reference so that we know that this is with the framing statement that USCDI has intended to be a general use case that would be supported in every EHR, and then, the recommendation on existing and compatible standards is intended to not impose specialty product requirements on every EHR?

Steven Lane

Sure. And, Sasha, you did include a nice comment on this one. I will just pull it over here so people can see it without us having to scroll over. Do you want to say anything more about this?

Sasha TerMaat

Sure. So, I think my fear is just that the certification process today is all or nothing, and I do not want to see there be a situation where a dermatology EHR or a nephrology EHR has other requirements that they look at and say, “Wow, now there is stuff in USCDI that is really not applicable to my users’ use case, and I cannot achieve certification, or I have to invest in a lot of features that are not applicable to my clients,” and it seems like either we will need to specify domains for certifications, when certain things are and are not applicable, like we do today on hospital versus ambulatory data requirements in some cases, or we would need the contents that you gave verbally to say that USCDI is intended to be broadly applicable, required for every product, and that we are picking things with that mindset, if that makes sense.

Steven Lane

So, I know that there is a counterargument coming. Come on, Mark. Do you want to let Hans in first, or do you want to jump in here?

Leslie Kelly Hall

Before that, I would also like to add that we are also talking about the cadence of what “in” means in the USCDI. So, you have ONDEC, comment phase, Level 1, Level 2, task force recommendation, draft, and final, and that process can drive new work in maturity of a particular standard. So, the ONDEC is that nest and the incubation period is quite long, so, with the kind of direction that this might indicate, we have a chance to have the stars align with the standards and the minority use cases, but to try to go to the low-hanging fruit first. Hans has a comment, too.

Sasha TerMaat





I do not know, Leslie. I think it depends on the use case. In some cases, the foreshadowing that ONDEC supplies might be helpful, but in other cases, I think there are going to be fundamentally data elements that certain systems do not need to capture. They might still need to be able to view them when other systems send them along, but I do think there will be some where we are just going to say, “This is never going to be the priority for that system.”

Leslie Kelly Hall

I think you are right, and I think the emphasis is on interoperability and viewability rather than collection.

Sasha TerMaat

Maybe we need to specify that because that is not how certification is today. Today’s certification says for anything in USCDI, every product has to capture, send, and view.

Leslie Kelly Hall

Yes.

Steven Lane

Hans, your hand is up.

Hans Buitendijk

Yes. I want to build on that a little bit further and react to a comment Leslie made, maybe starting with that one. I completely agree that when we use the term “USCDI,” it is not always clear which part we are talking about in the process or in the publication, so wherever possible, we can say that should it be in USCDI, most of the time we are going to be talking about something that is in a publication at some point in time, but it does not mean that it could not be in the process with different variations in criteria and otherwise, so I think that is very important to keep in mind.

The first line that you are modifying here is currently how the USCDI is being presented, and as Sasha describes, has been implied. To be certified, you must support all of USCDI. I think part of this is that we want to clarify and recognize that that is what it is today, but we think it needs to be more stratified. I think we have had conversations earlier around stratification as well. Do all dual systems need to support everything of USCDI in certain forms? So, if we are saying that our intent is to be broadly applicable to all EHRs, we would probably mean HIT because it goes beyond EHRs as USCDI is being defined. The second part is that I think we want to acknowledge that that is what it is today, but we do not necessarily want to say that is what it should be long-term. So, I think the impression that this is giving is too strongly that we suggest that it should stay that way. I think that would be more accurate because I think it flows better with the rest that we would like to recognize that you cannot do that if we move forward and it gets bigger. You cannot ask everybody to support all of USCDI.

Steven Lane

Abby?

Abby Sears

Yeah. This feels a little... Do we have an example of a data element that we think would not work for what we are actually saying? Is there an example, or are we speaking about the hypothetical? Because if there





is an example, I would love to pull that thread and see if it does or does not work because as I think about the types of data elements that we would be interested in around equity issues, which is a lot of what we are talking about here and why I am really asking for a different process to go a little bit faster... Whether you are a nephrologist, an endocrinologist, or in long-term care, you are going to want those data elements because you are going to want to be able to sort, do research, and understand based off social determinants of health if the care is actually different. So, I guess I am looking for an example of a use case where you think this will not work because otherwise, I am not sure I see the point of view, but I want to hear it. I just need to understand if you could give me an example because otherwise, I am just not seeing it.

Steven Lane

I will take a stab. I am not sure I fully understand your question, but I think this transplant example is a good one. A couple years ago, with the leaders of the prior of the USCDI Task Force, I met with representatives of the transplant community, and they were preparing requests for key data elements that they feel would be helpful to support their very important use case of identifying patients who are in a position to transplant an organ, identify those who need the organ, connect the dots, and make that all happen very quickly.

Clearly, I do not have their request in front of me, but I imagine there is a data field that says, "Patient is brain dead and their organs are available for harvest." Let's just say there is. That is a pretty minority use case, and not one that your average small-office-practice EHR necessarily needs to support the access, exchange, and use of that data element, but as we noted here, an organ transplant harvest report is probably somewhere in their recommendations or requests, and that could fit into a notes field that is applicable, and we have had these conversations before. We have talked about coroner's reports. We should be able to move around coroner's reports. Well, yeah, you can, you just have to know where to put it, and if ONC could provide that guidance, then everyone could say, "Okay, we are not going to have a special data element for coroner's reports, we are not going to have a special note type, we are not going to ask LOINC to provide it, but here is where it fits to support this relatively rare use case." I do not know if that gets at your question.

Abby Sears

Yeah, it actually did, and both Hans and Sasha gave examples, and that is what I needed to see. So, the suggestion that I put in the chat was what if we narrowed this? Maybe I am misreading this, but a lot of this is about some of the concern around some of the equity issues, as I recall from the last task force meetings, and if that is the case, then maybe we narrow the language...

Leslie Kelly Hall

It is also any minority use case.

Abby Sears

Right.

Leslie Kelly Hall

It is any minority use case. It could be data-underserved, it could be medically underserved, it could be a complex and unique case, or a small population with a high mortality rate when the data is not there. It is any smaller use case, as Steven explained.





Abby Sears

Well, then, I wonder if we narrowed the language so that it does not hit on what Sasha and Hans are saying. I wonder if that would actually help alleviate some of the concerns because I see the point now.

Leslie Kelly Hall

So, the recommendation that Hans has just put in the chat is that USCDI should enable stratification of data class elements where not all HIT needs to support a certain aspect, so that gets to the balance. How do you balance this need?

Steven Lane

And, Hans, you are suggesting that that goes in the commentary as opposed to the suggestion, or in the suggestion?

Hans Buitendijk

I think it is ultimately a recommendation that we need to look for stratification, and I am not sure that we have the answer on how best to do it, but we need to start to look at enabling that so there is more clarity on what the expectations are.

Al Taylor

Hans, this is Al. Can I [inaudible – crosstalk] [00:27:51] about that recommendation? Regarding stratification, are you asking for the recommendation to allow partial adoption of a USCDI version?

Hans Buitendijk

Correct. In other words, you have HIT that supports this. If you look particularly at the larger organizations that have HIT, you will see that it is typically made up of multiple systems from different parties providing more specialized capabilities. Each of those systems is serving a subset of the data that is relevant and that we are going to be looking at today or tomorrow, and therefore, asking every one of those HIT to effectively be able to support everything is not helpful. On the other hand, for what they do support, where they do focus, that is where they should support and that is where we expect them to support the data in line with how the USCDI and the supporting standards do it. It is a matter of HIT is not a monolithic thing. It is a very configurable environment, each one playing their part to their strength, part of the data, and that is what we are trying to achieve so that USCDI is not assumed to be done by everybody because that overlaps unnecessarily. But, where they do, please support standards.

Steven Lane

So, if you scroll up a little bit, Al, you can see how I have tried to capture this in a softened way. “ONC should explore how USCDI could enable stratification of data classes/elements so that not all certified HIT products need to support data classes.” I think that is what you are saying, Hans. We are not going to be able to nail this in this cycle, but I think putting this out as a desirable future direction.

Hans Buitendijk

Perhaps if you change the word “needs” to “is required...”

Al Taylor





And, I think, to capture Hans's intent, I would suggest changing the word "certain" to "all." Correct me if I am wrong, Hans, but I think that would capture your intent.

Hans Buitendijk

Correct, yes.

Steven Lane

Denise? A lot of hands are going up and coming down. I am impressed by that dynamic. Hold on just a sec, Mark. Denise, do you want to chime in?

Denise Webb

Yes. I just want to say I concur with Hans. I fully endorse what he is suggesting. I really think from a provider organization perspective that when a provider organization is trying to find products that meet needs and that are interoperable, having those stratifications would be really helpful because we do not just buy one monolithic system that is going to support all of USCDI. There are parts and pieces that work together depending on what the specialization is, and so, I fully endorse that suggestion.

Steven Lane

Mark, did you want to chime in?

Mark Savage

I just dropped it in the box. I am suggesting adding after "support all data" to say "support all data where not needed." In other words, this is a focused recommendation, not a general statement that we are now slicing and dicing USCDI.

Steven Lane

Okay. I tried to capture that. No hands up. I will take that as consensus, and we will go down to lower in the second column, and AI, you can zoom in a little bit just to make this a little bit more readable to folks on the screen. Let's just keep the first three columns, maybe. Okay. So, under "periodic review," we just made some tweaks based on our discussion. It now reads, "ONC should review all items submitted to ONDEC annually, or preferably semiannually, to validate current level and priority based on the latest information regarding maturity, submitted comments, and current criteria." I do not think that is a substantive change, but hopefully some clearer language. "Periodic review of ONDEC should identify opportunities for advancement of data classes and elements between levels." To me, that went without saying, but somebody said it, so we included that.

And, that was the only other change that we put into Column 2 based on the comments and feedback that we had received. Anyone have any problem with that? If not, AI, I think Column 2, representing our Task 2B recommendations, is ready to go. Again, my goal here is for us not to have to meet next week and for Leslie and me to spend the time with AI working on the final recommendations or drafting the recommendations and slides for our review the subsequent week.

So, moving on to Column 3 for Task 2C, we can probably zoom in a little bit more to make it more readable. So, I think here, again, we are going into the meat of the hamburger we are trying to make of the discussions that we have been having, so I will just read this aloud so it can sink in for people. "When prioritizing items





within levels,” not just only within Level 2, “ONC should separately access technical maturity, for example, based on the existence of vocabulary, semantic standards, structural syntax standards, implementation guides, testing, implementation, and use, and priority, for example, based on mitigating health inequities or disparities, responding to the needs of underserved stakeholders, and addressing public health and other identified priority use cases.”

So, this is a long sentence which attempts to capture a lot of discussion about how we, as a task force, differentiate maturity and priority in our minds. So, I want to pause here and give people a chance to respond. We have included some commentary below, which came from a number of you. The first one: “Maturity, content, and transport is a basic, very important factor, and the task force agrees with the ONC maturity levels to clearly assess and identify a data class element’s maturity at the time it is added to a published USCDI version.”

“Other priorities are important as well, and they, too, should be considered and balanced along with maturity in assessing overall whether a data class or element should be added to USCDI.” And, to differentiate this “What is USCDI?”, I am going to add some extra words to “a published version of USCDI” because, again, I think one of the things we are going to get at which we will get down to here is the idea that there should be different criteria for putting something in a draft version of USCDI, which is meant to stimulate discussion and activity within the industry, as opposed to putting it into a final published version of USCDI, which is intended to go on to SVAP and certification requirements. And then, inclusion of immature... Sorry, hands up, thanks.

Leslie Kelly Hall

Hands up. Michelle, and then Mark. Michelle?

Michelle Schreiber

Hi, thanks, Steven. I did not know if you were going to keep going through this stuff, but I just wanted to support this use case of having both prioritization for technical and the **[inaudible] [00:37:02]**. I think if we had not done that, for example, this time around, maybe some of the social and demographic stuff was not quite ready in terms of technical maturity, but it is such a high priority for the country that I think we need to be pushing some of those things, and other things will come up. Things have been needed for COVID, things may be needed in the future, and so, I just think that it is really important to separate both of them so that we always have high-priority items. By the way, sometimes it is only by putting them on the formally published USCDI that actually gets organizations to comply. We see this time and time again in CMS, where really, people do not necessarily actually make the investment until there is a formal regulation that says you have to do it, and I am sorry to say that, but that is just the way it works, and so, I think both of these have to be in place, so I just want to be supportive for having both.

Steven Lane

Thanks for those comments, Michelle, and I think really, the key is that we are trying to thread a needle here. We are trying to describe a balanced approach that we encourage ONC to take that takes all of this into account. I think drawing a bright line is not what we are trying to do here. Mark, go ahead.

Mark Savage





Thanks. I dropped my thought in the chat. I think the spirit of the recommendation is broader than just within levels, so I just made that point.

Steven Lane

Leslie, since I am not monitoring the chat as thoroughly as I can, if you are finding text in there that you think needs to be copied and pasted into the document, please do so, and then bring that to our attention so we can discuss it. I want to go on in the commentary, which is to say, we have received feedback that inclusion of immature or incompletely specified data classes or elements in USCDI can have multiple effects, and then, there were a few examples provided.

If there is poor specification, then the certification and SVAP process can limit and slow the ability iterate from a poor specification to a better specification because developers and users get locked into something that was put in before it was fully baked. If there is no specification at all, then that can cause implementers to delay adopting that version of USCDI, either through the SVAP or when they are required to for certification, and here, again, potentially put brakes on the industry and its overall advancement, and if there is no specification, different implementers can approach this in varied ways.

We certainly see this all the time, and even though messages may be flowing, the goal of semantic interoperability is not met, so I think these were some thoughts as to why holding out for more complete and mature technical specification is advantageous, but obviously, as we keep trying to emphasize, that needs to be balanced, and I think, Michelle, you made a really good point that there are folks, probably both in the implementer or HIT community and in the user community, that simply will not bother to do something until they are absolutely required to, so that makes the argument for sometimes putting things in that are going to be challenging for some.

Mark Savage

Steven, is this a recommendation? I do not see this as an actual recommendation. It seems like more of a comment.

Steven Lane

So, the recommendation is more at the top. The commentary follows in italics. So, scroll back up to the recommendation, and this has to do with just capturing all of our extensive discussion about technical maturity and differentiating it from priority, and let's keep going here. I am not sure that we have called out clearly enough that what we want is for ONC to identify these priority items within each level, and I think we say that when prioritizing items within levels, ONC should assess these things independently. I guess what I still think we may need here is this notion of an asterisk, that this item within this level has been identified as a priority item for any number of reasons, and therefore called up. I actually think that we captured that.

So, let's keep going down through Column 3, and I do not think we did these in detail last time, so I would like to continue on as we are, one by one, even though they are not in bold. "Items that are identified as high-priority but have insufficient technical maturity for inclusion in USCDI should be communicated to the standards community for expedited work and to stakeholders for consideration for pilot use and iterative deployment independent of inclusion in SVAP or requirement by the certification process." I think this is what I was just getting at, this notion that these priority items need to be flagged, informing the industry that they need love, and that we want them to move forward. Now, if it is in Level 2, that means we want them





to be included in the next version. If they are down in comment or Level 1, that means get to work and mature this so that at the next periodic review, we can move them to the next level. No hands up? I can see Mark's wheels spinning, so we will just keep going.

"Clarify that a published draft USCDI version may include classes/elements that may not be quite ready for inclusion in the next published version, and that would be included if certain criteria or met, for example, final publication of an implementation guide, prior to advancement to the next version. Those items that are not able to advance should be carried forward for potential inclusion in the subsequent version." So, here, again, this is trying to capture this concept that we have different criteria for putting something in a draft than in a final published version, that the draft really can be used to be aspirational to trigger the kinds of discussions that we saw and we sponsored between HL7 and ONC, and that this should be an intended part of the process. I am feeling really good about our work, Leslie. Nobody is raising their hands to complain. Maybe the bomb is coming under my bus here.

Going on: "Advancement to a final published version of USCDI requires a minimum degree of technical maturity readiness." Again, we are not drawing a bright line. "In particular, published implementation guides are important for scalable national deployment of a concept..." I think that says "...data element or class." So, we are really throwing our weight behind the need for implementation guides. And, did Ricky end up joining us? He did? Are you following, Ricky? Do you like this?

Ricky Bloomfield

Yes, that looks good. Sorry, I was muted.

Steven Lane

It is all good, thank you. I just want to expand the dialogue here. "Clarify that the requirement for a data class element within ONC certification and/or a CMS initiative is not an absolute requirement for inclusion in USCDI." This gets to a thorny point that Hans has been raising, which we will get to as soon as I read the last bullet here. "Continue to identify and prioritize data elements that are generated automatically and/or collected and exist routinely within HIT systems." This is Clem's ongoing point that we should not be stingy, and that things that are easy should be included when appropriate. So, this is about identifying and prioritizing those. So, Hans, maybe this is a good time for that second to last bullet, the whole issue of what happens if we include an element in USCDI and how that could have a potential impact on developers of certified HIT and their ability to embrace an SVAP and be able to continue to keep their systems certified. Do you want to lay out the challenge as you see it, Hans?

Hans Buitendijk

Sure, and before we go back and forth with Sasha on this to make sure we caught it, the challenge is that you have to go back from what certified software is supposed to adhere to and how that interplays between the certification rule, what is in there, and what is in SVAP, the annual enhancement that can increase the version of a standard that is referenced in the certification rule. So, it is that interplay that happens there, so it gets a little bit complicated, and we are all still trying to learn how it all works, but in the end, what we think and understand and how we see it in full right now is that if you have USCDI that starts to include data for which the supporting standards that might exist somewhere, but are not in regulations yet, then SVAP cannot technically pick them up right now. That means we have to be very careful that USCDI might have some standards, but they are not eligible for SVAP.





So, how do we deal with that? What is the clarification for it? But, the thing is that as part of SVAP, we need to adopt that, we need to take that on, and we need to have a variety of things there, so we are not sure if that is a standard that is going to be recognized or if there are different variations of it, so we just have to be very careful that USCDI cannot move too far ahead of what SVAP is really allowed to do, while when you get to certification, it can do a lot more because at that point in time, when you upgrade certification, new standards and new things can come into play that SVAP cannot do, so that is where we are trying to figure out and understand how much USCDI can be ahead where it is relying on certain capabilities that SVAP cannot do, but that are then causing certification challenges on how we do that because to certify, we need to do that and support USCDI with the existing standards that are there. That is what the requirement is right now.

So, that either requires a lot of clarification by ONC on how that would play, or we just need to make sure whatever we do with USCDI, while we are still in an SVAP-only cycle, not certification, large optic, what can we do to make sure that we keep that in sync? That is really where the problem on this point spins around, and Sasha, you might have a couple of other examples around that.

Sasha TerMaat

I agree, Hans, and I do think maybe an example might help folks who are not as far into the certification and SVAP weeds as we are. This is a totally hypothetical example, but let's say we wanted to add a data class like occupation, and the standards for expressing data class that have the requisite public implementation guides, maturity, and so forth are for FHIR Version 5. If FHIR Version 5 is not itself in certification, which it is not today, then there is no SVAP process that could incorporate that and that standard into USCDI certification, and we would have to wait until the prerequisite underlying standard of FHIR Version 5 was incorporated into certification before it could have that USCDI dependency. So, what we are saying here is we are either constrained by the certification standards to pick things that are expressible in CCD A 2.1 or FHIR R4, or we need to advance the underlying certification standards until or prior to achieving additional data elements. Does that example maybe help illustrate the problem Hans has brought up?

Al Taylor

Sasha, this is Al. I think having an example is good, but I am a little uncertain about how valid that particular example is because the content of USCDI is going to be a vocabulary standard, not an exchange standard, and so, with the example of work information, there is an existing new data standard called "occupational data for health." It has a FHIR standard. I do not know if it is going to be a FHIR 5 or 4 standard, but that is the exchange standard. The underlying vocabulary standard for occupational data for health is just that, a vocabulary standard, and that vocabulary standard is not something that would need to go through SVAP.

Hans Buitendijk

The question, then, Al, is that if USCDI is vocabulary, but in the rules for supporting SVAP and USCDI, the other standards, such as CCD A and FHIR US Core, are being referenced, then at that point in time, we still end up being required to use those two standards today to support all of USCDI. So, it is a combination of stratification that helps because that could clarify where some things are not. There might be times that maybe it is CCD A, if you can do that, or FHIR US Core. They are not necessarily all in sync at all times. It starts to just make it very complicated to understand. Our certification requirement is to support USCDI with





CCDA Version 2.1 plus companion guide, and with FHIR US Core. That is the requirement from a certification perspective. So, it might not be in USCDI, but effectively, SVAP is going to tie it all together.

Leslie Kelly Hall

So, Hans, we had in the recommendation in Task 3, which is not up there, that we wanted to clarify the relationship between USCDI, designated record set, EHI, SVAP, info blocking, and recommendations for standards to achieve interoperability and access with an emphasis on achieving data parity for all. Also, it is not just the relationship, but it is the uneven cadence of each. These structures do not necessarily have an aligned cadence, and that brings confusion in itself.

Hans Buitendijk

Correct, because that makes these kinds of relationships [inaudible – crosstalk] [00:53:32].

Leslie Kelly Hall

Okay. So, I am going to include that idea of cadence in where we are asking for guidance under Task 3, and then, Steven, let's continue on with the 2C column.

Steven Lane

Yeah, and the red text that I brought over from the Task 3 column was my way of thinking about this. I have to admit that I do not completely follow the issue that Hans and Sasha are raising. I think I get it at a superficial level. I want to be sure, though, AI, that you understand it because it is clearly important to them. They are the ones who are here representing vendors and developers of certified HIT who have had to go through the certification process, so I think the fact that they are both clearly concerned about this issue means, to me at least, that it is a real issue that needs to be addressed. So, AI, do you feel that you get it, and Sasha and Hans, do you feel that AI gets it, and do you think that we have captured this sufficiently in our recommendation, or is there still a gap here?

Hans Buitendijk

I think we collectively are all still trying to get it exactly, and we see some things there that we are concerned about based on past experience, what we have seen over the last 10 years with meaningful use promoting interoperability. I think there is more conversation needed to help clarify, so I think the key of the recommendation should be that, as Leslie was also pointing back to in the other part, we really need to work on that clarification, how it is all tied together, and how it works so we really understand that we need to push USCDI forward, but we cannot do it too slowly and exclude things that would be easy things to put in. We also cannot exclude too much because then, that is going to make it much more difficult to get adoption in the timeline that we all think can happen because of the ramifications of what is needed to actually make it happen from a certification/SVAP/adoption of standards perspective. So, it is a very intricate balance that we are trying to strike here that we want to nudge along and push along as fast as we can.

AI Taylor

So, the way that I see this, to make sure people understand that I think I get it, at least, is that there are two parts to this. The process that we use to add a data element to USCDI is based on the feasibility of implementation in CCDA and US Core. That is the homework that we do to make sure that what we are going to put in or are thinking about putting in can be implemented in these exchange standards. That is one piece of it. I think the SVAP is a little bit of a different piece, and I cannot come up with an example,





but I think hypothetically, we could create a version of USCDI that has some new data elements in it that the community, through the SVAP comment process, feels like makes USCDI Version X unimplementable, and therefore should not be SVAP. Those two pieces of that could be related, but our diligence in adding a new data element that could be implemented should take care of the comments during the SVAP comment process, but I understand the point of view that a new data element should be implementable, period, and that is our concern, as it is with you. So, we get that, and so, that might be... I do not know if the way I explained it is helpful to frame a recommendation or not.

Ricky Bloomfield

I share some of the questions here as well because I had always understood SVAP to be orthogonal to USCDI, and I feel like we are conflating a little bit by referring to USCDI versions, where I do not think SVAP was intended to talk about USCDI versions. I just pulled up the ONC page here. It really specifically talks about the fact that it enables health IT developers to voluntarily use a more advanced version of the standard for implementation specifications, not anything related to USCDI or USCDI version, which I think is a very different thing, and so, I feel like that point is still a little muddy here.

Al Taylor

So, Ricky, when we publish USCDI in July, Version 2 of USCDI will be considered during this current SVAP cycle so that developers can voluntarily update their systems to USCDI based on the certification criteria that use USCDI and provide that update to their customers.

Ricky Bloomfield

Got it. That is a helpful clarification, thanks, and that sounds like it might be where some of the confusion is. I do not see that clearly coming across in the public information on the SVAP site.

Al Taylor

Okay. As we enter that comment period, which will coincide with the publication of USCDI Version 2, we can make sure that we make that specific USCDI integration clear and what it means if we accept USCDI Version 2 as an SVAP-approved standard. We can definitely take care of that as far as the communication piece goes.

Hans Buitendijk

I think Leslie's suggestion to add the cadence component to it... Because there is a time lag between USCDI in July-ish and SVAP in December/January, and that creates some forecasting or the question of if we got everything in play because in the end, SVAP ties it all together. Does that work, and will that get rapid adoption or not?

Steven Lane

Hans et al., do you think it would be helpful for us to include that recommendation here in the feedback we are going to send to HITAC this time around? Is this of sufficient import that it goes in now, or do we keep it for our Task 3 and further discussion?

Hans Buitendijk





I think the comment that Leslie made and the suggestions for cadence in the other one... Being part of commentary, I think this ties together on the areas where we need clarification, recognizing that we are all still trying to figure out how this puzzle is being pulled together.

Steven Lane

Okay. So, Column 3, not Column 4.

Hans Buitendijk

Right.

Steven Lane

I am being very practical here. And, AI, scroll up a tiny bit. I am not sure that my comment above is really that valuable. I think this may go without saying. Should I delete this highlighted text here?

Hans Buitendijk

The first one that you highlighted in red?

Steven Lane

Yes, the first one there.

Hans Buitendijk

Yeah. I am looking at Sasha because I think that is pretty clear already.

Steven Lane

Yeah, people know this. Okay. If there is no objection, I am going to delete this, so we will keep Leslie's comment.

Hans Buitendijk

Just as a general **[inaudible] [01:01:59]** is that if you are new to the game and you come in with a new SVAP, I do not believe that you need to support the older version. There has been a comment, but you do not have to support an older version at this point in time if it is the first time you enter the market.

AI Taylor

Are you talking about **[inaudible]** Hans?

Hans Buitendijk

Our understanding is that if you have certification 2015 CURES, update now as it currently exists, and then, SVAP is going to put in version next of a particular standard. If you come in and have never been certified before but you come in and opt to immediately go for the now-available SVAP, and therefore the latest version, you do not have to go back and support the old version that was in the base certification component.

Steven Lane

You are saying you do not have to be backwards compatible, essentially.





AI Taylor

I think a better way to say it, Steven, would be to say that if you have not yet updated to the CURES update and USCDI Version 2 comes out in the March 2022 timeframe, you can opt to update to USCDI Version 2 instead of USCDI Version 1, which was required under the CURES update.

Steven Lane

Rather than update, I think Hans is saying you come with a fresh product that has never been certified before, and it is after USCDI Version 2 has been added to SVAP that you can certify your product on USCDI Version 2 and its associated requirements and not be required to be backwards compatible with systems that are only certified through USCDI Version 1.

Hans Buitendijk

That is how you...

AI Taylor

I am not sure [inaudible – crosstalk] [01:03:56] backwards compatible, but if you have a new certification, you can certify to Version 2 as long as you submit for certification after the March timeframe of 2022, assuming we add it to the SVAP.

Steven Lane

Right. I think we are saying the same thing.

Leslie Kelly Hall

Yeah. So, the recommendation is that certification should encourage currency. It should encourage adoption of newest and greatest versions. That makes no sense, but... It is not backwards compatible; it is really being forwards compatible.

Ricky Bloomfield

I think there is one important point there. This is Ricky. I agree with the general approach, and it seems pretty clear based on the published SVAP guidelines that you are allowed to certify against something that is newer. That seems reasonable. I think there is a reality, though, that in the market, if you have just a few that are certified to a newer standard but it has not actually been implemented at scale by the application developers, for example, it may not be that useful in the real world, although it certainly is on the leading edge of adoptions, so I think there is a pragmatic decision that they have to make in terms of how much they want to be used versus how much they want to be the leading edge, but either way, the goal is to get people to catch up.

Steven Lane

Frankly, I do not think that this is...

Leslie Kelly Hall

Right, but [inaudible – crosstalk] [01:05:35] versus a certification decision, right? That is the organization coming in and saying, "Hey, I am going to develop a product using the most current standards and innovate with that," and that is a business decision versus a certification decision.





Ricky Bloomfield

Correct.

Steven Lane

I also think it is worth pointing out that this whole discussion, while incredibly interesting, does not necessarily bear directly on our task with regard to advancing USCDI. It sort of goes to how USCDI fits into the larger ONC process, so I think it is a valuable discussion, but I do not think we need to... It is not going to drive recommendations as far as I can tell. So, there are no hands up. We actually came to the bottom of Column 3 and our Task 2C recommendations, and there is no blood on the floor, I am happy to say, so I want to thank all of you for engaging in this really rich discussion.

We do have just a little bit of time before public comment, a few minutes. Does anyone have anything else they want to add as we turn our attention to the drafting or the wordsmithing of these recommendations for the HITAC and preparation of our presentation? In terms of timing here, our HITAC presentation is on the 9th. We certainly have the option of meeting next week to go over the final recommendations here, and/or we could do that via email. Would anyone like to express a preference? I do not think there is a lot of value in us meeting on the 8th, the day before our HITAC presentation, because we will have already shared our materials with HITAC. I think we will want to send it out probably by the 2nd of June. So, question to the group: Do you think a meeting next week is in order to go over how this gets substantiated into presentation materials, or are you comfortable doing that via email?

Mark Savage

Steven?

Steven Lane

Yes, Mark?

Mark Savage

My general approach is to leave it on the calendar and just cancel it if it is not needed, which it sounds like is likely to be the case, but that way, it is there if you and Leslie conclude that you want it.

Steven Lane

I think that is a fine suggestion. Does anyone want to add to that? Thank you, Grace. Grace is in. No objections? Good. Well, let's do that, and I think we clearly have our work cut out for us. The co-chairs will continue to try to channel all of our joys, passions, and concerns into our recommendations. If everybody is okay, let's go ahead to public comment. Thank you, Abby. Again, I really want to encourage any members of the public who are here to step forward and share your ideas with us. We have not had a lot of public comment, either in the chat or verbally, in prior meetings, but we certainly do encourage it.

Al Taylor

Steven, before we do that, can we just clarify that your intent is to cancel the June 8th meeting?

Steven Lane

No. Our intent is to leave it on the books and cancel it at the last minute if you, Leslie, and I get our work done.





Al Taylor

No, I mean the June 8th one.

Steven Lane

Oh, I am sorry, June 8th. Yes, I believe we can cancel June 8th. I do not think we need that one. I think we should probably come back together on June 15th and share the HITAC feedback and outcome, and maybe talk about our timeline and cope for Task 3, if that is okay with folks. Thanks for your kind words, Abby. Okay, public comment.

Public Comment (01:10:15)

Cassandra Hadley

Operator, can you open the line?

Operator

Yes. If you would like to make a comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing *. One moment while we poll for comments.

Steven Lane

I just want to reflect back to the task force members my great thanks to all of you for your engagement. I know some of you have been more verbal than others, but I definitely appreciate the people who have been here thinking and who have been part of this process.

Operator

There are no comments at this time.

Steven Lane

All right. Well, with that, I think we are safe to end 15 minutes early, something I do not think this task force has ever done, and we will probably see you all on the 15th of June. If that is the case, enjoy a few weeks of needed Tuesday morning time, and if we can get our work done and send you all a timely presentation materials and transmittal documents for your review, we will be able to cancel next week's meeting as well. Have a safe and wonderful day.

Adjourn (01:11:53)

