Transcript

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

February 6, 2024 10 – 11:30 AM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Sarah DeSilvey, Gravity Project, Co-Chair
Steven (Ike) Eichner, Texas Department of State Health Services, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Ricky Bloomfield, Apple
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Keith Campbell, Food and Drug Administration
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Raj Dash, College of American Pathologists
Derek De Young, Epic
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, Centers for Disease Control and Prevention
Steven Lane, Health Gorilla
Anna McCollister, Individual
Katrina Miller Parrish, Humana Health Insurance
Aaron Neinstein, Notable
Kikelomo Oshunkentan, Pegasystems
Rochelle Prosser, Orchid Healthcare Solutions
Mark Savage, Savage & Savage LLC
Shelly Spiro, Pharmacy Health Information Technology Collaborative
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Hannah Galvin, Cambridge Health Alliance
Hung Luu, Children's Health
Michelle Schreiber, Centers for Medicare & Medicaid Services
Fillipe Southerland, Yardi Systems, Inc.

ONC STAFF

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

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

Seth Pazinski
Hi, everyone. My name is Seth Pazinski with ONC, and I would like to thank everybody for joining today. This is a meeting of the Interoperability Standards Workgroup, and I will be serving as the designated federal officer for today's call on behalf of Wendy Noboa. As a reminder, all workgroup meetings are open to the public, and public feedback is welcomed. Members of the public can type comments in the Zoom chat feature throughout the meeting, and at the end, we have time on the agenda for verbal comments for anyone who wants to take advantage of that and make verbal comments toward the end of the meeting. With that, I will start off our meeting with roll call of the workgroup members, so when I call your name, could you please indicate that you are present? I am going to start with co-chairs. Sarah DeSilvey?

Sarah DeSilvey
I am here.

Seth Pazinski
Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Seth Pazinski
Ricky Bloomfield?

Ricky Bloomfield
Good morning.

Seth Pazinski
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Christina Caraballo?

Christina Caraballo
Good morning.

Seth Pazinski
Grace Cordovano?

Grace Cordovano
Good morning.

Seth Pazinski
Raj Dash?

Raj Dash
Good morning.

Seth Pazinski
Derek De Young?

Derek De Young
Good morning.

Seth Pazinski
Lee Fleisher?

Lee Fleisher
Good morning.

Seth Pazinski
Good morning. We did get a message that Hannah Galvin will be absent today. Let me go to Raj Godavarthi.

Rajesh Godavarthi
Good morning.

Seth Pazinski
Jim Jirjis?

Jim Jirjis
Present.

Seth Pazinski
Steven Lane?

Steven Lane
Good morning.

Seth Pazinski
Hung Luu? We did get a message that Hung might not be available today. Anna McCollister? Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Aaron Neinstein? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Present. Good morning, everyone.

Seth Pazinski
Mark Savage?

Mark Savage
Good morning.

Seth Pazinski
Michelle Schreiber? Fil Southerland? Shelly Spiro?

Shelly Spiro
Good morning.

Seth Pazinski
Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. All right, is there anybody I missed? Well, thank you, everyone. That completes our roll call, and now, I will turn it over to Sarah and Ike for their opening remarks.

Opening Remarks (00:03:37)

Sarah DeSilvey
Good morning, everybody. I do not have incredibly in-depth opening remarks. As we head into the actual labor of this workgroup, I want to thank everybody who went into the share drive and already offered comments. We hope to dive into the work, as I mentioned today, and really look forward to reviewing all the comments and the elements that we already have in the spreadsheets. I do want to note that we will be identifying things that need to have subject matter expert review, so we will be discussing those, and we already have some great ideas of who needs to come back and speak. Again, if you have any ideas about additional needs, please let us know. Ike, any further comments before we proceed?

Steven Eichner
You did a great job, as usual, so I would just like to echo your welcome, and I am excited to get into the meat of the material.

Sarah DeSilvey
I know. Here we go! All right, I believe that is it on this slide, Seth. Next slide. As I mentioned, we always try to ground ourselves in the charge because this is the work that we have set to complete in order to disseminate the transmittal letter back to HITAC in early April. This charge is to review and provide recommendations on ONC's draft USCDI Version 5, and then to provide specific guidance on those elements from USCDI v.5 that should be considered, and we talked a lot last meeting about what that recommendation means. It includes provisions, definitions, addition of supporting elements, alignment with existing standards, including everything available in FHIR, general HL7, and specific data standards recommendations.

So, the kind of recommendations we offer from each of our expertise can be very vast. Beyond draft USCDI v.5, it also includes elevating and perhaps revisiting any Level 2 data classes and elements that were not included in draft USCDI v.5 that we think should be considered, and again, thanks to all those members of the committee who have started to populate those Level 2 elements at the bottom of the spreadsheet so we can discuss them over the course of our charge. Ike, is there anything else to say?

Steven Eichner
No, I think you covered it beautifully.

Sarah DeSilvey

Go team! We got this! All right, next slide. These are the specific questions on a slide from last time. Al, do you want to cover this, or should I review it?

Review of New Draft USCDI v5 Data Elements & Review of Level 2 Data Elements (00:06:31)

Al Taylor
I can. Thanks, Sarah. This is not officially part of the workgroup's charge, but these are some specific questions that we have asked of the public through our standards bulletin. When we publish draft v.5, we also publish the standards bulletin, which provides more background and details about the rationale for adding certain data elements to draft v.5. We are asking the public specific questions, so these specific questions may guide the workgroup members' comments and recommendations, and it is just that. They may provide a guide, and these are to reflect some specific questions.

Sarah DeSilvey
We have already seen those questions be responded to because we transmitted them onto the spreadsheet. That was very helpful. There is already conversation regarding them. All right, next slide. And then, I believe, at this point in time, Al, we are entering into our work, correct? Next slide.

Al Taylor
Yes, I am ready with the spreadsheet, and however you want to work through the list and get started on the list is fine. Let me find where my Zoom button is and share my screen.

Sarah DeSilvey
As Al is pulling up the spreadsheet, I am just going to note some of the approaches we are thinking about for this meeting. Because we have a lot of new members, what we are thinking of doing is running down the list, and then, if there are elements that are so solid that we feel like there is not a conversation that needs to happen, we can move them through. It is also an opportunity for people to note comments, or need for additional conversation, or need for additional SME representation, so we are going to run down the list from the top to the bottom. Again, we are hoping to move some things through to the stage where members are drafting the final recommendation in time for the transmittal letter, but we are mostly just making sure that everyone feels comfortable with the element as represented and making sure that we really are thorough about things that need more in-depth conversation so we can plan accordingly. How does everyone feel about that? Does that sound good? Ike, any other thoughts, or are we good to go? Should we start?

Steven Eichner
I think we are good.

Sarah DeSilvey
Okay, so this is why the last meeting was probably the only meeting we will ever leave early, because this is when the work actually starts. So, if we scroll over a little bit, I just want to remind everybody that each of these elements has an entry number, just because things can move around a little bit, so there is the entry number that is assigned. Al, thank you for all your work setting this up. And then, things that were elevated from ONC via draft USCDI usually start right at Column E. So, the first element we have of note,

which is not meant to have a pun, because it is a note, is an element that has come up repeatedly across other IS WGs. The data element is emergency department note, the definition is summary of care delivered in emergency department, and there is an aligned data standard, which is, at minimum, the emergency department note LOINC code. In Column I, you can see it is elevated to draft USCDI v.5, and this is part of our review, so we think about our two elements of the charge. This is the first part of the charge, which is reviewing those draft v.5 elements, and you can already see in Column J a fair bit of conversation.

And so, we are just going to walk through this as an example of how, at the top level, whether any members have any concerns with moving this along, you can see the conversation that has happened in J, you can see that Steven Lane started us out with a member recommendation of including it in v.5, and multiple members of the committee have added their pluses, and then, some people made independent commentary. And then, Hans, as he often does, has a little bit more in-depth recommendation. Hans, do you want to come off mute to talk about what that member recommendation is and to see whether or not we need additional commentary before recommending it for inclusion?

Hans Buitendijk
Sure. So, I will start with one comment that some of you have heard, but others may not have. Typically, the comments that I make are not concerned with or a priority of the element, but they relate to how implementable and practical they are at this point in time in the progression from USCDI's current scope to PHI, if we think about it. So, I want to make sure that it is clear that I am not trying to address the importance of it, just the clarity and what that means to ensure that when standards are being defined and implemented that we all know what it is. So, in this particular case, I will make one comment for both emergency department note and a little bit more for emergency department. What are we really talking about here? There is some confusion that has come up in USCDI as clinical notes start to come in. Are we talking about a narrative summary, if you will, one or two paragraphs of just narrative, or are we talking about a document that has the narrative plus additional information, structured results, other structured data, image, and whatever else might be out there?

What has happened is that the same LOINC codes have been used for both. As a result, depending on how you are trying to get access to the data, it is getting too confusing as to what you are going to get. Are you going to get both, one, or the other, and what would you like? So, the question is very much around if we can have clarity that we truly mean, and, as we have done so far predominantly, that we are focusing on narrative summaries, and if there is a need, that we also have a little bit more clarity around if it should actually be the same LOINC code that we identify as the recommendation, even though it is stated as a minimum, or are we really looking at that as two different concepts, a narrative summary and a document that includes that? USCDI has defined it in a way that could go in either one of those directions, and in the execution of that, it has started to become a little bit unclear. Which one are we really focusing on, first, second, or third?

So, that is the general question that is raised on both notes specifically to the emergency department. Just as a backdrop, if it is beyond a narrative summary, particularly on the C-CDA side, on the document, there is currently not an agreed-to emergency department document type with templates and everything, so there is a little bit more standards development on the operative note. There is one already there, so the definition of the supporting standard is already there, so that is just a little bit of context.

Sarah DeSilvey
Thank you so much, Hans. Mark?

Mark Savage
Thanks, Hans. I want to pick up on that last point. Is there any kind of general timeline for how long it is going to take before we start adding structured data elements to the notes? I am just asking in general so we have a sense of the arc.

Hans Buitendijk
So, that is not a question to me, it is a general question to others.

Mark Savage
You may have a thought on it because I am picking up on what you said. I understand that we do not have the structured data elements there yet. They are in process. Is there any sense of when that will begin to pop?

Steven Eichner
This is Ike. It is not necessarily that the elements do not exist. The elements are not currently included in the USCDI.

Mark Savage
Ike, my question was about the structured portion, to Hans's comment. There is a narrative, but that is where we are, and I am wondering about the structured part.

Steven Eichner
Right, but exactly to that point, there is a difference between what is included as a structured document outside of the conversation specific to USCDI. In other words, there is currently not a structured document element within the USCDI that speaks to a post-surgical note. There may be other resources outside of the USCDI as a document that include a structured document as a post-surgical note. So, is your question more along the lines of structured content within the USCDI or structured content outside of the USCDI for potential inclusion?

Mark Savage
Structured content within the USCDI, and I was not thinking that structure made it a separate data element. I was just thinking it was a different way of capturing and exchanging it within the existing USCDI data element. If I am wrong, let me know.

Sarah DeSilvey
I am going to try to move through a few more of the comments. First, we will go to Rochelle, and then I believe Al is queueing as well. I think the general question that Hans has needs to be answered as well. Rochelle?

Rochelle Prosser
Thank you. So, in listening to the overall discussion, and thank you, Sean, for explaining that a lot better for me, when we are looking at the notes particularly, what is contained in that? Is that coming from nurse-

driven documentation? Is it physician-driven documentation? Is it coming from the lab? It just helps me to understand a little bit better and clarify to look at what those data elements are, to look at HIPAA, and to look at the description. I just need a little bit more clarity around that.

Sarah DeSilvey
Al, do you want to answer that as it stands right now with LOINC 3411?

Al Taylor
Yes. I wanted to try and answer all three questions at once. So, No. 1, the clinical notes data class is intended to encompass the narrative components of notes in general, not the structured documents as defined by CDA, but the intent of this is to capture the narrative component within the context of the name data element. So, where there is narrative text in the setting of emergency department, the intent of this data element would be to be able to exchange that narrative component of the structure document.

Rochelle Prosser
Understood, thank you.

Al Taylor
Using the LOINC code is one way to point to the context so that when compiling a response for exporting or exchanging emergency department notes, there is an understanding that it is within the context of emergency department. If it is a progress note, it is within the context of a progress note. However the health IT categorizes it as a progress note, it could be a nursing progress note, it could be a provider's progress note, or it could be a care coordinator's progress note. If it is tagged as a progress note, the query should pick that up, and it should be exchanged.

Now, that is the intent of the data class, and we try to make that clear in the definition of the data class, and as we respond to questions like Hans's and Mark's, we are trying to be consistent with our response that the intent is to capture the narrative. It is not our intent to turn these data elements into defined, required structure because those are easy. If you are looking for a structured document of a certain LOINC code then you could potentially query that document separately, but this is intended to capture the narrative component because many, many times, the only information that is available is in the form of free text, so there is not an intent to restructure these or to provide structure to the content. We are just looking for the narrative.

Rochelle Prosser
Thank you.

Sarah DeSilvey
That definitely answered a few of the questions at once, and Rochelle, I did put a note in there regarding the specific LOINC codes and the clarification on roles aligned with those. That being said, Hans, your hand is up. Does that resolve the comment? Noting your conversation on considerations for implementation, noting that Al has clarified the intent of the element as written as narrative, how does that change your note, or do you feel comfortable proceeding with that clarification in mind?

Hans Buitendijk

Based on that clarification, and when you look at that data class, it starts with the word “narrative,” but then, as you go into the notes themselves in the definition, that concept of narrative starts to change because either the LOINC code is shared between the note and a document type that is already out there, so that starts to create confusion and challenges, and if you look at operative note, the usage note starts to use terminology in there as well that can start to imply that it is more than narrative.

So, the suggestion from that would be not only to describe it in the data class that it is a narrative summary, but on each one of those, rather than stating “summary of,” indicate “narrative summary of” to be clearer that that is what the intent is. That is one part of the suggestion that I would still want to move forward to reduce ambiguity and varied interpretations. The other one is that we should generally reconsider whether the same LOINC code used for a narrative summary is actually appropriate to be used as the code for a document, that fuller, larger concept, which is more than a narrative summary. At this point in time, mixing the two is causing a challenge, so I think there are still two parts to the suggestion, to add the word “narrative” to the description on each and every clinical note to avoid that and to look at the LOINC codes and reconsider whether they actually should be differentiated between narrative and full document.

Sarah DeSilvey
Just for newer members, this kind of subtlety is what we can address in our transmittal letter, so the kind of recommendation to refine definition to include and have implementation guidance, and possibly seek additional code for. That kind of text is usually what we try to capture in our formal recommendation, just to make sure that we are all understanding and building knowledge together at the same time. Shelly?

Shelly Spiro
Thanks, Hans. Just to help me clarify in my mind, in whatever FHIR resource is being exchanged, is it in the header that it is an emergency department note, and is that different from another type of note that would be transmitted? Are there two places for LOINC codes, or am I missing something?

Hans Buitendijk
I do not want to go too much into detail, but there are a couple of different ways in which this is being expressed, and LOINC codes are used to identify what the rest of the information represents. When you do that, in documents, you have sections, in FHIR, you have either observations or other things that are being used to express information, and at that point in time, the LOINC code tells you what it is. So, if you have a LOINC code attached to one concept where the intent is to express a narrative note, then you know what to expect. If you are trying to express that you are working with a document, then, at that point in time, you know what to expect there.

So, it is not that there are dual ones right now, it is that when you look at the data, you have an understanding of whether you are going to get a CDC or a LOINC code, you are going to get a document fully blown, and you can expect what to look at, or you are going to get a narrative note that can be included in the large document as well. If they are the same, then a document, like an emergency summary document, would probably have the narrative note as its first section that carries the same LOINC code. In that sense, yes, you could see the same LOINC code in the same structure and wonder what you are talking about. That is what we are trying to avoid when it goes beyond human-readable into something you want to compute, and it provides the necessary support.

Shelly Spiro
Thank you.

Sarah DeSilvey
Al, I am wondering if we are considering advancing this element and capturing the refinement that is required in a recommendation.

Al Taylor
What ONC is looking for is a very actionable recommendation, and Hans alluded to a particular actionable recommendation, to change the definition to employ the word "narrative." That is a tight recommendation, and that would be a great thing to see, because we can very easily look at that, digest it, and make a decision on that particular recommendation. One of the other things that Hans is talking about is related to how USCDI data elements are implemented into the US CORE and C-CDA IGs, and that is a separate conversation that happens during the design phases of those implementation guides, and it is not something that can be solved in USCDI, it is something that can be solved during that design process, and that has been a question that has been raised, and the solution has been expressed in the IGs in the four years since clinical notes became data elements in USCDI. So, I would say that the part about how it is expressed should be deferred to the design phase of the updates to US CORE and C-CDA.

Sarah DeSilvey
Thank you so much, Al. There is a lot of good commentary in the chat regarding just this topic. Jim?

Jim Jirjis
I would like to clarify, Hans. When we talk about structured versus narrative, let me just make sure we understand. If you look at it from the point of the workflow of a lot of ERs, there are three different things. One is an automated, structured note that is a sort of discharge summary that is generated automatically without the physician narrative. Then, there is physician documentation, which may include highly structured note capture, may be a dictated narrative, or there may be subsections. Are your concerns to make sure that people cannot just use the automatically generated discharge summary, but instead, that we want to make sure we are talking about the narrative, which could be either a dictated note or a note that was entered in a semi-structured or structured and nonstructured fashion. If it is the latter, then USCDI just needs to clarify that it is the doctor's note or the clinician's note, not just an auto-generated note, and that goes to Al's point about the details getting fleshed out in the implementation guides.

Sarah DeSilvey
Jim, I think you are clarifying what Al was mentioning earlier regarding the intent, and I see some great comments from Ricky and a comment from Raj.

Jim Jirjis
If I am correct that Hans is just wanting to make sure that the robo-note that is auto-generated is not what we are talking about, but instead, it is the clinician's note, then USCDI should have language that makes it clear that it includes clinician narrative, not just auto-generated discharge summaries from various fields extracted automatically.

Sarah DeSilvey

We have a suggestion or that in two different ways that I have heard so far. We could change the definition, the actionable element Al was talking about, to clarify that it is the narrative we are speaking of, both here and as applicable to other note types, which we can have conversations regarding, and then we also can include implementation guidance and design guidance just because if we want to represent that complexity at implementation, we can do that in our transmittal letter. I am just trying to formulate a way forward. Hans?

Hans Buitendijk
At the request of Al to be more specific on the second recommendation, considering that this may be something that needs to be worked out in the implementation guide and that USCDI is meant to represent the concept and the vocabulary, not the structure and everything else, given that right now, it does provide a LOINC code recommendation, it should actually be removed, and it then leaves open for the implementation guide discussion to sort out how we can distinguish the two sufficiently and then identify as part of that which LOINC code is actually best for the narrative and which one is best for the document. Once that is done, we can go back to USCDI, update that, and say the conclusion of resolving it is whatever that is.

At this point in time, by stating a LOINC code that has the potential and has demonstrated with the other clinical notes to date that actually end up using the same LOINC code for two different things, that creates a concern. I would suggest that the specific recommendation be that a LOINC code for the notes is established once we have resolved how to distinguish if that is necessary between a narrative and a document.

Sarah DeSilvey
Thank you so much, Hans. I am going to go to Raj's comment after Ricky. Ricky?

Ricky Bloomfield
I am not sure I have too much more to add here now. I think this has been a great discussion. I agree that it would be useful to remove the LOINC codes right now, but I think we should be very clear that, as part of that design process, a LOINC code should be chosen. I will put a link to what I think is the LOINC code for a surgical op note as an example. If you look at how these LOINC codes are modeled, there is the high-level code for the surgical op note, and then there are associated observations where it actually defines all of the structured components of that surgical op note if you were to create a C-CDA document, and so, I think this gets to Jim's comment earlier. If we are talking about structured notes, there are all different types of structure, and I think the specific type of structure that is being implied here is the structure defined by LOINC in creating this type of note with very specific sections and with specific identifiers and that type of thing, but you can define structure all sorts of different ways.

Typically, the way EHRs create these notes today is not in the C-CDA LOINC structure as defined here, it is putting a bunch of data together in what ends up being just a narrative summary, and that is what most have implemented today, so I think it makes sense to push a lot of this conversation to the data modeling phase, which happens afterwards, because I think there are differences in how it would be implemented for US CORE and for C-CDA, but for US CORE, it is pretty simple. They already describe a lot of this and how it works, and you just need another LOINC code to be selected as part of that process, and then that is implemented in that way.

Sarah DeSilvey
Okay, so, I am going to try to synthesize what we are hearing. Thank you, Steven, for dropping in the element from the standards bulletin about the intent. It definitely clarifies the intent along the conversation we have been having regarding narratives. We hear a specific actionable plan to revise the definition to specify that we really are talking about the narrative, and this will clarify the intent, aligned with what Steven just put in the chat. We also hear a recommendation to remove the LOINC code because it pegs us into a morass of different implementation strategies, and because we have the definition of the element and the intent of the element very clearly explicated, and then specific standards that apply can come back after conversation with design and implementation. Is that what I hear? Is that the thought? Should we move forward with this, clarify that it is narrative, and remove the LOINC code? Steven?

Steven Lane
I am just concerned about removing the LOINC code. It seems like the industry is really asking us for more specification. The less we have, the less we have. When I look at the LOINC code itself, it seems pretty clear, so I get that there are pros and cons to specifying it, but I am not personally ready to throw it out. Perhaps we could say, "e.g., using this LOINC" so we are not completely tied to it, but I would hate to lose that level of specification.

Sarah DeSilvey
We could certainly keep it, and then note our concerns in the transmittal letter, as we have in the past. Hans?

Hans Buitendijk
I do not think we are trying to lose the LOINC code. The question is in what stage of the process do we arrive at the LOINC code that now is clearly understood to be the one? The progression right now is that USCDI is defined first, published, and then it does not change. So, if we include the LOINC code and then find out that that is what we are stuck with and need to use, then we have a challenge that we have started to recognize increasingly over the last three or four years that we identified early on, but now are really starting to see the effects of. So, I think it is much more of a process.

We need to be clear that we want to end up with a LOINC code. There is no argument around that, but when do we get to that, and is it appropriate that we consider that we bifurcate the narrative from the structured document? We can have the discussion in USCDI and come to that conclusion so that USCDI now recognizes that from the start, or we can recognize that we need a little bit more discussion leading up and resolving it, and then come back and say, "Now we have figured out in the implementation how to do that in the guides," and now we come back and say, "Oh, based on that, we need to update the USCDI to reflect that we arrived at LOINC code XYZ." I do not think it is the intent to get rid of LOINC codes. It is to get the right LOINC codes.

Sarah DeSilvey
Hans, can I ask if the "e.g." resolves your concerns? We are talking about it as an exemplar, and then we can note the risk implementation in our comment.

Hans Buitendijk

To date, examples have demonstrated in USCDI that they actually add to ambiguity because if you have an example in the USCDI published and in the implementation guide development, for one reason or another, it is actually a better way to do it, "This is the best way, we have clarification," etc., and you come up with something slightly different, then readers of the USCDI are going to have an expectation that it is there. In procedure, for example, in medication administration, if you look at FHIR US CORE, you will not find it. So, we have to be very careful with examples that they serve the purpose of guiding what we need to do and work through the process of getting to the guides, the Excel standards, but then we need to have a process and ability to go back and say, "Now we learned, we improved, we got something, and we settled on it." Can we go back to the USCDI and clarify that to avoid confusion when somebody reads USCDI and is not going to find it in an implementation?

Steven Eichner
Right, because here, we are looking for a common standard that would serve as an identifier across the board for what this content contains, and if we just put "by example," that becomes a challenge because you have not provided enough implementation guidance, if you will, for that common definition to be in place. Two different implementers produce two different LOINC codes to represent what they perceive to be the same concept, and then you are not going to be able to exchange it well with the common intent of interoperability.

Sarah DeSilvey
Thank you, Ike. I am going to have Al speak, and then I am going to try to steer us to consensus. Al?

Al Taylor
I have two things. If moving the recommendation for the minimum LOINC code, like how the USCDI is phrased, "at minimum LOINC code," moving it from that "at minimum" standard of LOINC to the example… That recommendation has some merit, but I did want to address Hans's question about going back and changing USCDI after US CORE and C-CDA have been designed. That has happened four or five times since we first published USCDI clinical notes, and it has never happened that US CORE and C-CDA have felt like there needs to be a different example of clinical note, so there has been no need so far, over the last five updates to US CORE, for example, to change the LOINC code that we provide as a minimum LOINC code for representing these data elements.

Sarah DeSilvey
Thank you, Al. There is a lot of conversation back and forth on the LOINC code element. In general, I hear us agreeing that this is an important element to include. We are based at there. Do all members of the committee understand the conversation implications of having the minimum standard for the LOINC code or not? I really want to make sure everyone hears that conversation. And then, there is also a conversation of, if that move is made, whether it should be applied to all the other note types in the set. I just want to make sure everyone is with us. Okay, good, I am hearing yes. There are definitely different directions, so I am going to try to do an old-fashioned vote. Steven?

Steven Lane
I am looking at the tab on the website, draft USCDI clinical notes, and the way it is phrased there is "at minimum," and then they specify a LOINC code, and I think what is being proposed is changing those words "at minimum" to "for example," just to clarify that.

Sarah DeSilvey
Correct. But then, there was a conversation about whether putting "for example" aligns with the intent of the question, and then, there was another question about whether "for example" would have to be changed to all different note types, correct?

Steven Lane
Yes. Whatever change we make, we should make for all the note types.

Hans Buitendijk
And if changing to "for example" now in USCDI allows for the process, as we learned with the IG, was it actually the correct one to use or was it something else, based on how it goes? Based on the discussions over the last couple of years, it has been a challenge to recognize how much we are tied to this or how much we could really consider variation, but if there is an opportunity that we know, if we come to a different conclusion, it can be updated in USCDI with an updated example or an actual firm one that now is definitely settled. I think that helps because it also gives clarity to the process because having been part of that process as well, it is helpful to be that clear in the flexibility that you have. Otherwise, the discussions are not easy.

Sarah DeSilvey
Thank you, and I appreciate that Ricky is raising his hand, because I was going to call on him anyway. Ricky, what are your thoughts on arriving here?

Ricky Bloomfield
I just want to make sure I understand what we are describing. I know there was a discussion around changing the language of US CORE from saying "at minimum" to "for example," and I actually think that would be a huge regression and a big problem if we changed it to "for example" in the US CORE guide. I thought we were just discussing "for example" for our guidance that we would share for the group that would be developing the updates to US CORE. The reason I say that is because when it says "at minimum" in US CORE, it is not referring to that LOINC code at minimum, it is referring to "at minimum, these eight note types should be required to be shared by the FHIR servers," and I think that is a really important distinction because I think it could be really problematic from an interoperability perspective if we gave these servers the ability to choose whatever LOINC code we wanted, and we were just giving them examples of what to use.

I think there has been a lot of benefit in having a prescribed LOINC code for a discharge summary or a history and physical so that you can count on getting that note type with a specific code, which makes the downstream use cases much, much easier. I just want to make sure we are talking about the same thing when we say "at minimum." I think "at minimum" would actually be very confusing language in our guidance if we were to share that because the context is lost in terms of how it is used in US CORE, where it is actually referring to "at minimum, these eight note types," not "at minimum, this LOINC code," if that makes sense. I am happy to have a side conversation, and we can dig into this more if there is confusion, but this is an important point. I do not know if the time in this meeting is best used by digging into these details.

Sarah DeSilvey

I think that clarification is exactly what we need to do, so I think we are actually only talking about applying to our recommendation with reference to USCDI, and we are not talking about US CORE, as I think Hans stated in his explanation. Is that correct? Hans, that was what you wrote.

Hans Buitendijk
That would be. I completely agree with Ricky that once we get to FHIR US CORE and C-CDA, we must know the specific LOINC code and the rest around it, but at this stage of USCDI to IG locking in a LOINC code, either we need to have a discussion here on which one is the right one in light of the challenges that we run into, or we need to leave the flexibility for the IG to resolve it, and then update an example accordingly or otherwise. But in the end, we must have specificity, or it will not work.

Sarah DeSilvey
Okay, I am going to try to synthesize. Al, can you just weigh in with whether you feel like the concept we are discussing makes sense to you from an ONC perspective?

Al Taylor
I have heard a number of different potential recommendations being made. The exact phrasing of it is up to the workgroup. I think that specific recommendations that I have heard include, but are not limited to, removing the LOINC code and changing the language from "minimum" to "examples." Those are a couple specific ones that I have heard, and I may have missed some, but whatever specific details are requested by the workgroup should go into those recommendations as opposed to a broader, vaguer concept of reducing ambiguity or increasing clarity. Those are not things we can actually act on, unless there is a specific area of ambiguity or specific area of confusion that should be reflected in the recommendation.

Sarah DeSilvey
Okay, I am going to try to synthesize the recommendation in parts. Much of this discussion applies to other elements, so it is kind of a first challenging conversation that we will apply to other elements. So, can I have a show of hands on the addition of narrative in the definition column, Column D, to clarify that that is the intent of this element? All in favor, please raise your hands just so we can see.

Mark Savage
Sarah, I would add that it is "at this time."

Sarah DeSilvey
"At this time"?

Mark Savage
Yes. You said "to narrative." We are just recognizing that that is the current state of development of USCDI.

Sarah DeSilvey
Correct, okay. And then, are there any opposed to adding narrative in the definition? I am going to give some time for hands to come down. So, we have a couple opposed. Just to make sure, Pooja and Hans, am I clearly documenting you as not agreeing with the addition of narrative?

Pooja Babbrah

Sorry, I think mine was delayed. I agree with having it in there. I am just going through security.

Sarah DeSilvey
That is why I called you out. Okay, we all agree on that, fantastic. And then, I hear us all agreeing that it is a critical element. I am not even querying on that, but maybe I should. I just want to dive down into what is in Column H. I hear a few different approaches there, and I want to lean into them. I am going to lay them out. We have removal of the LOINC code altogether, we have a change from "at a minimum" only in reference to USCDI, not talking about US CORE, to "example" or "e.g.", and then we have leaving it as is with "at minimum." First of all, do those seem like the three options we are talking about? I see no objections. Again, the three things are removing the LOINC code altogether, which applies to many different concepts, change to "example," or leave "at minimum," understanding that each of these elements has implications and guidance that we are going to have to include in documentation in the transmittal letter to describe why we did it. So, for removal of LOINC code altogether, raise your hands please.

Christina Caraballo
Sarah, this is Christina. Before we go, I think there is still a little bit of question around being able to vote for those based on whether we agree this specific LOINC code makes sense.

Sarah DeSilvey
Okay. Can you talk more about that?

Christina Caraballo
I am hearing different rationale for making this "at minimum" or "as an example," and it seems like people agree that we need to have clearer direction, so, having a LOINC code pointed to makes sense. However, there is concern with how US CORE is updated, so where is this specific LOINC code in the process, and why did ONC point to this LOINC code? So, my question is more around this specific LOINC code as opposed to whether we have a LOINC code as a minimum or an example. Does that make sense?

Sarah DeSilvey
Yes, you are wondering what the origin of this particular LOINC code as the standard was, correct? Is that what I hear you saying?

Christina Caraballo
Yes. Do we have concern that this LOINC code would not be used with US CORE, C-CDA, or other…?

Sarah DeSilvey
I believed Hans kind of covered that because it is actually being used for multiple purposes. Can anyone answer Christina's question? I am assuming Pooja still has her hand up because she is in security, unless I am wrong. Pooja, do you have a thought, or are you going through security? I am going to assume she is going through security. Hans?

Hans Buitendijk
Generally, what you see with document types in LOINC, which who knows how many there are, is that they are currently different, right or wrong, which we think is confusing, for different purposes, for narrative and for documents. So, for emergency, the LOINC code that is being expressed there generally covers the topic

of emergency department documentation very well to describe that state, but differentiating between a narrative version of that versus everything fully structured together would be confusing if you used the same LOINC code to try to express it. That is where the crux of this issue is around clinical notes. So, this is a reasonable one to think about, but to already put it in USCDI as a definitive minimum that cannot change when you go forward because it will be a hard one to go back to USCDI update is where the challenge is. It gives less opportunity to resolve that issue that we have, how to manage narrative versus full documents.

Sarah DeSilvey
Steven?

Steven Lane
Just to be clear, Hans, your concern applies to all of the clinical note LOINC codes, right? Listening to Christina, I thought you were raising the concern specific to this clinical note type LOINC code, but the issue is generic across all of them.

Hans Buitendijk
It is across all of them because the issue happens across all of them. The same LOINC code is used to express the narrative as well as the full document, and that is what is confusing.

Sarah DeSilvey
Have we had sufficient conversation on the matter at hand to proceed to some kind of assessment of how to proceed? Do we feel like anyone needs further conversation before we move? Raj?

Raj Dash
I just have a quick comment. I think the best thing is to probably defer to implementation guides, where the subject matter experts in that area spend a lot of time identifying the appropriate coding for different parts of the report. This seems like a fine code to me, and there is a benefit in everyone agreeing to use the same code, but we just need to recognize that different EHR systems and software may structure the report differently, and trying to figure out what the best single minimum code is at the outset may have some value in terms of data aggregation abilities, but one of the criticisms of LOINC has always been that folks pick different codes, and sometimes it is the wrong code, and it is not picked consistently.

I think we may be forcing that situation to occur if we mandate that single LOINC code as opposed to deferring to an implementation guide where it is clearly spelled out what part of a report, whether structured or unstructured, represents and which code to use. If we say the supporting standard is HL7 CDA, that has a mixture of SNOMED CT and LOINC codes for different parts of emergency services reports, all variants and renditions of it that exist out in the space, so I think it is just very hard to predict the unforeseen consequences of stipulating a single code, even if we say it clarifies a narrative part of the emergency department report.

Sarah DeSilvey
Raj, can I ask if changing it to “example” resolves that concern for you, as opposed to “at minimum”?

Raj Dash

When you put in “example” and you put in a single code, I have a feeling folks would have a tendency to use it.

Sarah DeSilvey
Yes, which may be of assistance as the ecosystem works it out within implementation guides, but that is correct. Mark?

Steven Eichner
This is Steve. Just to interject quickly, looking at a minimum LOINC code seems a little peculiar to me. That would imply there was a maximum as well, just from a logical perspective. If you are saying “minimum,” what becomes your alternative? I do not think you can say anything except for an example, since LOINC codes are really not stratified.

Sarah DeSilvey
Thank you, Ike. Mark?

Mark Savage
This may be too broad and general a question, but I am thinking about the implications for interoperability. We have made progress when we have gotten to specifying minimums, like FHIR R4, and I am wondering if anybody has an opinion about what it means to start taking out references, even as an example, to codes that may help get people toward commonality. Thanks.

Sarah DeSilvey
It looks like both Hans and Ricky are weighing in here. Hans?

Hans Buitendijk
Mark, I would say that minimums are extremely important to have a basis for interoperability. The question is not whether we need minimums, but at what point in time can we establish minimums? I would argue that at this point of the conversation of USCDI, the scope, the outline, drilling down into the IGs and consequences, if you query for the data, is it okay to have the same LOINC codes or not? What we are seeing is that the timing of when you set the minimum is mostly at question here, not that we need to have a minimum, but at this point, if we set it now and USCDI, when stated like this, is unchangeable after we have learned what is happening in the IG development and possibly subsequently thereafter, which may make a year or two before it is implemented and we actually see how it goes, that is the part that we have to be careful about because in the meantime, what happens is there is already a demonstrable gap between what the USCDI could be and can be reasonably interpreted as to what you expect it to do and what the actual implementation guides are telling you what you actually are supposed to do.

That is what we are trying to manage, to make that gap as small as possible so there is no confusion around what is expected, so no matter which one you read, you have a good understanding and end up in the same spot. It is more about the timing of when we set its minimum versus when we need a minimum. We need a minimum, but today, in the first round, that seems too early.

Sarah DeSilvey

Again, just for the point of hoping to keep new members up to date, that kind of statement with Mark's concern and Hans's question is often conveyed in the text of our recommendation to HITAC. Ricky?

Ricky Bloomfield
This is a great conversation. I would just agree with everything Hans said, and I think that overall, we are actually more in alignment than we think we are, and I think that is a good thing. At the end of the day, I think if you were to ask everyone in this group if our ultimate goal is to have a single LOINC code or at least very specific guidance around a LOINC code in USCDI, US CORE, and C-CDA, at the end of the day, once everything is done, once US CORE is published, once the C-CDA guidance is published, I think we would all say yes, we want that to be very specific, and I think what we are saying right now is that we just do not need to make all these decisions right now in this meeting or as part of our report because we do not have all the experts at the table right now that would need to decide which exact LOINC code to use, and I think that makes sense.

So, I had proposed above that we include in our guidance something to the effect of "Can we ask the modeling groups to 'select' the appropriate LOINC code?" I do think the "at minimum" language in our guidance is confusing because there is not really the same type of hierarchy here, where "at a minimum" would make sense. If we want to give an example, that is fine. I think there is some risk that they might think that is the code they have to use, but I honestly do not think that will happen. I think these groups know how we work, they have done this before, and they will do the right thing, but I do think the "at minimum" language here is confusing, and we should remove that and use "for example" or something similar.

Sarah DeSilvey
Ricky, thank you. Al, and then, Steven has an example in the chat of where to place the "e.g." if we are using it, but I want to back to it. Al?

Al Taylor
I just wanted to say that historically, when we first came up with clinical notes, we picked the "at minimum" code based on what the Argonaut Project had defined as an acceptable minimum note type, and following that along, we chose what we believed to be an appropriate "at minimum" note because, with the exception of the surgical operative note, which Argonaut does define, we selected what we thought was an appropriate minimum note, high-level note, and emergency department note, should that particular code not be acceptable as they developed and added that to the clinical note types, then if, for some reason, that was not an appropriate note to use, we would certainly update USCDI in the next version to reflect that new note, and likely change the test guidance and test method to support using whatever note is deemed to be more appropriate.

Sarah DeSilvey
Can you answer Ricky's comment in the chat about the definition of "at minimum"? Ricky has a comment directly responding to what you are saying that might resolve both. Do you see it?

Al Taylor
He is right. We do not define "at minimum" in USCDI, but what we mean by "at minimum" is that this is the context of narrative we are looking to get under this within the data element of whatever the data element

name is. Since that previously had aligned with the note types that Argonaut defined and then led to the US CORE document reference inclusion, we felt that the minimum was just really to define the context to align with the way that Argonaut/US CORE has done it in the past. If there is a request to clarify the definition of it, "minimum" is certainly something ONC will look at, but we used the same language that Argonaut and US CORE use, and we felt like that was sufficient, but if there is a request for a better definition of "at minimum," by all means, send it our way.

Sarah DeSilvey
So, in my mind, if that is the intent of "at minimum," it seems to represent the same thing as "e.g." in implementation, as an example. Am I incorrect? If it is context and not mandate, then it is an example, and ONC's intent is suggestive already.

Al Taylor
I guess depending on how you look at it, you could think of it as an example or as a minimum standard. When we say "at minimum," it has to be able at least to capture narrative that is identified by that particular LOINC code. That is what we mean by "at minimum." It must be able to exchange narrative content that is identified by the LOINC code, if that makes sense. I think that that makes sense. That is probably a clearer definition than we have ever given before.

Sarah DeSilvey
That does make a lot of sense, and that seems to allow for the evolution and refinement that Ricky and Hans are speaking to as opposed to being what some might interpret "at minimum" meaning, which is that you must use this. Does anyone have a commentary? If ONC defines "at minimum" with that intent, as we have heard so clearly stated in this visit, does that meet the concerns of the members who wanted to have an "example" statement as opposed to an "at minimum" statement? Can I hear from Hans and Ricky?

Hans Buitendijk
Sarah, I think this discussion has been very good. Right now, we are starting to really figure out how to best phrase our recommendation, which may include that we want to reaffirm what Al just said, including a clarification of "at minimum" meaning this, and if it means that, then "at minimum" can stay in there. We have to keep in mind that "at minimum" is not limited to just this place. "At minimum" is used all over USCDI, so we need to recognize that the moment we change the definition of that, it would apply to everything. Is that really correct everywhere? I would argue that in some places, "at minimum" is absolutely correct, and that from the start, it is clear what it is. In this case, it is a challenge because we have a narrative and an actual document to distinguish that there is an interest to not use the same LOINC code for that. That is where locking in on an "at minimum" with that definition would not be enough.

So, I think we can work on a draft recommendation, take everything that was discussed today in mind, and then come back and say, "Did we capture that? Is there enough guidance for ONC to make that real or not?", and then see whether or not we met that goal before we finalize that. I would be hard pressed to say we have got it and we have the text.

Sarah DeSilvey
Especially right now, given we just arrived at an understanding of what "at minimum" means. What I am going to capture as an action item is, given there is a definition of ONC approaches to standards here,

which is the conversation on “at minimum,” which needs to be clarified, and then, if we all agree and understand that, that will guide our recommendation, building right off of what you said, since this also applies to the surgical operation note, I am going to recommend that ONC try to draft what is on their side for the definition, which is a definition of what “at minimum” means that we can all look at, see, and digest, and then we have someone who volunteers to start working on the draft recommendation from us, which would be in Column L, and then we come back next meeting and discuss it further. Again, it seems like this conversation could apply both to emergency department note and operative note. Does that sound like a good plan? Is someone willing to make an attempt at the recommendation for emergency department note? I am assuming ONC will take a lead on defining “at minimum” so we all can understand it.

Ricky Bloomfield
This is Ricky. I am happy to take a pass at some short language there that I can put in Column L.

Sarah DeSilvey
Yes, and I want to know what Hans is saying. We understand there are implications to defining “at minimum,” and it might have implications across USCDI. Thank you, Ricky, for taking the lead on that. Rochelle?

Rochelle Prosser
Ricky, I would like to offer my assistance to you on that if you would like.

Ricky Bloomfield
Sure, that is great. I can add something to the column, and you can comment on it there, so we can just do that publicly if you are okay with that.

Rochelle Prosser
Yes, that is fine.

Sarah DeSilvey
Hans is offering to help as well. I feel like what Hans raised originally is correct, that given that we are talking about implementation, the recommendation we have regarding this, which is implementation- and refinement-focused, will likely apply to the surgical note too, or it could possibly apply to the surgical note as well. Hans?

Hans Buitendijk
I agree, and I have one general comment as we frame the language. Al might be able to help clarify that. We have understood that USCDI is not only used to inform the implementation guides for FHIR US CORE and C-CDA, but it is used in other programs as well, and in that context, in our phrasing, we always need to keep in mind whether USCDI can be read on its own without the benefit of the IGs and still lead you to the same answer if you were to read the IGs, because we would like to make sure that no matter where the interpretation about the same data is, wherever it is being exchanged, that we actually land on the same expectation. So, that is just a general consideration, unless that changed, and maybe Al can clarify it, that we cannot rely on the IGs being available to everybody. If you are certified HIT, you would certainly be familiar with it, but if you are not, you would not have it, and you would still need to come to the same conclusion.

Al Taylor
Sarah, can I address that question?

Sarah DeSilvey
Please.

Al Taylor
I agree with Hans that, to a certain extent, USCDI should stand alone, especially if somebody is using it for purposes other than certified EHR technology or health IT technology. We have yet to have a comment to that effect, that it is too vague to implement, too vague to understand, but that does not mean that that comment may not come up some time in the future.

Sarah DeSilvey
And then, I see additional comments from Christina, as we are talking a lot about process this year, that it would be helpful for ONC to provide text on they arrive at a specific LOINC reference for that "at minimum." That might be part of what ONC brings back. We have been talking a little bit about that element today. I do want to get to a summary, just so people can see the USCDI v.2 elements, and then we have a little bit of time for public comment, and then I want to make sure that, if there is anything Al wants to mention in our last agenda item before public comment, we can get to that as well. Again, this is a very fruitful conversation, and it is really helpful for figuring out implications of what needs to happen going forward. There are so many brilliant people on the call. Ricky, any final thoughts before we move on?

Ricky Bloomfield
I was going to say briefly that there is one difference between the emergency department note and the surgical op note, which is that the surgical op note actually does have a LOINC code already included in existing guidance, it is just not required. It is only suggested. So, that is a case where there is more specificity currently available, whereas for ED note, there is nothing in current guidance.

Al Taylor
Ricky, that is how we picked that note, for that particular LOINC code for operative note, and what we selected for the ED note LOINC code was what we felt to be the most generic ED code note type, but should that not be the case, according to whoever the experts are, certainly the ones that are drafting US CORE and C-CDA, we would be willing to adjust and find a more appropriate LOINC code to represent that for the "at minimum" standard.

Ricky Bloomfield
Great, thanks.

Sarah DeSilvey
That is helpful, especially when we are considering the same term, "at minimum," in both instances. All right, so, we had a very in-depth conversation, though not on whether the element warrants inclusion. We all settled on that. We had a conversation on revising the definition to more clearly reflect the intent, and lots of conversation on the process and the evolution of applying applicable vocab standards to any of the elements, given considerations of implementation and, of course, other standards in the ecosystem. So,

we have a group of people drafting the example recommendation based on this conversation, we have ONC coming back with a conversation on what "at minimum" means, we are going to be considering implications for applying that "at minimum" across other elements of the USCDI, and then we will come back and discuss this again next week.

Have I captured the conversation well enough? Is there anything that I missed in that summary of what we did today before we move on to a quick highlight? I just want people to see the v.2 elements before we move on. Does that sound like where we are? I am going to have silence be a yes. For people who did not engage in the spreadsheet, Al, can we quickly scroll down? I just want people to see how people are populating the v.2 elements all the way down.

Al Taylor
Do you mean the Level 2 data elements?

Sarah DeSilvey
Sorry, yes, my apologies. I mean the Level 2 elements. You can see that it starts on Row 18, so we have members leading the submission, so in Column D, we have workgroup members owning the submission, we have representative data classes and elements, working definitions, discussion on standards, and then you can see all the other elements apply. This is a great template and example. I want to thank Mark for often leading the charge here. Thank you so much for putting those Level 2 elements in there. I just want people to understand that so that if they want to do that in between now and the next meeting, they can. Al, the next thing on the agenda before we go to public comment was to talk about disposition of the working document, but I think we might have covered that. Is there anything else you want to discuss in that element before we move on?

Al Taylor
Sorry, that particular slide references what I have been doing driving this. After we sent homework out last week, we did get some responses on some data elements or sets that should be discussed separately, and if you want to highlight those, we can confirm that we will get the ball rolling on getting these scheduled and getting the right people in line. Do you want to go there yet, or try and dig into one of these other elements?

Sarah DeSilvey
This is the last element, and that was what Mark's comment was on as well. We did get recommendations for subject matter experts regarding advance directives, and we did get recommendations on bringing back Gender Harmony to rediscuss the three elements in the original submission, sex parameter for clinical use, pronouns, and name. If we go to that row, if we can go across to the row that has the SME suggestions, I think it is in Column L.

Al Taylor
Sorry, are we starting with advance directive observations?

Sarah DeSilvey
No, I just wanted people to see the SME recommendations that are currently populating Column L. So, we had a SME recommendation regarding bringing somebody in regarding differentiating or possibly adding in medication to immunization lot number, and we have members of FDA on here, and we have our pharmacy

workgroup friends, so maybe there should be consideration for that. Any commentary on that before I move on? Again, this is regarding Mark.

Mark Savage
I will throw out the question that was in my mind, which was do we need a SME? Somebody may offer to bring one, but do we need it, given the amount of time it raises? I thought it made sense to do one for sex parameter, and it makes sense to do one for care plan, but I was not sure whether we needed one for author. That is going to take up a lot of the meeting.

Sarah DeSilvey
It is going to take up a lot of the meeting. That is a good question to frame it. Do we feel like we need a subject matter to expert to help us guide whether we are to apply lot number to medications and not just immunizations, again, stating very clearly that this was an ONC question? Would that be helpful? Without a clear yes, I am going to state… Sometimes that comes up in conversation, so I am going to keep on going. What about the author question? Do we feel like it would be helpful to have a SME come and discuss the author element? I do not believe that was part of the email exchange as yet. Again, we have advance directive and Gender Harmony coming back for those other ones here. For author, do we feel like it would be helpful to have SME guidance?

Mark Savage
Maybe that is a good question for ONC, in my mind, because they did ask a question about it. Does ONC think that a SME presentation would be helpful?

Al Taylor
Well, possibly. If the workgroup has enough subject matter expertise that it can speak to those questions and answer them, whether it is some of our health IT developers that are on the call, like Hans and others, to see what progress has been made since USCDI v.1 came out without author, that is one of the specific questions. We have already heard from some of the members of the workgroup that indicate that the author role component or the author role concept is a valuable addition, but if the workgroup feels like there is enough collective wisdom and experience to address those specific questions, maybe Mark is right, and an SME presentation is not needed, just a discussion amongst those people with enough expertise.

Sarah DeSilvey
So, what I hear is that this is similar to lot number. We should just proceed with the conversation, and as we do sometimes, let's identify whether we need additional expertise if we hit sticky problems we cannot resolve. Does that sound good? However, we are inviting and seeking subject matter experts specifically for the Gender Harmony elements and for advance directive, based on the emails. Does that sound good? Those are the only two specific SMEs we have heard so far. Al, am I missing anybody?

Al Taylor
Advance directive observation orders…

Sarah DeSilvey
Oh, and care plan.

Al Taylor
Yes, Mark suggested care plan, and then, SPCU, pronouns, and name to use were the other ones.

Steven Lane
There are certainly a number of them further down on the spreadsheet where SME has been recommended.

Al Taylor
Or as some Level 2 data elements.

Sarah DeSilvey
Oh yes, I can see that Aaron has offered. My apologies. So, we have care plan captured, we have advance directive, we have the Gender Harmony elements, which are all three, and then, we also have Aaron's clear recommendation for SMEs in the substance food data element, and then we have the health insurance elements. I think that captures it. And so, if you have specific guidance about who those SMEs should be, please let us know. We do need to get those subject matter experts enlisted. I work very closely with Rob and Carol, so I can reach out to them, Mark, or you can, however you wish, regarding the Gender Harmony element.

Mark Savage
I do not care. I just want clarity, not ambiguity.

Sarah DeSilvey
I am happy to take the lead. Rob is working very closely with that right now.

Mark Savage
You can give them my contact, and I can work with him to bring it to the committee.

Sarah DeSilvey
Fantastic, okay. Any additional recommendations before we go to public comment? We have one more minute.

Ricky Bloomfield
Sarah, I am just noting Al's comment there that it will come from ONC.

Sarah DeSilvey
Correct. I saw that. All right, and now, after a very robust conversation, expect the homework this week to be similar to last week's. Seth, we are moving back to you for public comment, I believe.

Public Comment (01:24:08)

Seth Pazinski
All right, thank you, Sarah. At this point, we are going to transition to open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the raise hand function, which is located on the Zoom toolbar at the bottom of your screen. If you are just participating by phone only today, you can press *9 to raise your hand, and then, once called upon, press *6 to mute and unmute your line. We will

give folks a minute to queue up. Okay, there are no comments. I am not seeing any hands raised either, so that will conclude our public comments, and I will transition it back to Sarah and Ike to close us out.

Sarah DeSilvey
Ike, do you want to lead in the closeout?

Steven Eichner
Sure. Thank you all for contributing actively in today's meeting. This is an example of the wonderful things we can do with collaboration. We have a few more weeks to go through the rest of the elements, and I am looking forward to it.

Sarah DeSilvey
Exactly, we are looking forward to it, and I want to make a specific callout to any newer members. If you feel like you need any help in orienting to the work or participating in the conversation, we want to make sure we include all of your wisdom in our work, so, just reach out, and we are going to be happy to try to rev you along. I was new last year too, so I understand how it feels. Seth, I believe we are ready to move to adjournment.

Seth Pazinski
All right. Well, thank you, everyone. We will officially adjourn the meeting, and we look forward to talking with you all next week. Just be on the lookout for the homework message, which should be coming out tomorrow. Thanks, everybody.

Sarah DeSilvey
Thank you, friends.

Adjourn (01:26:20)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Sarah DeSilvey: noted, Steven! that seems wise

Kikelomo Oshunkentan: Yes, it is clear and extremely helpful to have your lens, Hans. Thank you!

Mark Savage: Thanks for that clarification, Al. Narrative only.

Mark Savage: But not sure why. Do we have two separate data elements: ED note--narrative, and ED note--structured. That will confuse?

Sarah DeSilvey: the aligned loinc codes are "ANY ROLE" in definition

Rochelle Prosser: Thank you Sarah That helps. I guess this will help with add on codes for additional testing that are completed late after the sample is addressed and there is a need for further or broader view. I can understand the challenges for coalescing this information.

Sarah DeSilvey: Aaron, good question!

Katrina Miller Parrish: Agree for recommendation to LOINC to update for structured vs unstructured notes, where needed.

Rochelle Prosser: @Raj +1

Hans Buitendijk: @Aaron: Yes. We have the challenge with all of them.

Hans Buitendijk: As USCDI is meant to be the place to define the vocabulary as well and it is indicated this should be resolved in the IGs that a LOINC code is not specified in the USCDI.

Ricky Bloomfield: https://loinc.org/11504-8.html/

Steven Eichner: Clarifying whether the note is clinician-generated or AI-generated may b helpful, but may also be complicated, especially if AI is used to generate a base note for clinician review/approval. At what point does the note become auto-generated?

Rochelle Prosser: Thank you @Ricky

Katrina Miller Parrish: Thanks Ricky - we see the narrative subtypes here but I wonder how the summary narrative would be represented. Perhaps still could be opportunity.

Hans Buitendijk: As in C-CDA it is addressed through Documents, the ambiguities become clear. E.g., a query using FHIR US Core would yield for the same LOINC code both a narrative and the fully structured documents.

Rochelle Prosser: I am very concerned about removing the loinc code. Can we have both?

Pooja Babbrah: I agree with Steven. We can use e.g

Ricky Bloomfield: @Katrina, the narrative summary format is typically left up to the IT vendor today (for US Core). Those notes can be shared as PDFs, free text, HTML, etc.

Naresh Sundar Rajan: +1 for supporting LOINC code to be present. Truly guides us from an implementation standpoint. I do like Sarah comment as providing “e.g. LOINC” until we stabilize.

Steven Lane: Also, LOINC codes have been specified for other specific Clinical Notes since USCDI v1.

Ricky Bloomfield: One of the very important goals here is to enable data to flow with as little friction as possible. Requiring additional structure where none typically exists today can create additional hurdles for implementation.

Rochelle Prosser: +1

Ricky Bloomfield: We can be careful with examples, but the ultimate goal should be for the guidance to include a very specific LOINC code to ensure interoperability.

Rochelle Prosser: @Hans +1

Steven Lane: If we embrace the concept of “e.g., LOINC code XXXXX-X”, this change should be made for ALL specified Clinical Note data elements included in v5.

Mark Savage: Is this a place where something like preamble guidance to USCDI mentions "e.g., LOINC code", but actual text of data element does not? (Similar to regs.)

Katrina Miller Parrish: @Ricky - Thanks - Opportunity to clarify and standardize!

Hans Buitendijk: @Steven: This discussion has to be applied to all Clinical Notes as the challenge exists with all.

Steven Lane: E.g., the existing data element Procedure Note https://www.healthit.gov/isa/taxonomy/term/631/uscdi-v1 specifies Procedure Note (LOINC® code 28570-0).

Hans Buitendijk: The need is becoming more clear as users are challenged with querying and getting what they expect. So this is a learning process from USCDI to IGs and from IGs to actual use.

Katrina Miller Parrish: Yes, yes

Mark Savage: Think we're hearing, but key factors head in different directions.

Naresh Sundar Rajan: +1 😳

Rochelle Prosser: yes

Albert Taylor: @steven, to clarify Procedure note doesn't specify that loinc code, to provides "at a minimum" that loinc code.

Zeynep Sumer-King: Yes

Christina Caraballo: +1 for supporting min LOINC code, especially based on Al's comments.

Rochelle Prosser: Correct

Steven Lane: This is the page that uses the terminology “at minimum”: https://www.healthit.gov/isa/uscdi-data-class/clinical-notes#draft-uscdi-v5

Steven Lane: Note that the “at minimum” language was added in USCDI v3.

Hans Buitendijk: +1 Raj

Hans Buitendijk: Agreed with Ricky it is just for USCDI at this point, while in FHIR US Core it must be resolved with a specific LOINC code. It just may not be the one considered by USCDI at this initial stage.

Kikelomo Oshunkentan: Helpful explanation, Ricky. Thanks!

Rochelle Prosser: Thank -you for that clarification in the C-CDA

Rochelle Prosser: @Raj +1

Mark Savage: If we get specific about "narrative," should we still articulate an expectation of including structured data in notes when we can? Telegraphing direction and expectations, so no one misunderstands this delimitation to "narrative"?

Hans Buitendijk: Minimum is a hard requirement to use at least this one. Example has the opportunity to arrive at another one. Either way, we may end up with another LOINC for narrative vs. full document and once settled in the IG definition (FHIR US Core and C-CDA) in which case it would behoove USCDI to be updated to reflect what that final disposition through the IG is.

Rochelle Prosser: Often I have found in Emergency notes the additional information within the Lionc code reimbursement and accuracy if found in having flexibility in the narrative notes.

Naresh Sundar Rajan: Just to clarify again, Ricky's comment was more aligned to providing for examples, rather than changing "at minimum" language. As implementors, for example act as a guide, but "at minimum" should not be changed, as it sets minimum expectation.

Katrina Miller Parrish: Still concern on the context of "at min"

Hans Buitendijk: At minimum in the USCDI text is premature until the IGs have finalized this and are considered the place to resolve whether the same LOINC code should be used for narrative and full document.

Hans Buitendijk: Suggest that some craft specific language for proposal that leaves the assignment of the specific LOINC code to the IGs.

Katrina Miller Parrish: Agree @Hans

Jim Jirjis: so then at minimum seems to make sense

Ricky Bloomfield: Can we just provide guidance for the modeling groups to "select the appropriate LOINC code"?

Naresh Sundar Rajan: Would it make sense to roll up to the LOINC groups at the minimum?

Naresh Sundar Rajan: For example, LG41825-7

Hans Buitendijk: @Jim: minimum at this stage when the focus is only on narrative is not helpful. Updating USCDI when that has been settled.

Hans Buitendijk: +1 Ricky at this phase.

Albert Taylor: @naresh one problem with that idea, which ONC thought of as we draft new data elements, is the LG codes are trial codes, not published codes

Naresh Sundar Rajan: @Al, that makes sense.

Steven Lane: If we are to add “E.g.,” suggest that we place this before the text “Logical Observation Identifiers Names and Codes (LOINC) version 2.76”, as opposed to replacing the text “At minimum:” in front of “Emergency Department Note (LOINCcode 34111-5)”.

Katrina Miller Parrish: When a LOINC is chosen for the note, is the header code and subcodes used?

Keith E. Campbell: The terminologies are more dynamic than a static standard…

Keith E. Campbell: I think we should plan toward making use of the dynamic nature of terminology.

Keith E. Campbell: If you want a “static LOINC code”, you could just create a static FHIR resource in its place.

Keith E. Campbell: Specifying a single LOINC code in USCDI seems overly static, and odd.

Ricky Bloomfield: If that’s the case, we just need to define what “at minimum” means here. You’re saying that it means the same thing as it means in US Core today.

Hans Buitendijk: In this case we need to clarify that it is o.k. to land on another code and that we can split a code for narrative summary vs. document (which would include that narrative summary). At minimum once published in USCDI v5 requires certified HIT to support that code, even though the IG may deem it not the correct one.

Ricky Bloomfield: That makes sense. You’re saying that “at minimum” means that it should be added to the “at minimum” list of LOINC codes that already exist in US Core.

Ricky Bloomfield: Agree. It’s clearly throwing people off who don’t have the prior Argonaut/US Core context.

Hans Buitendijk: We have been reminded also that USCDI is used outside of the certification program, so the consumers of USCDI would not have the benefit of the IGs specifying something different than what USCDI would imply.

Ricky Bloomfield: This is what US Core says today:

Ricky Bloomfield: This implementation guide defines how systems exchange eight “Common Clinical Notes” and three DiagnosticReport categories.

Servers SHALL support, at minimum, these eight “Common Clinical Notes”:

Steven Lane: Perhaps someone could type the recommended text into column L so we can see it.

Naresh Sundar Rajan: Agree, with Hans, this is great conversation, as it gives a great clarity on conditionality of the data elements.

Hans Buitendijk: Agreed that all at once for all is "dangerous". This one has a specific challenge we need to resolve. Many at minimum-s that should not change in its meaning.

Hans Buitendijk: Happy to work with Ricky.

Naresh Sundar Rajan: Happy to help on this item @Ricky.

Mark Savage: Agree with Hans's comment to check/recommend data element by data element, not apply across the board.

Christina Caraballo: It might be helpful for ONC to provide insight into on how they determine adding a specific LOINC reference as an "at minimum"? Al did give an overview on this earlier. It could help guide future discussion too.

Hans Buitendijk: The issue would not be vagueness, but ambiguity that leads to a different interpretation than after reading the IGs. There are clear examples of where just reading the USCDI would yield a different scope than reading the IGs.

Naresh Sundar Rajan: Not to over extend this topic, while LOINC is in its beta stage on Groups, would it make sense for a note in recommendation for future implementation?

Katrina Miller Parrish: What I called the "header code"...

Hans Buitendijk: Groups may have great value to enable queries to encompass "like" concepts. that still would require that the granular codes can recognize the difference between narrative and document, while USCDI then indeed can indicate "something in this group" while leaving it to the IG to identify the specific LOINC code for the specific topic at hand.

Mark Savage: Will we have time to discuss what elements need SMEs? Takes time to prepare.

Katrina Miller Parrish: For Author - if there is a SME in this group - that is fine with me!

Katrina Miller Parrish: 1. How is author authenticated, 2. what are the choices for role?

Mark Savage: Care plan.

Hans Buitendijk: The last is key as we also need to understand author vs. informant on specific data where it involves PGHD, ADI, Preferences, etc.

Mark Savage: Who contacts Gender Harmony Project for presentation? I can if you wish.

Albert Taylor: ONC will send an official invite on behalf of the ISWG.

Albert Taylor: or can send the official invite

Katrina Miller Parrish: TY!

Mark Savage: I'm available for reach out.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

IS WG Webpage
IS WG - February 6, 2024, Meeting Webpage

Meeting transcript approved by Wendy Noboa, HITAC DFO, on 2/12/2024.