



Transcript

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

August 3, 2021, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL



Speakers

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





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

Operator

All lines are now bridged.

Michael Berry

Great. Thank you very much and good morning, everyone, and welcome back to the USCDI Task Force. I am Mike Berry with ONC, and I want to thank our task force members for all their hard work over the past many months. We are going to kick off today's meeting with roll call, so when I call your name, please indicate that you are present. I will start with our co-chairs. Steven Lane?

Steven Lane

Good morning.

Michael Berry

Leslie Kelly Hall?

Leslie Kelly Hall

Hello.

Michael Berry

Ricky Bloomfield?

Ricky Bloomfield

Good morning.

Michael Berry

Hans Buitendijk? Grace Cordovano?

Grace Cordovano

Good morning.

Michael Berry

Jim Jirjis? Ken Kawamoto? I know John Kilbourne is absent today, but he will be back next time. Leslie Lenert? Clem McDonald? Aaron Miri? Brett Oliver? Mark Savage?

Mark Savage

Good morning.

Michael Berry

Michelle Schreiber? Abby Sears? Sasha TerMaat?

Sasha TerMaat

Good morning.





Michael Berry

Andrew Truscott? Sheryl Turney?

Sheryl Turney

Good morning.

Michael Berry

Dan Vreeman?

Daniel Vreeman

Good morning.

Michael Berry

And, Denise Webb is also out today. She will be back next time. And, I would like to now turn over to our co-chairs, Steven and Leslie, to get us going. Thank you.

Past Meeting Notes & Discuss AHIMA USCDI Survey Results (00:01:36)

Steven Lane

Thank you very much, Mike, and welcome, everybody. I apologize that my camera is not working, but I assure you I am still standing. We have Leslie on camera, which is a much more pleasant vision anyway. Let's go ahead and jump in today. I would like to remind us of our plan. We continue to try to post past meeting notes as quickly as possible to the website. I think we have not yet posted last week's notes, but look forward to doing that. We are going to talk about some input that we received from AHIMA after we made some outreach to them, and then dig into our Task 3 recommendations before public comment five minutes before close, and then we are going to close it out.

If we can go to, actually, Slide 5, if you can drop down there, again, to orient us to our task, we have been through Tasks 1 and 2, focusing on the draft V.2 and the expansion process, and now, really, our focus is on providing recommendations and priorities to ONC for the USCDI Version 3 submission cycle, and to be clear, really, the recommendations that we will be providing in this phase of our work will inform ONC's work in crafting the draft Version 3. We anticipate that this or another task force will be stood up next year to go through this cycle again, evaluating draft Version 3, making further comments on the expansion process, and then preparing Version 4, but everything that we should be focused on now is really how to help ONC approach draft Version 3, and that means not only how to approach items that are already leveled as Level 2, but also how to approach other items that might already have been submitted and be included in comment or Level 1 and might make it into Level 2, or some items that have not yet been submitted. So, really, we can make comments on things that are already Level 2, things that are below Level 2, or things that we just may know are out there and are coming in. So, I just wanted to be clear on that.

We have done some targeted outreach as the co-chairs, and just to be clear, we have reached out to and met with the Argonaut Project leads about whether there were any needs for USCDI related to their work, and there really were none at this point. We have obviously reached out extensively to the Gravity Project around their work on social determinants. We have also met with the CodeX team, another FHIR accelerator, about their needs related to cancer care. We met yesterday with CDC NIOSH about work information that has come up in our discussions here, and as noted, we also reached out to AHIMA with a





question that came up here in the task force specifically around what information was being requested through the release-of-information process and whether we could learn anything from that domain to inform our work.

So, really, very excitingly, the AHIMA group, understanding that they were not doing this on behalf of ONC or on behalf of the task force, they did see the value in serving their membership, and they went ahead and did that, and they compiled the data, and they posted it as a public comment on the website. If you look in the public chat, I put a link to the document. It was also included as an attachment to today's meeting for those who were not on the meeting invite.

And then, we are going to go ahead and pull up a copy of that just to display it to you, but I think it has really been heartening to see how interested people are in various corners of our ecosystem in meeting with us, in discussing the work of USCDI, and really better understanding the work. I think a lot of these folks have already either made submissions or been involved in discussions with ONC, but my experience has been every time that we have met with them and discussed the process, there has been an opportunity to answer questions, to encourage them to make submissions, or to comment on others' submissions, and I do believe that part of the positive impact that our task force has had has been in doing this stakeholder outreach. Leslie, do you want to comment on any of that before we pull up the AHIMA document?

Leslie Kelly Hall

Only that I think you have done a great job of describing what the outreach has done, but I do think that really importantly, you touched on the fact that each group we talked to felt that there was value in asking for the questions of their constituents and contributing to the USCDI process, so I thought that was a great lesson for all of us.

Steven Lane

Great. So, let's go ahead and pull up that AHIMA document just so people know what we are talking about if you do not have it pulled up already from the link that I provided. We are not going to go through it all in detail, but really, great thanks to the AHIMA team for the work that they did to really try to provide this input. They did the survey; they analyzed the results. At the bottom of the page here, they do summarize their findings, and really, what they primarily did was that they found that there were six commonly requested data elements: Laboratory and diagnostic test results, diagnostic imaging, orders and reports, discharge summaries and instructions, procedure and operative reports, cardiology and neurodiagnostic tests, and emergency department records, and then they went on, and those were the ones that were most routinely requested across all of the different stakeholder types.

And then, they found that there were some others that were requested commonly by some recipient types, but not others, and these were ambulatory notes, rehab service records, and encounter, diagnosis, and immunization records. So, they really did dig deep, and they separated out their priorities by how commonly they were requested by different stakeholder types. And then, they went on in their recommendations at the bottom of Page 2 and pointed out that all six of the survey data elements that were commonly requested across recipient types were really already included in USCDI or were in the process of being added, so I think that was a real confirmation that the work of ONC in crafting and evolving USCDI really does match well with the needs that are seen in this community.





And then, they also point out that there were some of those items that were requested by some, but not all recipients, which were not necessarily specifically called out in USCDI, and they identify outpatient notes and rehab service records. Truly, having been through a lot of work myself with information blocking compliance, I think most people consider outpatient notes as being included under the rubric of progress notes, as noted in USCDI Version 1, and I would anticipate that a lot of folks consider rehab service records there as well. We have discussed with AI and others that USCDI does not intend to be exhaustive in identifying every sub-item that might fit under a general item like progress notes.

So, I think truly, I wanted to bring this up because a lot of work was done to pull this together, not officially at our request, but based on discussions with us, and I think that this input really does give us a good sense that USCDI is going in a direction that aligns with the identified needs of the HIM community. And, I think that Grace, this was actually your idea, to reach out to HIM to identify commonly requested data, so I am just curious how you feel about this. Does this address the issue as you saw it when you made that recommendation?

Grace Cordovano

I absolutely love the results here. I think it has definitely caught on with what we see in the real world, but as I am reading that, I was just curious: When we focus on the HIM department and the findings that we have from the AHIMA survey, and when I think about different healthcare delivery organizations and how they are structured, all information requests and medical records requests may not necessarily go just to the medical records department. Many radiology departments have their own process, many pathology departments have their own process, and I am just curious with respect to USCDI how the task force may feel about reaching out to a radiology point person or pathology point person to see if there are, for example, things that we could be also incorporating and get more data on what is requested from their end, not just from an HIM department, if that makes sense.

Steven Lane

No, it makes perfect sense. In radiology, there are really two data types. There are textual reports and there are images, and we know that the textual reports are already there, and the images are not, so I do not know what value there would be in digging deeper into that. I think with pathology, it is sort of the same thing. There are textual reports, which are already included, and then there may be images related to specimens which, again, are not yet included. So, I think you make a good point that HIM does not primarily manage all requests, but I guess I do not see... And, maybe you just do not know what you do not know, and any member of the task force certainly has the opportunity to outreach, but I do not immediately see the value of digging into those two that you mentioned. I am curious whether others do.

Grace Cordovano

Just to clarify, I guess I am thinking more from a volume-of-requests perspective: When you are looking at the different things, if you are actually counting or trying to get engaged on volume of requests, that not included the radiology and pathology pieces may skew it a little bit.

Leslie Kelly Hall

Well, Grace, I think the systems that would be reported on, even if the request went to radiology or pathology, would still have the record available that that information has been released, and the HIM departments are responsible for any policy around how documents are released and the audit trail of that.





So, I would propose that even if the request itself did not go to HIM, they would have knowledge of that with their constituents, but that is a question we can ask them. But, I agree with Steven. I do not think we are going to get any different types of data elements than the imaging and the actual reports, the orders, and the order results, so I agree with that.

Steven Lane

I did mention that one of the groups we reached out to was the CodeX group, a FHIR accelerator focusing on cancer-related data elements, and I must say the experience of chatting with them was similar to the experience of chatting with the folks from Gravity. There are so many people working so hard to advance interoperability within specific domains, and they have tremendous collaboration, and engagement, and pilot projects going on, and I think that it really speaks to this question we continue to raise, and I do not know if Hans has joined us yet, but each of you has your own question, and this is the Hans question: How, whether, and when the gap will close between USCDI and all EHI. There is clearly lots of electronic information out there that needs to be exchanged, that needs to interoperate to support all kinds of use cases, but how much of that belongs in USCDI in the short, medium, or long term is a question that we will continue to chew on with ONC's help. I think it was sort of in our Task 2 work, so it is not the work of today, but it is a very interesting question.

So, I think we are ready to move on... Oh, with regard to the CodeX folks, by the way, and with all of these folks, what we have made clear to them is that the way to get information in front of this task force is to post it to the USCDI site as a public comment, and then and only then can we raise it here with the task force, so that is why we were able to raise the AHIMA stuff. Again, CodeX provided a lot of information, which they have been invited to post, as have other groups. The other thing that really struck me especially in the discussion yesterday with AI and the folks from CDC NIOSH is how much work is continuing to go on independent of our task force that ONC is really working diligently with stakeholders to work on new data classes, new data elements, help to move them forward, and I think they deserve a lot of credit for that work that will benefit us all in the future. All right. Any other comments on that before we turn our attention back to the agenda?

Mark Savage

Steven, I had one if this is a good time.

Steven Lane

Absolutely.

Mark Savage

I just wanted to lift up the chart on Page 8, which looks across the recipient types, which are patient, provider, and payer, and note the number of times where the percentage of patient very frequently or frequently is often equal to the others, but sometimes higher, and I think this is good feedback for the importance of patient access. I think it is a good piece of information around the recommendation for patient-generated health data. Patients are engaged. They want to participate and contribute.

Steven Lane

Very well put, Mark. Thank you. So, the other thing I wanted to do before we dove into our tables, if it is okay with you, Mark, at the last meeting, we really focused on social determinants of health and the work





of the Gravity Project, and I think we all learned a lot about the great work being done there. We came to the end of that discussion still with the question of what the Gravity Project's priorities are vis a vis a USCDI Version 3, how to build on the inclusion of the data elements that were put in the now-published Version 2, and whether there are any specific recommendations that our task force might include as part of our Task 3 to continue to support that important work. We clearly took a strong stand in Task 1, and I think that contributed to ONC's willingness to include the USCDI data elements that they did in Version 2. There is still so much work being done by that and the other FHIR accelerators. So, Mark, if you wanted to just take a moment to briefly summarize where Gravity is going with Version 3 recommendations, and then, any role you particularly feel there is for the task force for our recommendations to support or encourage that.

Mark Savage

Thanks, Steven. Yes, I did go back to the Gravity team with the input and comments from the last task force meeting, and so, Evelyn did lay out the plans for our submission for Version 3, so I will not repeat that, but we did have two slides of more generalized recommendations for Version 3, and I can come back today with something a little bit more specific. That recommendation was to think about what might be called the multiplier effect with other data elements. With some data elements working together with the SDOH data elements, you can improve care and benefit the use cases even more. So, the Gravity Project has four data elements to list up and make that recommendation more specific. Those four are functional status, cognitive status, pregnancy status, and health insurance information, and these four not only have the benefits for health equity in reducing health disparities, but they would also have crossover benefits for care coordination, value-based care, patient safety, and other critical national use cases. So, that is a more concrete addition to the general recommendations we put on those two slides.

We did talk about some other comments that the task force had. We talked more about the outcomes data element, and I think we appreciate even more some of the comments that were made and why the outcome data element was not as clear as we might have thought it was, and we will work on clarification in our resubmission for Version 3. There was a question about HL7 security tag and how that might work with Gravity's consent data element, and after an internal conversation, the thought on our end is that those really are rather different and do not consolidate, but I will be reaching out on behalf of the Gravity Project to collaborate on HL7 with this and talk further. If there are any changes in that thinking from them or from us, we will be sure to get back to you pronto.

Al asked the question whether we could constrain the value sets so that they were just specific around social determinants of health, not LOINC generally or SNOMED CT generally. Yes, we can, and we are constraining them to reference just the SDOH value codes, and we are indeed doing that, but it is in our supplemental IG, and on a reference implementation, we will work on making that explicit. It is not in the IG that was just published by HL7.

Lastly, in the spirit of what you were talking about, Steven, about reaching out to others, I will also be reaching out to others who have been making some submissions of SDOH data elements that are at comment level and Level 1 to see if there are ways that we can work together and any collaborations and consolidations that might be possible. I think that covers the big picture from the last task force meeting, unless you think I have missed something.

Steven Lane





No, that was great, and you have commented about outreach. I think one of the bits of value that we have derived from some of the outreach that we have been doing is helping to inform submitters that there have been other data elements submitted that might be related or duplicative. I think ONC has done the best job they can to try to drive out the duplication in the submissions, but I think we certainly do see that there are items that one group may not be aware of, and the encouraging, as Mark mentioned, the consent that Gravity is looking for aligns with the security tags that HL7 is asking for. Whether it can or not, I think it is really good when folks are working in similar areas for them to discuss, to align their work, because that leads to stronger submissions to ONC and a greater likelihood of things moving up to Level 2 and to a future version. Mark, in the beginning of your comments, you mentioned four specific data elements that you were driving for Version 3, and I did not have my pen ready. Can you say that again real quick?

Mark Savage

Sure. Functional status, cognitive status, pregnancy status, and health insurance information.

Steven Lane

Great, okay. Obviously, as you mentioned, those go across use cases beyond SDOH, and I think that that is a really good point. Wherever ONC can identify data classes or elements that need multiple stakeholder groups and multiple use cases, it multiplies the benefit of adding them to USCDI. Great. Any questions for Mark? One question for you: Mark, do you feel that there is a need for our task force to include a specific recommendation related to SDOH in our Task 3 recommendations?

Mark Savage

Personally, I think it is helpful to do that. In including the four data elements in Version 2, ONC made a tremendous contribution to moving the ecosystems forward. I think is not one and done, though, so I think there is room for showing some of the additional reflection that the task force has done in thinking about the benefits of Version 2 and how they interrelate with some of the other elements of USCDI and how that can be improved even further going forward. Some of the things we have talked about actually harken back to our second round of recommendations about how to think about priorities, so the discussion about SDOH may give some good examples of the general recommendations we made on the last round to the HIT advisory committee.

Task 3 Recommendations (00:25:49)

Steven Lane

To set us up for the rest of our discussion today, I would just say that we have two more meetings after today to finalize our draft recommendations for Task 3. As we all know, recommendations need to be succinct, focused, and logical. Mark, if you would like to craft one or a small set of recommendations related to SDOH that you feel the task force might be able to support as part of our Task 3 work, please do so. Clearly, no one on the task force is better informed about this than you are. I think something generally saying that we support the advancement of SDOH, whether or not we go into the specific details of Gravity's V.3 submission, is perfectly fine. I am not convinced that it is going to make a big difference because I think ONC is fully engaged with Gravity already, but I think it is fine for us to include that, and I am sure HITAC would even support that. So, Mark, if we can ask you to prep that for discussion at our next meeting, that would be great.

Mark Savage





I will do that today or tomorrow so that folks have a chance to look at it ahead of time before next meeting.

Steven Lane

Marvelous. And now, what we are going to do is...oh, sorry.

Leslie Kelly Hall

Daniel has a question.

Steven Lane

Dan?

Daniel Vreeman

Hi, thanks. I will just briefly say I am very much in favor of advancing the recommendations that Mark proposed. I think it is quite aligned with many of the conversations we have had about multiple use cases, and very specifically, the proposed data classes and elements are quite important. I wanted to make one specific note because I was quite involved in the submission of the data class and elements around functioning that there is a comment in there from American Physical Therapy Association around the leveling of that data class and those data elements advocating that it is under-leveled as a comment level, and really should be considered at least a Level 2, and for sure, in the context of understanding equity-related issues around functioning and disability, I feel like this is a really important topic, so I wanted to point that out to the task force and I look forward to Mark's recommendation.

Steven Lane

Thanks, Dan. That is very helpful. Again, there are so many comments that have been submitted on the website. I had initially vainly thought that I would be able to keep up with them to inform our discussion here, but there were too many, so my hat goes off to the ONC team, who is reading and answering every one of them as people submit them. AI, before we jump into the rest of our **[inaudible] [00:29:08]**, is there anything you want to say about where you are at, and the ONC team, and what is coming in over the doorstep in terms of submissions?

AI Taylor

Yeah, not a lot to add. We have not gotten that many. We did get a small collection of submissions from Grace, actually. We have not gotten any other submissions, to my knowledge, since we opened it up or announced the submission period for Version 3. We continued to meet with a variety of different stakeholders to get the word out about USCDI V.2 and the V.3 process. There were not a lot of additional submissions or recommendations, but we do still continue to do outreach.

Steven Lane

And, is it safe to say, AI, that in addition to watching for new submissions coming in, you are also reading the comments as they come in, like the one that Dan just mentioned from the Physical Therapy Association about the leveling of functional status? It seems to me that those kinds of inputs could potentially impact how you have leveled something in the past. I think what you said before is that you make those adjustments on an ongoing basis, that we are not looking for a particular point in time when everything will be re-leveled, as we sort of suggested. Can you clarify how you envision that process of re-leveling?





AI Taylor

Sure. So, like we said before, we basically review top to bottom and, like I said, we are looking for things that could move up in level, whether that is because additional information is available, or additional comments have been made, or maybe duplicate submissions have been put in that add up to something greater. So, we will look at all of the levels, all of the data elements across all the levels, not just the thing that is coming in on Level 2 or new submissions. So, we intend to do that. I cannot promise that we are going to respond to each comment as it comes in and take immediate action to move it. We will probably allow all those comments to come in, or a greater number of comments to come in, and then assess them on the whole.

Leslie Kelly Hall

One comment I received from folks is when leveling is done, is there a time/date stamp so that folks know that it has been, in fact, revisited and when it was revisited?

AI Taylor

Not for the public. We do not have a timestamp on the change for the regular public users, but the submitter will get a notice that there has been a change in the status or any change to the document.

Leslie Kelly Hall

Okay. That might be worth some consideration just because I think there are often questions like, "Wait a minute, we just did that work." I am thinking of some of the advance directive work that is going on and how that has been moved forward, and that group is eager to have things done. How do they know when the leveling was addressed so they can come back and say, "You might not have this particular information"?

AI Taylor

Yeah, I will look and see what kind of information is available as far as updates. I know that we have that information available on the back end, but I do not know what would go into exposing that metadata. I am not sure if that is feasible, but I will look at it.

Leslie Kelly Hall

Okay. Thanks, AI.

Steven Lane

Wonderful. I do not see any hands up, so I think what we are going to do next is turn our attention to the Word-type document that we all share access to on the Google Drive, and big thanks to Leslie, who has done a tremendous amount of work trying to sort through the various submissions that people have put there, and what she did was create a new table that is at the bottom of that document where she separated out the various suggestions into three broad categories, one related to regulatory guidance, one related to public health needs, and a third related to stakeholder engagement, and I think that was a very useful categorization.

And, what we have here is really a whole set of bullets, and I think the Accel team can share that when they have a chance, but I encourage others to just pull it up **[inaudible] [00:34:27]** monitor to do so. And, I think that this really captures the various recommendations that we have made to date related to Version 3 and to the general process as a whole. So, Leslie, do you want to take us through this? What we really want to





do, again, is identify those recommendations that we are comfortable with, including in our Version 3. As I said, we have this meeting and two more to get through this. I think what we are going to start to do is as we finalize and approve these, we will start moving them over into more of a Word document that will look like the recommendations and start to draft that out. I have seen that done in some of the other task forces I am working on. That is why we are drafting that iteratively as opposed to just doing it all at the end. So, Leslie, take it away, and maybe you can expand that so that the table itself fills the display screen instead of the comments on the right.

Al Taylor

I am displaying.

Steven Lane

So, just zoom in.

Leslie Kelly Hall

So, one of the things... We were looking at all of our Task 3 comments. At this stage, it is really important to consider both the process improvement and the expectations we have of ONC or desires we have of ONC of how they go through and make selections on V.3. The individual data element discussions that we will have will be at a later date when we are further on, so I think that would be the October/November timeframe. Is that right, Steven? So, this is really taking all of our comments that we have made and reframing them, trying to consolidate them and put them in these buckets. Some of them are taken verbatim from our discussions and some I have paraphrased. So, it is important that as we go through these and you have questions or comments, we can make sure we go through them. So, maybe we will just take it one column at a time.

So, regulatory guidance seemed to be a big theme that we have heard over and over again. How do we connect these dots? How do folks know by working on one process, it is informing the other? There is a little bit of a feeling of whack-a-mole going on in standards. "If I do this in USCDI and I do not do this in SVAP, or if this is working in HL7, how does that all get connected?" And, that is a common theme, as well as the Hans question of "How do we coordinate the gaps between USCDI and eventually all-EHI?"

So, these are recommendations for making sure there is clarity around what gets included where, and also to make sure that it is easily understood, so if you are doing a point of entry on the ONDEC process, you can see not only the recommendations you are making toward USCDI, but also how that then supports cross-reference and moves to other opportunities within standards and regulations. So, it is really a primer on how to move through and connect these dots. We also had mentioned some need for a rapid-cycle process for USCDI inclusion. This might have to accommodate a more urgent need. It might be a public health need, but how could ONC provide guidance to the community at large to really motivate and move in a rapid-cycle development?

Also, we looked at stratification of data elements so that not all certified HIT products are required to support all data elements. This has been brought up, especially in small specialty practices or areas that simply do not do the work that is required to document, and we would like to see that explored. Is there a possibility? And then, also, consistent with the requests that we had from outreach with SDOH and also what we have





heard about research is that there are big gaps in data gathering. So, what would the timeline be for right-access APIs for specific data elements?

We talked about the exchange, and I think this was a big surprise to all of us. We did not realize that in the leveling process, there is a requirement for four HIT vendors, and we want to suggest that that goes down to two, any two. And then, also provide direction for standards bodies so that the actual IGs in play are cross-connected and referenced in HIT certification. We looked at the guidance for EHI release regarding standards creation, reuse, repurposing, and the appropriate use of free-text and narrative approaches. This is somewhat the Clem question that said, "Wait a minute, how can we take what is already there and repurpose easily through adopting a different take on the same approach?" So, that is all about reusing narratives, reusing free text, and how we encourage that kind of use.

We talked about extensible structure for USCDI so that we could have different levels of precision and understand that. Also, that we would have examples for vendor-neutral technical specifications that have been represented, and that was a discussion, and please let me know if I have captured that correctly, but that was an idea that was talked about that there are approaches that are very specifically vendor-neutral, that are somewhat agnostic, and we want to make sure that that is identified throughout.

Also, prioritize adoption of data elements that benefit multiple use cases. This is the multiplier effect that Mark brought up, and there are significant ones. I probably should have included this, but in the ONDEC process, we would like to see the ability to identify more easily how that could be repurposed and how multiple use cases can be informed. And then, we looked at prioritizing data elements and classes that aid national imperatives and use cases like patient access, value-based care, immunization, and so forth, down the list. So, have I captured the items that we have talked about for regulatory or policy recommendations, or are there some to add?

Steven Lane

Leslie, I will just say I think you have done a tremendous job winnowing these down and categorizing them. Again, I want to keep our focus on our Task 3 recommendations, which is to say, recommendations for content and priorities related to Version 3, so what I have done just as you were going through that is bolded the ones that I think would be most likely to fit in that box of Version 3 recommendations. I think a lot of these are higher-level discussion points that we worked on in Task 2 and will probably work on in Task 2 again next year.

So, just as we go through these, if you guys feel they really do belong in our Task 3 recommendations, please call those out, and for now, I will just make them bold, and we can talk about them. Similarly, if there are wording recommendations, I would invite any of you to jump in there in suggesting mode and make those changes. And then, I do not know whether you saw my comment in the public chat, but Dan Vreeman did a lot of work on this notion of a clear and extensible structure for USCDI entities to specify data content with different levels of precision. Dan, you posted that publicly sometime back, and we said we were going to get back to that. Do you want to take this opportunity to give us a high-level on that and tell us whether you think that the task force should include recommendations related to that?

Daniel Vreeman





Sure. Thanks, Steven. Yeah, that document has been up on the site for a while, I think since last fall, and it has been the subject of some conversation in a few different standards groups. There are really two main recommendations that we proposed back then, and I will actually start with the second one, which Leslie described earlier, and it is around this idea that USCDI should document or link to the examples of the vendor-neutral technical specs that represent the stuff in USCDI, and to be more precise, it is the idea that when there are FHIR profiles, or C-CDA templates, or stuff in common data models or wherever that effectively implements these things, it sure would be nice for users to be able to have links to examples of how those things work so that they can see the implementation of it.

Again, recognizing USCDI is architected to point to the vocabulary or content standards and that something like a FHIR profile has more stuff around it, but it sure helps provide the example of what this is. And so, that was actually the second recommendation from that proposal, and before I go to the first one, I will just pause and see if there are any comments or questions about what we just described. I know that Hans and others have made this point before about linking to or pointing to instances of FHIR specs that meet the intended USCDI implementations.

AI Taylor

This is AI. I had a question about those. It seems like those two bullets that are adjacent are related, and I wanted to ask a question about how this bullet is different than the... The ONDEC system does ask for both vocabulary representation and technical specifications, and I think that is what you mean by “vendor-neutral specifications,” some FHIR profile, some FHIR IG, or some C-CDA template. Is that what we are talking about when we are talking about vendor-neutral technical specs? Because there is already a specific entry in ONDEC for those things.

Daniel Vreeman

Yes, AI, that is what I was referring to in terms of basically identifying a particular profile or IG, recognizing that it might not be an HL7 thing. Certainly, C-CDA and FHIR are, but there are other kinds of specs that might be relevant for the use cases where USCDI is important, but I think the difference is that in the ONDEC system, it is the submitter’s idea, and frankly, I may or may not be totally correct that these are validated, proved, or ONC “stamp of approval” kinds of specs, and in addition, there has not yet been a clear way in which submitted content gets pulled through into the official publication of USCDI. So, sometimes, if you just pull up “What is USCDI V.2?”, all you see is the data element name and the vocabulary standard. You do not see that reference material. And, I think what this is getting at is...

AI Taylor

Dan, the information that was submitted is available. It is not always displayed, but it is available for things that did not come in from Version 1, things that came in from the ONDEC system. So, the additions to USCDI...the submission information is available, it is just collapsed for the higher-level view.

Steven Lane

But AI, I think what Dan is saying is that it is one thing for it to have been submitted and be posted with the submission, but it is another thing... Once you have taken a submitted element or class and made it part of USCDI, is that a reference to whatever was submitted, or are you working with the submitter to update that, to make sure that it is accurate, to make sure it is complete? Are all of the details in the submission





fully blessed by ONC when it is moved into USCDI, or is there a need for ONC to be more specific or to take a piece of that submission and specify it? I think that is what you are asking, Dan.

Daniel Vreeman

Correct.

Al Taylor

So, we do some editing of the submission data that comes in. Sometimes, we do not do a high-level edit on it. We leave a lot of the submitted content. Most of the submitted content remains as is in that submitted information. There are examples where we have to clean up fields for applicable standards, we have to clean up fields for data element definitions and things like that, but we leave the bulk of the submission information as submitted. But, all of that information is available to the reviewer.

Leslie Kelly Hall

We have a question from Clem. Clem? You might be on mute, Clem.

Clement McDonald

I am not on mute and I got permission to talk, so I do not know what is going on, so I am screwed.

Steven Lane

No, we can hear you.

Leslie Kelly Hall

We can hear you now.

Clement McDonald

Oh, I am not screwed, good. So, I think Dan is right on. I think ONC has done a nice job of receiving suggestions, but the bottom line is that the end gives us the synthesis, but you convert it into some specifics with specific examples so it can get done. What are we really trying to do? As a more general comment, in all these things, I am not sure I recognize where we are going to get... So, it has been a long-term argument or complaint that we have data out there, like spirometry, EKGs, et cetera, that are measurements the patient cannot... They do not know what is in it. A lot of the stuff where folks now with the patient can tell you again because they are good memory systems, but they cannot tell you that, and they would like to see it, and we are not sending any of that stuff except for the lab data.

And, I think there is a new window called... I forget what it is called, not "laboratory diagnostic studies," but we have to get that done. I went back to ISA. ISA is missing all that. It used to be there! Who took it out? It is like there is some sort of demon working against us trying to get this...? It is very expensive. I think we have probably spent something over \$5 billion a year just on electrophysiology and stuff, and it is just not available per USCDI. So, I would just like to make a pitch that we get that stuff going in this next round.

Leslie Kelly Hall

Okay. So...

Steven Lane





Dan, I think that was your recommendation too, and again, just to put voice to it, what you are saying is that there could be value in ONC doing more than simply cleaning up the submission, putting in a line, if you will, putting ONC's specification of this data element above the line and putting the original submission with all the details about the use case, et cetera, below the line. I think for historical purposes, that is really helpful, but boiling it down so that when an HIT vendor or somebody else goes to look at it, they can see just what ONC has said about this data element or class and what they need to do to be able to access, exchange, and use. Is that what you are saying, Dan?

Daniel Vreeman

It is, precisely. So, if someone goes into the vital signs thing and says, "Hey, here is an example of the FHIR profile," they can click the link and get right to it so they know that they can implement this terminology in the context of that other exchange specification, and I think having that as part of ONC's final product of USCDI would be very valuable to users.

Steven Lane

Al, does the way that has been put make sense?

Al Taylor

It does. I feel like to some extent, we already do that by publishing what we believe to be the best applicable standard and the best, most informative working definition for those data elements. As most people know, USCDI is not just implemented as a dataset. It is implemented through the variety of certification criteria which are covered in many cases by an IG like the U.S. CORE, the C-CDA, or a few other implementation guides that actually implement USCDI in systems. And so, that is how USCDI is actually implemented, not just a list of data elements, and we refer implementers to those IGs as they update to incorporate the USCDI data elements in it as the "how" for implementing them, especially how to implement them for exchange. They are all implemented for exchange through those certification criteria which involve exchange, such as transitions of care, view/download/transmit, APIs, et cetera.

Leslie Kelly Hall

So, given that approach, for Clem's comment, it is really using existing standards as other diagnostic reports, and it includes specific examples within that recommendation. Is that the approach you would suggest in our recommendation?

Al Taylor

Are you asking Clem or me?

Leslie Kelly Hall

Both of you, actually.

Al Taylor

Let me just jump in and let Clem finish my thought. So, in addition to the IGs that I mentioned, what I failed to mention is that ONC does provide some additional guidance through the certification companion guides for the USCDI reference document that gives additional implementation detail along with the test method and test data that we publish in response to changes in USCDI and other certification criteria, but that can include both referencing test data that is going to be used to verify that things are updated properly as well





as giving examples in text or reference value sets that represent a collection of data elements that are part of USCDI. So, we do intend to do that. Like we do with every change in our certification criteria, we do intend to add additional information to help with implementation of USCDI.

Clement McDonald

Well, my main goal is to just get it done. I am not a kid anymore. I have been pushing this for 30 or 40 years. It would be really nice if we got some of these things done. GE, previously Marquette, used to send EKG results in V.2. I think they still do. They had a very slick interface you could set up. That was back in '83, and we still are not putting it into USCDI. It just makes me cry. Those are the kind of things... We have a lot of **[inaudible] [00:57:17]**, and that is all well and good, but you do not... Ordinarily, the patients can tell it to you. Again, if you do not know what the EKG shows, you cannot get it. They do not know it. They would like to see it; they would like to keep it.

I am just arguing, and maybe it is what the opening was last time... Steve, if it is still available, I will send a list of 20 or 30 examples of things that are now done on a large scale, they are contained in computers, they are typically sent around inside of a hospital, they all work with V.2, they do not necessarily have specific data specifications by test in FHIR, but you do not need them, just like you do not need them for labs. You do not have a separate specification for hemoglobin, so there should not have to be a separate one for systolic blood pressure, which there is, and the PR interval on the EKG. They are all the same kind of thing. So, anyway, that is what I am hoping and praying for, and Steve, are you still open to me sending you a list?

Steven Lane

Yeah. I think what you have talked about, Clem, is the idea of fleshing out and providing specific examples under the new clinical test data class, and we have talked to AI about this. I think this is potentially an appropriate Task 3/Version 3 recommendation going to a deeper level, and I think this does not just apply to the data class of clinical tests. This could apply to other data classes, like assessments. What we see is that the ONC team created these buckets, which I think is the term you have used, AI, that can be used to access, exchange, and use various, more detailed-level data, but thus far, many of the buckets have not been specified down to that level, and when we look down at Level 1 and comment, what we see is a lot of very specific asks that will probably never make it into USCDI because they are more detailed than the vision that ONC has for USCDI.

So, I think your ask, Clem, is to say, "Here is a finite list, not an exhaustive list, but a finite list of **[inaudible] [00:59:49]** that could be included in this bucket, and if these are exchanged, this would be the value set, the standard, or what have you that goes with that." Again, this has come up in other discussions. There are requests for Karnofsky scores, very specific tests related to functional status, and my guess is that USCDI is never going to have a data element called "Karnofsky score," but it is going to have a bucket where the Karnofsky score goes. If that is the case, if ONC can say, "This is the bucket for Karnofsky scores, this is the bucket for interocular pressure, and if you are going to send interocular pressure in this bucket, this is the appropriate value set and standard," as an individual, I personally think that is a good idea. Clearly, Clem, you think that that is a good idea. If the task force as a whole thinks that that is a good idea, we can certainly include that in our recommendations. Whether or not it will get incorporated in draft V.3 or simply inform thinking that goes on next year, it is hard to say. Does that make sense as a response, Clem?





Clement McDonald

It does to me. March on.

Steven Lane

So, Dan, before you go back to your first recommendation, in the document here, I have tried to capture what I think we were saying, so tell me if I have got this right. For data classes/elements included in a published USCDI version, ONC should specify vendor-neutral technical specifications, applicable data sets, standards, and implementation guides that meet the USCDI requirement and be separated from the details submitted by the requester. Is that it?

Daniel Vreeman

Yeah, I think that captures the nuance pretty well.

Steven Lane

Okay. Do you want to go to your first recommendation?

Daniel Vreeman

Sure. And, it relates quite a bit to these discussions that we have just been having. For those of you who have a more informatics-y perspective and want to dig into the details of what I have proposed, you could follow that link, but I will just talk here for the task force at a high level. So, what I was aiming to try to help clarify were some of the ambiguities around what really is the difference between a data class and a data element in the stuff that gets put in these different categories. A lot of the data classes that currently exist are basically the same things as the data elements that are inside of them, such as immunizations, procedures, concerns, smoking status, and in some cases, the data elements are really variable, like body height or heart rate, but in other cases, the data element is test name in the context of labs.

So, what the proposal is trying to do is help clarify the overall structural model to make it easier to make direct connections to the appropriate vocabulary places in that structure because you cannot really use a vocabulary standard correctly if you do not know the shape that the data takes, which is the specific place where this thing should go, and the current haphazard organization makes it pretty tricky to make those kinds of connections precisely.

So, the proposal is an outline or a sketch of a slightly more refined structure where the idea of the things that we call data elements is much more closely aligned with how FHIR considers the data elements. Basically, it is kind of a field within the resource. When we talk about address, we talk about that as a component within a broader structure, whereas the data class is really sort of a composite structure that has a list of enumerated data elements, and so, that class is what defines the overall shape. It is sort of the template for how instances of those things should be stored or exchanged.

So, what I am trying to do is align this idea of a data class with the conceptual notion that is similar to a FHIR resource, or for those of you who are in academic medical centers who are familiar with common data models like OHDSI or PCORnet, it is like what would be a table in a common data model and to keep the things that we call data elements at the level of the specific fields in those tables or the specific elements of the FHIR resource. So, that is kind of the gist of it.





What that buys us is the ability to do the kinds of things that Clem was just talking about, which is to have another level where we say those things, whether they are PR intervals or other EKG measurements, have the same exact shape as other kinds of observations, so we need to know the code to identify what the measurement is, we need to have a place to store the result value, we need a place to store the units of measure, and we can just say that they conform to that same shape, and that is a useful thing to be able to do rather than having a whole other class of stuff that has exactly the same physical characteristics when it is exchanged and, in many cases, the same vocabularies to align with those different elements, for example, test names, result value, units of measure, et cetera.

And then, the last thing that I included in that structural recommendation was this idea of being able to describe groupings, and I think AI has talked about this as they have thought about the context of social-determinants-of-health information. In my proposal, I think I called them collections, but it is basically the idea that for some purposes, you might want to be able to describe the collection of particular data classes or profiles that are organized together for a particular purpose. So, this would be the idea that when we talk about all of the social-determinants-of-health-related stuff in the current proposals, they are sub-elements of main classes like conditions, goals, et cetera, but describing them together as a unifying thing might be helpful, and I proposed this idea of labeling that thing as a collection and gave a few examples, such as with medications, where you might want to group together data elements around medication ordering, medication dispensing, and medication administration together under a broader collection related to medications.

So, without spending a lot of time going through all the details, certainly, we would appreciate any individual comments about this proposal, but this idea has gotten support from many of the standards development communities, the HL7 vocab group, and the LOINC community et cetera. It felt like this level of precision would be much more helpful for expressing the USCDI elements. I would still welcome any comments if anybody has had a chance to review in more detail. I will open it up for comments or questions.

Leslie Kelly Hall

It seems like it would really kill a bunch of birds with one stone by having this kind of approach. It organically creates situations where the multiplier effect is easily understood because you are repurposing, reusing, and/or classifying things in ways that have a broader context, but are able to then get to precise levels for any element within those classes. Did I get that right?

Daniel Vreeman

Yeah. I think what you expressed is exactly what I was trying to do: Find the simplest approach that gets to the level of precision we need, but also repurposes all the things that we want to be able to reuse.

Leslie Kelly Hall

Thank you.

Steven Lane

Does that all make sense to you, AI, what Dan is saying? Do you have any questions about it?

AI Taylor





I think I understand. I would like to take this offline with Dan and make sure that I understand it the way that he has expressed it, but I think I understand what he is saying, and it is something that we can look at.

Leslie Kelly Hall

With that review, I think it would also inform additional things within ONDEC that would have to be identified in order to demonstrate this hierarchy that Dan has described. Mark, you had a question.

Mark Savage

Yeah. I just wanted to... Using my own words, I appreciate this notion that the categorization is not mutually exclusive, that things can fit into multiple buckets because of multiple use cases. I think there is also a relationship to Al's request that Gravity defines value sets specifically for the SDOH data elements, that there are some ways in which being more specific and granular about what is being used for what helps the ecosystem, so I just wanted to point out that connection in case there are some even bigger benefits from thinking the way that Dan has laid out.

Daniel Vreeman

Yeah, Mark, you are right on, and I would say it extends to, for example, if we go down the road of thinking about functioning and disability kinds of observations, it is a very similar-type connection.

Leslie Kelly Hall

Dan, furthermore, I think you could include multiple stakeholder originators of the data. If you take this kind of approach and you are talking about any sort of assessment, that could be a patient-generated finding observation self-assessment. That **[inaudible] [01:11:20]** that you have defined seems to also not only be vendor-neutral, but stakeholder-neutral.

Daniel Vreeman

Oh, you are right on, for sure.

Leslie Kelly Hall

Right? So, I think that should be articulated in that so that we see that is a matter of trading the author or the actor for that definition, and the definition is equal. Does that make sense?

Daniel Vreeman

It does. And again, we had some conversation around this, and I know you and Mark had some proposals that rather than, say, creating an entirely new class or structure for patient-generated data, it is being sure there is an attribute or a way to represent the author/actor for producing that. That is the way it could be represented in this kind of structure.

Leslie Kelly Hall

Right. Clem, you had a comment.

Clement McDonald

Yeah. So, again, I want to first reinforce Dan's idea. He had so many that I am just worried that they are all good, but they will get lost. But, a very key, central, early idea that you want to stop mixing elements and classes by conceiving of the class is the class is sort of a table type, and the data elements **[inaudible]**





[01:12:49] within the class. That could be an object instead of a table, for those who are into that exotic side of it. It is just that that mix-up causes problems, and once you get... In ISA, there was a category called “assessment,” and it was just what you wanted. What happened to ISA? It got ripped out. I just looked at it again. It has got none of the stuff it had two years ago or a year and a half ago. Anyway, that is a separate issue. Thank you.

Leslie Kelly Hall

But, it does get back to our coordination question of making sure that when one thing, like a USCDI data element, is put forward, there is coordination across other areas, whether that is ISA, SVAP, or more. So, thank you for that.

Clement McDonald

I vote for stability in standards because it does no good to have a standard that is not the same year by year.

Steven Lane

So, I have a question, Dan, which is... So, I have tried to capture what I think combines part of what you have said and what Clem has said here in bold recommendation. I will just read it real quick. “ONC to provide for clinical tests, assessments, and other applicable data classes a list of specific items that would be included within the data class with any associated technical standards, value sets, implementation guides, or data models. This list would not be intended to be exhaustive, but could grow over time to specific data that should be included within the data element.” Does that get at it? It does not get at the part of your recommendation, which is that ONC needs to be crisper about what is a class, what is an element, and how they are going to be defined and organized. That is a hard recommendation for me to put into words, but as AI said, he will talk about it and try to take that into account, and maybe that could be structured, but I do want your feedback on this that I have drafted here.

Daniel Vreeman

Sorry, my audio cut out for a second. I think your general recommendation there at the top is good, and I would be happy to set up a separate meeting with AI where we could talk through some examples to see, but I think your highlighted item there gets at it. When you say “a list of specific items that would be included,” were you thinking that those would be the attributes for data elements per se, like test code and result value units, or were you thinking that those would be specific items, meaning the actual variables, like EKG results, heart rate, et cetera? What did you mean by “items”?

Steven Lane

Well, I think it is going to vary by data element or data class. Clem is really thinking about clinical tests and identifying maybe 20 specific clinical tests with their associated standards that belong and should be considered a part of clinical tests. I think others could do the same for assessments, specify five, 10, or 20 very specific assessments, each with their own standard. So, I did not quite get the differentiation between the two things you were saying, but if you can add to this, please do.

Daniel Vreeman

Well, I think the point that Clem and I were trying to make is that those different items might share that common structure, so there is one thing to describe the kinds of tests, but there is another thing to say that





whenever you send a clinical test, you should always include a standard code to identify it, you should always include a standard for the units of measure, et cetera, and so, that is the kind of delineation between instances and elements, but I think in what you have said, if AI understands where we are going with that, then the recommendation is sufficient.

Steven Lane

I just added a couple of words. Are there other data classes that come to mind beyond the clinical tests and assessments where this approach would be particularly valuable?

Clement McDonald

This is Clem. I hate to break in, but I think it applies to lots of stuff. It does not all jump into my mind, though. I am going to go back and find the old ISA. I think there were some other ones introduced like it, but it is gone.

Steven Lane

Okay. And then, Leslie, you bolded the link to Dan's document. What does that mean, exactly? Could you envision taking that language and turning it into a task force recommendation? I just want to understand.

Leslie Kelly Hall

I would, yes, and I think... Perhaps this is a different conversation, but I did think that document provided the examples that are necessary to understand this one fully. And then, I did not know where to put the idea of the stakeholder use because this is really a structure that says it is independent of vendors, or, not independent, but inclusive of...I guess "neutral" is the best way to put it, that it is for all stakeholders as well as for vendors.

Steven Lane

So, we have a few minutes until public comment. We have spent our time focused on this regulatory guidance column, and we have identified a subset of the items that are in it in bold as recommendations that would go into our Task 3 recommendations document that we will then take to HITAC. If people have other thoughts of recommendations that should be pulled out of this column for this particular set of recommendations related to the creation of draft V.3, please provide them in this document, and then, what we will do is work with the ONC to actually take these items and move them into a draft Word doc so that we can start to prepare those for our submission. And then, my proposal would be that when we come back in two weeks, we go on and tackle the public health and stakeholder engagement columns, doing a similar thing: Identifying those specific recommendations for our Task 3 document that will inform ONC's creation of draft V.3. Does that make sense?

Leslie Kelly Hall

Yes, it does.

Steven Lane

Great. I do not see any hands up. Okay, let's cut to public comment, and then we will come back and collect additional ideas for people to work on between now and our meeting in two weeks.





Public Comment (01:20:51)

Michael Berry

Thank you, Steven. Operator, can we open up the line for public comments?

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

And, for all of you members of the public who have been listening intently for the last 90 minutes, please do not be shy about submitting public comment.

Operator

There are no comments at this time.

Michael Berry

All right, thank you.

Steven Lane

Okeydoke, thank you. So, we have six minutes. I do not think that we can start in on any of the other columns, but I really do want feedback from task force members about the approach we are taking in trying to winnow down a tremendous number of ideas into a specific set of recommendations that we will take to HITAC in just over a month. Is the way we are approaching this working?

Mark Savage

This is Mark. I think it is.

Leslie Kelly Hall

Al, do you have suggestions? We have many comments in here that are not specific to USCDI, but touch on the coordination efforts and the clarity across multiple standards efforts. How and where do we capture that in our recommendations? Because it is not specifically about selecting and making decisions around V.3, but it is trying to provide clarity, which we are seeking across all efforts. Where do you think we should capture that?

Al Taylor

I think that when we... It reminds me of additional recommendations the task force made to the HITAC at the end of Phase 2, where the task force sought guidance from HITAC on either an approach to Phase 3, so I would suggest that maybe it be submitted to the HITAC as a supplemental recommendation, if that makes sense, so that like you said, you can separate it out because the scope of the task force right now is USCDI V.3, but they have a lot of other thoughts, and those kinds of recommendations about what ONC should do and how they should do it coming from the HITAC would be fine, so I would recommend that.





Leslie Kelly Hall

Okay. So, I am going to add another column to this that talks about additional comments or addendums to these, and they will be the more general ones. I will pull them out of these three and put them into that column. Does that sound like a good approach? Steven, are you okay with that?

Steven Lane

Yeah, I like it.

Leslie Kelly Hall

Okay. All right, good job. Thank you, everyone.

Steven Lane

Yeah. Any other comments from other task force members? Clem, Dan, Grace, Mark, Sasha, Sheryl? All right. Well, again, thank you all for your thoughts, time, and attention. We will continue on this process, and Leslie, maybe if you are reformatting, making more columns is not going to be so **[inaudible] [01:25:03]** displaying. Maybe just **[inaudible]** on top of one another so we can put regulatory guidance, followed by public health, followed by stakeholder engagements, followed by general comments, just because I think it might make it a little bit easier for that to display **[inaudible]**.

Leslie Kelly Hall

Okay.

Steven Lane

With that, let's adjourn, and we will be back in two weeks. I imagine some of us might see some of us at HIMSS next week. I think a lot of people are still up in the air about that. The ONC team is not going to be there, but any of us who see each other will give a special elbow bump, bow, or wink of the eye, and we will see you all back here in two weeks.

Adjourn (01:25:52)

