Transcript

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

February 13, 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
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Jim Jirjis, Centers for Disease Control and Prevention
Hung Luu, Children's Health
Steven Lane, Health Gorilla
Anna McCollister, Individual
Katrina Miller Parrish, Humana Health Insurance
Alex Mugge, Centers for Medicare & Medicaid Services
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

Derek De Young, Epic
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Aaron Neinstein, Notable
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
Welcome, everybody, and good morning. This is our Interoperability Standards Workgroup meeting. I am Seth Pazinski with ONC, and I will be serving as your designated federal officer for today on behalf of Wendy Noboa. I just want to remind everyone that all workgroup meetings are open to the public, and we welcome public feedback throughout the meeting. Members of the public can type their comments in the Zoom chat feature throughout the meeting, or we will have time at the end of the agenda for verbal comments for the public who are interested in taking advantage of that opportunity. With that, I am going to kick off the call with roll call for the workgroup members, so when I call your name, please indicate that you are present. I will start with our cochairs. Sarah DeSilvey?

Sarah DeSilvey
Present.

Seth Pazinski
Steve Eichner?

Steven Eichner
Present, 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.

Seth Pazinski
Hans Buitendijk sent a message that he would be joining late, so we will be looking for him when he joins. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Good morning. Good morning. Christina Caraballo?

Christina Caraballo
Good morning.

Seth Pazinski
Good morning. Grace Cordovano?

Grace Cordovano
Present. Good morning.

Seth Pazinski
Good morning. Raj Dash?

Raj Dash
Good morning.

Seth Pazinski
Good morning. Derek De Young? Lee Fleisher? We got a message that Hannah Galvin will be joining late as well. Let's go to Raj Godavarthi. Jim Jirjis? Steven Lane?

Steven Lane
Good morning.

Seth Pazinski
Good morning. Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
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? Mark Savage?

Mark Savage
Good morning.

Seth Pazinski
Good morning. Alex Mugge? Fil Southerland? Shelly Spiro?

Shelly Spiro
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Is there anyone I missed or that joined late? All right, thank you, everyone. That completes our roll call for the meeting, and now I am going to turn it over to Sarah and Ike for their opening remarks.

Opening Remarks (00:03:24)

Sarah DeSilvey
Welcome, everybody. Good morning. I have no opening remarks other than to say that I am very excited to get into the work today and I look forward to moving some elements or having further discussion to help complete our charge. Ike, anything else?

Steven Eichner
Not much. I just noticed in the chat that we had a couple of people just join, so our workgroup is coming together even more together, but I am excited for the day.

Sarah DeSilvey
Wonderful. Those are the opening remarks, and now on to IS WG charge and timelines. This is our agenda. We are having the general opening remarks, and then we are going to try to do a preliminary review of everything on the spreadsheet to make sure everyone is aware. We are planning our SME attendances, and we are really grateful to all of you who have leaned into identifying SMEs, so thank you for that. If a SME is invited, we are not going to be discussing it until that SME is leading and guiding the conversation. Again, we are hoping to do a really thorough review, so everyone understands what is on the spreadsheet

and further conversations today. Ike, anything else to say about the agenda? It is pretty straightforward. Next slide.

I just want to ground us in the charge before we go through. Again, we do this as a common grounding every single time we gather. The overarching charge is to review and provide recommendations on Draft USCDI v.5. When you break it down, the specific charge is to evaluate Draft USCDI v.5 elements that should be considered for final USCDI v.5 release, and then to elevate, discuss, and add commentary on any Level 2 data classes. Again, I want to make sure everyone sees all those new Level 2s that are added there, and most of them are going to be requiring some level of SME guidance and conversation, but I do want to note that in general, we have perhaps a set of some complexity in our elements, but it is a pretty tidy list of elements to address in our charge, so I think we are going to be able to aim for our final recommendation being delivered on time. Ike, anything else to say on the charge?

Steven Eichner
Not in that space. We did have Anna McCollister and Lee Fleisher join us as well.

Draft USCDI v5 New Data Elements Recommendations & Level 2 Data Elements Recommendations (00:05:53)

Sarah DeSilvey
Welcome. Wonderful. All right, I think we are good on the charge. Can we go to the next slide? We just wanted to discuss some of the elements that we are hoping to move into drafting recommendations, so we did have extensive conversation on emergency department note during the last meeting, and we really want to thank all the commenters who worked. Ricky led the charge, and then Hans commented, and Katrina also added notes, so we are trying to get to a point where we are working on drafting our final recommendations, even just preliminarily, so we can move to a point of delivering that final transmittal letter.

There was a draft final recommendation given for operative note as well, but I do want to note the LOINC element is a little bit different with operative note, as I think it was Ricky who elevated last time as well. Pardon me if I got the name wrong, but it might warrant brief consideration for members to go into the final recommendation and add commentary there, just so we can make sure we can move through. Again, you can always find the recommendations in process in the aligned column on the Google sheet. Anything else? It looks like Al is ready to share when we are there. We just want to make sure everyone knows we are hoping to move these two elements from our open conversation into drafting the final recommendation. Ike, anything else?

Steven Eichner
The information from the discussion can be synthesized into a final recommendation. The workgroup works in a consensus-based process for approving the language, and there are a couple of loops for refinement until we get to a point where everybody is comfortable with the language, and then we will actually approve it and move it into our final version text for forwarding it to HITAC.

Sarah DeSilvey
Thank you so much, Ike. Your audio is a little choppy, so, just to make sure, I think he was trying to make sure everyone understands that our initial recommendations that we are drafting are an iterative consensus

process, and that is really a great place to engage so we can make sure everyone has their perspectives in there. Next slide.

Mark Savage
Sarah, just to confirm, when you say "finalization," it is a movement towards finalization, but we still have time.

Sarah DeSilvey
Thank you, yes, exactly. That is what we are trying to say. So, in order to move toward a final recommendation, what we try to do is put text of a possible final recommendation in that section of the spreadsheet, understanding that it is a consensus and iterative process that will not be truly final until everyone is on board, but it is helpful to have text to respond to just to keep us moving along. Does everyone understand that? Again, you can see that process happening, and we are really grateful to all prior and new members for commenting in that column.

Another thing we want to make sure everyone is aware of is, as I mentioned, even though these elements are on the spreadsheet, because we have identified as an IS WG that we would appreciate SME guidance, these elements are not going to be discussed until the SMEs are able to attend. Again, thank you so much to our friends on the committee who have advised that SMEs attend. Actually, there are a fair number of elements on here that we are going to be discussing today that have additional SME thoughts. These are the initial ones, and again, thank you to our ONC team for reaching out to these individuals. So, we have a cluster of elements that came out of Gender Harmony from Carol and Rob. Mark, thank you for connecting us there. We have advance directive and possible clustering of orders yet to be determined, and then we are working on SMEs for care plan, which is a Level 2 element. All right. Any other questions on this? Aaron, you also had some elements that you added for SME guidance, and we are just thinking through that as well. I just want to note some of your Level 2 elements. Next slide.

I think we are pretty close to getting to the spreadsheet now. Sorry, my apologies. This is a running list that we have to try to help us understand where we are in space and time on the data classes. This is a format we used last year where you can see things that we have discussed, and then you can see things that are finalized, meaning the discussion is fairly complete and we are moving on to fully drafting and feeling comfortable with that final rec. Comments are put in yellow when we have discussed them, and they move to green when we have completed them in prior IS WGs. All right, you can see this, so, again, we are hoping to get through some new data elements and at least have a discussion on them today to keep things rolling. Ike, anything else to say here?

Steven Eichner
No, I think we are good.

Sarah DeSilvey
Great. And then, understanding that some of these are those SME conversations, we will not be discussing them until our SMEs are here, and we will come back with dates on that. Next slide. So, we are almost ready to go to the spreadsheet. I think we just want to get through these slides. So far, these are all the Level 2 elements that have been elevated by members of the IS WG. You can see them at the end. We will see them on the spreadsheet very shortly.

You can see a suggestion for adding health literacy within health status assessments, suggestions for adding specimen collection date and time, and Aaron, this is what I was mentioning prior, allergies and intolerances substance food, family health history, and then, a set of health insurance information elements, coverage, carrier, policy number, Medicare, patient identifier, payer name, plan name, plan identifier, and group name, and then, we had a request for adding maternal SDOH note within clinical notes. Again, we are hoping to get down to those elements shortly in our conversation, and if we need SMEs to help guide us in that, we will reach out and do so. Any other thoughts on these Level 2 elements, again, just to make sure that everyone sees these? All right, next slide.

Ricky Bloomfield
Actually, Sarah, can I ask a quick question? On that last slide there, there were some SME discussion possibilities that may not be needed. Is there anything we need to do now, or are we in a holding pattern?

Sarah DeSilvey
I think we are still waiting. So, in the SME column on these, we have each of these elements, and again, I think this is where Aaron had put in suggestions for SMEs. We just need to figure out which SMEs we would want and then reach out to them. Once we go to the spreadsheet, we can see that very clearly. There is that column where we have tried to encourage people to identify SMEs, and whatever work we can do collectively to get names so we can send invitations would be appreciated.

Ricky Bloomfield
Thank you.

Sarah DeSilvey
Next slide. Al, I think the best place to have a discussion now is on the spreadsheet.

Al Taylor
All right, I am pulling it up now.

Sarah DeSilvey
Thank you, and thank you, Steven, for your commentary on those Level 2 elements.

Al Taylor
All right, you should see it now.

Sarah DeSilvey
Fantastic. Again, we do not have an incredibly long list of data elements in Draft USCDI v.5 compared to last year's, and this is a sense of getting to a point of refinement, so we hopefully do have time to get through them. If we scroll over, I just want to make sure everyone sees the conversation that is happening in the final recommendation. We asked someone to take the lead on drafting the recommendation for emergency department note. Could we move over to that recommendation in process, just so people can see? Great.

So, this is in workgroup discussion, and again, my apologies, it is not the final recommendation, but it is where we are trying to draft it, and you can see that Ricky took the lead on drafting that. Again, this is just orienting for members of the group. Hans did some commentary, and Katrina also added some. I am just making sure that everyone sees that in process. We would love to make sure that that conversation continues here, just so we can keep moving along. If there is anything that needs to be rediscussed, we are here to have that conversation, but we would love to just keep on moving a little bit through the elements, just so we can raise risks in other elements. Grace?

Grace Cordovano
I am just curious. Many of the discussion points are from standards and codes, and I can appreciate all the technicalities that need to go into this. Would there be a benefit of including patient stories or experiences of anyone that is a caregiver or provider for patients for why it is so necessary to include any of these particular elements? That is something that has not been included in these spreadsheets, and even when you go into ONDEC to submit elements or data classes, you do have to provide a narrative as to why it matters, and I feel like there is room for improvement in us capturing why it matters, and I am curious if that would also be helpful in convincing ONC why some of these so strongly should be included moving forward across the finish line. Those are just my two cents.

Sarah DeSilvey
I hear you asking ONC that, so I am going to go to Katrina, and then go to Al. Katrina?

Katrina Miller Parrish
When I am looking at this, I am just trying to figure it out. Is the recommendation a recommendation to ONC or a recommendation for what will be stated in USCDI? I feel like it should be chosen as part of the subsequent data modeling discussions. I am not sure who we are talking to there, so maybe I need to be realigned with exactly who the audience is for this recommendation or the document this terminology is for.

Sarah DeSilvey
That is a really good question. Maybe we can go to Al and have him do an initial response to both Grace's comment and your observation, and then we can try to add thoughts as well. Al?

Al Taylor
First of all, to Grace's question, the justification and rationale statement evidence for adding a data element is really important for data elements that are not already on the Draft v.5 list. The reason that we put it on Draft v.5 is because we think it should be in v.5. I do not think that there is a need to highlight why at least these two data elements are important because ONC is already convinced of that. For data elements that are not on this list, I think the justification, whether it is provided from the patient perspective or any other reason why it is important, is really important to put in the narrative of the recommendation.

To Katrina's question about who the audience is, the workgroup is developing recommendations that will go in a formal transmittal letter from the HITAC to the National Coordinator, so the audience is the National Coordinator for the recommendation. Now, if the recommendations are technical in nature, that is fine. We have had a lot of discussion about changing the codes or changing the definition, maybe changing the examples. All of those are perfectly appropriate technical recommendations, but if it is something more than that change in the examples or the direction of this data element, that can also go in the recommendation.

Katrina Miller Parrish
Thanks.

Sarah DeSilvey
Are we comfortable? So, there is everything in the chat, and what Al's saying, Grace, is that the patient perspective is really critical in justification, especially in the Level 2 elements. We have heard in the chat that if we can, especially with those Level 2 elements, come out with strong recommendations, that really helps from the point of moving things along from Level 2 to the next draft of USCDI, or even the current version of USCDI. And then, we heard Al clarify that the audience is the national coordinator, so we consider that as we are framing our discussion and final recommendations. Grace, that is lovely. Grace is advising that we add the clarifying points in the headers. That is a good thought there.

So, again, we will come back in time to refine the emergency department and operative note elements. Are we okay to move to discussion on the elements now? Can we move along? Ricky, I would like to briefly touch base on the differentiation I think you made in the last meeting between the specificity of the LOINC code for operative note and how it is different from emergency room note because of the existing structure of the operative note. I want to make sure that even if we are considering addressing them in similar fashions, that what you were trying to call to light last meeting is understood and included in the discussion. Ricky, does that make sense?

Ricky Bloomfield
Yes, that makes sense. The difference that I raised last time is that, at least for US CORE guidance, there is already a LOINC code in the suggested clinical note guidance for the surgical operative note. The distinction is that it is not in the required category, it is simply recommended, but there is an actual code, and that is the 11504-8 that has already been mentioned. So, what that means is if certain health technology or EHR vendors have implemented support for this, it is likely that they have chosen that code for these narrative operative notes already, since it is part of that guidance, and so, the distinction here that I made was including that code, which already exists, for the op note.

For the other note, emergency department, I chose a LOINC code, but for both of these, I put "for example" or "e.g." rather than a requirement. I do not think Hans has joined yet, and I do not have the list, but I am sure he will have thoughts on this when he does join. Hans made a comment here that the LOINC code should be distinct from the LOINC code used for the full emergency department document, and I think he is referring to the LOINC concept of "document," and then he used the word "must be chosen." The only feedback I have for that is that I would be hesitant to include such strong wording as "must" here because I think that might limit the ability for those who are doing the modeling afterwards.

Based on our recommendations, they might feel like they cannot choose some specific code, and I would rather have full flexibility because they will bring experts to the table that we do not necessarily have here, and they will have a lot more people come and start discussing it, so I just want to make sure that we give good guidance, but we do not limit their ability to choose what might work best for the whole ecosystem, and that is why I use the word "should" rather than "must." If it helps, we could even leave out the examples. If that is too limiting, we could not include any LOINC code. I know we had a conversation about that before

and just let them have those discussions, but I want to make sure they have full ability to choose what they think is best.

Sarah DeSilvey
Thank you so much, Ricky. I am glad I remembered it correctly. If we can scroll down, I would like individuals to see the workgroup discussion regarding emergency room note and operative note at the same time. We might need to zoom in or out slightly to make sure. For new members, you can see Hans and Ricky going back and forth on this. Again, we will come back to this to finish our discussion, but we did hear caution about completely removing the LOINC code from enough members last time, so I just want to note that that is something that, as a workgroup member, you can add to the workgroup discussion column as we move along to touch on other elements and work on this iterative process of finishing our final recommendation. Does that make sense?

So, there is a discussion going on in the workgroup discussion column. In Column L, you can see there is a process of refinement, so if someone said something in there that you find to be concerning, I am just elevating the fact that there was some concern in removing the LOINC code altogether that many members expressed last time, so we will work on refining the recommendations in Column L over time as we work on other elements. Does everyone feel comfortable with that, just to keep the ball rolling? All right, I think we are doing okay. So, we are going to try to keep on moving through, so we are going to try to touch on, again, another discussion and another element as we go forward. Again, I am making sure that we are familiarizing ourselves with the different elements, and again, we are not going to be discussing anything where we have a SME coming.

So, the next element that we have here is lot number, and again, this is a Draft v.5 element. The definition is a sequence of characters representing a specific quantity of manufactured material within a batch. It is currently in the data class immunizations, and it looks like most of the conversation has to do with whether or not it should be extended to different data classes. You can see this aligns with the ONC question. This is the question they put in the public comment, and this is the question they are asking us to consider. Should lot number be scoped more broadly to apply to medications and other data elements or kept specific to immunizations?

So, there are a couple questions here. One is on support of the element as it stands, lot number under the data class immunizations, and one is supporting leaning into ONC's question about whether to expand it to medications and other data elements. So, just to iterate, you see Steven supporting this current iteration, and then wondering if there are standards for medications, you see Hans replying there, and then, I would love to just open it up to discussion. You see justification for recommendation to include medications, but wondering whether the standards exist to support this. Steven?

Steven Lane
Just to reiterate that, I think it would be great to include medication lot number. It could be very helpful with medication recalls, which happen not infrequently, but as I looked around the standards, it was not clear to me that that was even a thing. When we have recalls and we have to deal with that within health systems and pharmacy systems, I think people just scramble around and pull the data out of their own database fields, but I may be wrong, and I am interested in hearing from the people on this call who might know about that, like Shelly and Pooja.

Sarah DeSilvey
I know! Our pharmacy friends are all cued up and ready. We are so grateful for the Venn diagram of expertise in this committee. Shelly?

Shelly Spiro
I had a call with the HL7 pharmacy workgroup yesterday about this topic, and there is room for lot number in the medication dispensed resource for medications. So, at least from an HL7 standpoint, there is room to add the lot number, so I just wanted to reiterate that, but it would be under medication dispensed, which would fit nicely in to the medication data element class.

Sarah DeSilvey
Thank you, that makes a lot of sense. Pooja?

Pooja Babbrah
That is what I noticed as well. Just to add to that, I was just reviewing the Level 2 elements, so I think medication administration was a Level 2, which I know we talked about last year, but that could be a possibility that we bring up as well, so that could be an option there.

Sarah DeSilvey
Shelly?

Shelly Spiro
Under medication administration, one of the things that we are working on now for an implementation guide is the standardized medication profile, and it is meant to capture different types of medication lists, which would include medication administered in the hospital and medication administered in a skilled nursing facility. This is all part of the Post-Acute Care InterOperability (PACIO) project that is overseen by CMS and administered by MITRE as the consulting group on that. So, I did add medication list type to ONDEC, and in that, though they are still pending publication, we have already approved LOINC codes for the different types of medication list, which would include medication administration, thereby you would be able to use the medication resource and identify all of the different elements of the medication, but then would be able to identify if that was part of the medication administration, and that was the suggestion that came out of last year's USCDI Version 4 when we had this discussion about medication administration.

It is very difficult to come up with medication that has been administered without adding all of the data elements that are in the medication resource, and so, by classifying the medication list of administered medication, you would be able to make that distinction. So, for AI, I added it. This time around, we are hoping to get proof of concept of the medication list types in the May Connectathon so that we can test this concept, and it would be up to ONC, AI, and USCDI if they want to move this up into USCDI, but we have done the work of actually creating the LOINC codes that would handle the different types of medication lists.

Sarah DeSilvey
Thank you so much, Shelly. I have two questions for the workgroup. It seems we have consensus that lot number for the immunization data class is fairly straightforward, and we feel like we should move forward

on that, and there is an exploratory aligned with what ONC's question was on whether or not we are ready to apply this to medications at this time. Does that seem like a fair summary? I do want to note Hans's questions regarding the draft vocab standards, but conceptually, I hear us having seen that in the spreadsheet and hearing that from our experts in pharmacy and standards. I am going to float that around. Again, I am trying to see if we can start drafting what a final recommendation might look like in the workgroup discussion. Hans?

Hans Buitendijk
Thank you, Sarah, and apologies for being late and catching you on the tail end. I am trying not to repeat discussion, but if I hear you correctly, we would recommend that it is appropriate for immunization lot number and makes sense to move forward with it for medication administration dispensed, and otherwise, it would be explored in the future, not for USCDI Version 5, but we need to figure out how to do that. That makes perfect sense. The question on the LOINC code is a side component, but just generally, I am not seeing the way that it is expressed in standards unless Shelly or others have identified it. I am not seeing the use of LOINC codes in lot numbers, but you do not need to repeat that if it was discussed, and I will pick that up on the notes.

Sarah DeSilvey
We have not talked about that yet. Shelly, can you answer Hans's comment?

Shelly Spiro
Yes. It is not. You cannot codify a lot number, since they changed, so it would have to be a text-based number that is added in. You cannot codify LOINC codes.

Hans Buitendijk
Okeydoke, that is what I thought. Then, I think the other part of this suggestion would be not to reference LOINC in the vocabulary. I am not sure how you would use it.

Shelly Spiro
Yes, it would be how it is used in the medication dispensed. Now, lot numbers need to go to medication dispensed, not medication administration, in the cycle. It is more of an inventory type of element, so it would have to go in as text-based, but it is covered in the medication Fast Healthcare Interoperability Resources (FHIR) resources under medication dispense, not medication administration.

Hans Buitendijk
But for immunization administration, it is there because that is how it being reported to IISes.

Shelly Spiro
That makes sense for administration. There is sort of a difference between administration and medications in HL7, and that is why.

Hans Buitendijk
Okeydoke.

Sarah DeSilvey

It looks like Pooja has a move to talk about medication administration and how lot numbers for medications would fit in that within Level 2. So, specifically right now, talking about the immunization lot number element, can we just lean into the comment on whether the LOINC code is appropriate for this immunization lot number case, Al? You are the only person with your hand up. Do you want to talk?

Al Taylor
Sorry, I was muted. I apologize for particularly this aspect of the conversation. I think that the inclusion of LOINC as an applicable standard is a mistake. I am referencing the webpage, which does have it, which is actually why it ended up on this list like this, but the PDF itself does not include LOINC, and we recognize that it is an alphanumeric text string that is universally used to communicate lot number, so I would just disregard the LOINC code applicable standard. It is a mistake. We should not worry about LOINC being in there.

Sarah DeSilvey
Fantastic. That helps a lot.

Al Taylor
We will fix that on the website today, and fix it on the…

Sarah DeSilvey
Right now!

Al Taylor
Right now.

Shelly Spiro
I totally agree with Al. That is appropriate. I think I was the submitter of this request. What people might not realize is that lot number is something that is required on the IIS form for immunizations, and that is why it is important to include it as a data element, but it would have to be text-based because the manufacturers assign that lot number depending on when it is manufactured, and I think it would be appropriate to include it under medication administration for immunizations because it is not administered to the patient in that process when you are submitting your IIS form, but for medications, it is very different. It is related to what is dispensed. That is technically why there is a difference between immunizations and medication when it is in relationship to lot numbers.

Sarah DeSilvey
I am going to try to move forward with having someone… So, I sense consensus and a feeling like lot number is an important element within the immunization data class. I see Pooja elevating and Shelly echoing that we can consider medication lot numbers within Pooja's move to put medication administration up for further discussion, and I hear Al saying that if the LOINC code is removed, it answers Hans's question. Is someone willing to take the lead on drafting a final recommendation in Column L? I do not hear any concern for this element per se, and I hear us agree on its importance, and I hear us answering ONC's question and some of the questions in the member recommendation category by specifically focusing in on lot numbers for medications in the appropriate data class down in our Level 2 discussion. Does anyone want to take the lead on drafting a rec there?

Pooja Babbrah
Sarah, I can take the lead and get Shelly and a couple others of us to take a look at it.

Sarah DeSilvey
Thank you. I appreciate it. I was about to try, but you do not want me to try.

Pooja Babbrah
I was looking for the mute button.

Sarah DeSilvey
All right. Thank you so much. Again, I feel like we have a pretty good response to the specific element and specific class and a good response to ONC's question moving forward to considering medications within medication administration, and again, we will come back to this. This is an iterative process. Moving down to the next element, of which I am trying to get to the formal name, which is test kit unique identifier, this is an old friend from last year. I am really grateful that the data class made it into USCDI v.5. The data class laboratory, the data element is test kit unique identifier, and the definition is numeric or alphanumeric code representing the collection of materials necessary to perform diagnostic tests. It lists an applicable vocab standard, and it is, of course, a Draft v.5 element.

Again, you see the ONC questions, and we asked them to put these questions in the spreadsheet so we can see what their thoughts are regarding this. In what scenario would this data element be useful? What experiences do health IT developers have exchanging this element? We had a robust discussion regarding this last year, and I anticipate a similar discussion today. Again, many of the other elements on the Draft v.5 have SME guidance, so I think it is okay to settle on here a little bit to have an initial conversation. Hung, I imagined that you would be raising your hand. I am looking forward to hearing your thoughts.

Hung S. Luu
Okay. We all are familiar with this, but I think that the iteration this year seems to be less nuanced than what people put forward last year, which is that we understand that the full UDI, including the production identifier, gives people pause because those are instance data, which, similar to lot number, can change over time. Those are like serial number, lot number, and expiration date. While we eventually want to achieve the Unique Device Identification (UDI), which is device identifier and production identifier, what we are initially looking for here is inclusion of it in the USCDI so there is device identifier information that allows people to know at least what kit line it was performed on, and I think that was something that we kind of all coalesced around last year, but I do not want to speak for Hans.

Sarah DeSilvey
That makes sense. I guess this is a conversation for the whole workgroup. Do you feel like the element itself, as defined, is sufficient to meet that purpose? Hans?

Hans Buitendijk
Thank you. I think this has indeed been a challenging discussion, and I completely agree with Hung that if you talk about the full FDA-defined UDI, it is going to be hard to get that from a lab system, and even a simple text model equivalent of a DI, device identifier, is going to be hard, so that is one part. It is not that

there is not an interest and a need for it, but it is just hard based on the flow, and only focusing on HIT that is going to be certified would not include the lab systems typically and increasingly, since they would have to support a lot more than they currently would do by having to support USCDI. So, I think it is a challenge, and we need to figure out how we can get past that.

The second question would be that there is a clear use for having the model or an identification of the test kit of sorts, and we need to understand if it includes reagents, if it is just the "hardware device," both, or multiple, because sometimes it is the combination that tells you how you can use it, and as Hung and others have explained before, how you can use it is around comparability, and to whom that is most important, the immediate user, who is generally the first receiver or ordering provider, if you will, in that system, is it secondary data use so that FDA or others can use it and have that access, is it more for research institutes, medical research or otherwise, or is it for the individual practice that receives that data, and would they use it?

So, I think we still have a couple questions on what the best path is to step us into this that is reasonable that any HIT would reasonably have good reason to need to support that because USCDI is growing, and it is meant for HIT, not just EHRs. Are we creating a larger set in USCDI, or should it be dealt with in another way to get the user base that needs it, have it available there, and progress into it, but not systems that support other users for which that immediate use is not as relevant? I am trying to get a better picture of that, and I do not think we are totally clear on that yet as how much we can do on that now as a result or if there is still some effort that needs to be done on the lab side to start to be able to actually get the data in as well so it is easier for subsequent systems to take advantage of it.

Sarah DeSilvey
It looks like we have Raj and then Hung, and then, Keith, I might ask you to come and bring your voice into the conversation as well. Raj?

Raj Dash
Thank you. I can understand some concern about this, but I would say that we need to start somewhere. I would say a test kit UDI is a very specific way of identifying the test that is being performed in a laboratory. It is true that there is a Level 1 data element, the instrument ID, that may be more globally unique, and if you want to actually get into lot numbers, that would be the production identifier, but the level of challenge for a laboratory, as was probably discussed last year, continues to increase the more stringent you get. I think this is a great place to start for a laboratory.

I think every laboratory would know exactly what to put here for any FDA-approved test, and Hans, maybe to answer your slight concern that I was hearing in between the lines, for non-FDA-approved tests or tests that are awaiting FDA approval, an alternative vocabulary standard, such as LOINC, could be used, and I actually put a link to a LOINC data element that might suffice. The comments for member recommendation here are so long, but it is towards the bottom. I am very supportive of getting this into v.5, and I think it is going to take us most of the way there for comparability and interoperability of lab results. Thank you.

Sarah DeSilvey
Thank you, Raj. Hung?

Hung S. Luu
I think that the applicability of this is across the board because there is really no other healthcare element that touches everything. Laboratory results touches everything, and the accurate interpretation of it is required in terms of comparability, but more than that, there are other use cases that are coming forward that require the use of this. If we want to be able to import patient data that they have collected from their home instrument or from their monitoring devices, we need to have information about what device that came from, and part of this is so that we can differentiate the ones that were performed in the hospital based on the mainline chemistry analyzers versus what the patient is bringing in.
A further use case is we can collect that data and determine trends. As a diabetic, I would want to know that my home device has a bias and consistently gives me a false sense of security when compared to the laboratory-obtained results. That is the kind of calculation analysis that is more meaningful and compelling when it is performed on population-based things, but we cannot do that if every single time a patient brings in their device, we are not able to record who the manufacturer is. We cannot compare things when we do not know what we are comparing.

Sarah DeSilvey
Thank you so much. That makes me think of the amazing advocacy that Anna has done from the perspective of patient-collected data. Shelly?

Shelly Spiro
I hope I am understanding this right, and Hung, I totally agree with you. There are pharmacies across the United States, especially in the community setting, that have all of these test kits. Look at what happened with COVID and the amount of test kits that had to be utilized. This is really an important area for us to track and trace and to make sure that these are being used appropriately and recorded appropriately, and I just wanted to make sure that the use case of a pharmacy providing a test kit, whether that is for a UTI… We have lots of mail and other types of locations that give UTI test kits out and sell them, so this is a little bit beyond just a laboratory issue. Unless I am totally off on this, and Hung, please tell me if I am, I think this is very broad, and I am in total support of this data element.

Sarah DeSilvey
Thank you so much, Shelly. Ike?

Hung S. Luu
Thank you, Shelly.

Steven Eichner
Thank you. I have a couple points. First, I think it is important that it be included in USCDI, not just USCDI+, but a related component is potentially looking beyond just the model number at the full FDA identifier because that becomes relevant where you are looking at what test methodology may be used on a particular sample in the laboratory environment. It is not just that it was done on this model equipment, but what was the actual test protocol used? That could affect how results were impacted. A third piece is looking at the use of UDI in research. I have personally been in the patient mode of research where research was really dependent upon the particular device used for CT scans and the like and looking at that as a consistent identifier. Did everybody in this particular test cohort use the exact same equipment for scanning? That was

really important, as they were looking at data analysis across the patient population. I think those are three really good examples of why we need to include it here.

Sarah DeSilvey
Thank you. Hi, Anna. I called you. What are your thoughts?

Anna McCollister
Hey there. Sorry, I was attempting to put on my earbuds because they are jackhammering outside my window, and it messed up my sound, so, my apologies. I just wanted to say that on the specifics of how we do this around UDI, etc., I will defer to those who are more expert in the different coding systems, but from a patient perspective, just bringing it home, the fact that we do not have laboratory results and data that could be shared, or that it is so far down the roadmap, is a little mind-boggling because if we do not have any immediate horizon for the notion that laboratory values can be shared, what exactly are we sharing? Yes, there are absolutely critical things that need to be shared as it relates to medication, diagnoses, imaging, and all the other things, but laboratory values are so basic.

That is the stuff that, again, as a patient who has 13 different specialists and a lot of different medications, that is the stuff that really needs to be communicated, so we have to find a way to get beyond some of the concerns about specific coding and just figure out what is going to make them happen because without this, it just seems like this entire enterprise is a useless endeavor, and patients just feel like nobody is listening and nobody is trying to make their lives easier because we still have to bring this data manually to each of our doctor's appointments.

Sarah DeSilvey
Thank you for raising that incredible point and thank you for your patience and persistence in elevating that.

Anna McCollister
Sorry for the jackhammering.

Sarah DeSilvey
We cannot hear it, so you are good. Hannah?

Hannah Galvin
Hey there. So, I really agree with a lot of the points that have been made, and to Hans's point in the actual text, a lot of laboratories, especially commercial laboratories, are not sharing this data and not sharing it electronically right now with certified EHR technology, but I wonder if some of our goal here in including this with USCDI Version 5 is to be forward-thinking. Nothing is being mandated right now, but it is to say, "Hey, this is the way the industry needs to go, and for you commercial laboratories and commercial vendors that are releasing these test kits, the expectation going forward is that you share this data in a structured way," or that is the goal, and by including it, we set that standard and expectation as a future thinking state, even if that is not the industry standard to share it today.

It is not required, but it is the forward-thinking goal to be able to do that because ultimately, the points that have been made are absolutely the case. You can go to any pharmacy today and buy all sorts of test kits over the counter. You can order them online, and nobody is sharing this data or tracking this data, and so,

I think there could be something to be said for us saying, “This is the way that we should be doing this in the future, even if it is not current practice today.”

Sarah DeSilvey
Thank you, Hannah. I think you are really drawing together some of the focus that Hung was talking about in the beginning as the evolution from our last IS WG iteration last year, even though you were not here, so thank you so much for those comments. Keith, thanks for coming. I pulled you from the chat.

Keith Campbell
Good morning. I really want to just build on a lot of the comments from Anna. One of the things that I think people might be mistakenly believing is that the UDI is only helpful in a very narrow circumstance, particularly with regard to regulatory decision-making, and that is just not the case. As I look into it more and more, I learn more and more about how this can affect things across the board. We recently did a study we refer to as the five-lab study where, when we went to a Clinical Laboratory Improvement Amendments (CLIA) high-complexity lab, we found that the laboratorians only assign the same LOINC code to the same test about 58% of the test. That is not 99.5%, that is 58% of the time. I think that number is abhorrent. Having the unique device identifier provides an anchor that can bring you back and say, “Well, what was actually performed?”

There is another study that was in the *Journal of Nephrology* that looked at serum albumen tests, so if you want to talk about how this can affect an individual patient, for the serum albumen tests, which are important for somebody who may need anticoagulation because they are having an acute kidney condition, using a particular test or particular method, it is 59%, which I had to double-check, and it is kind of ironic that our other test study showed only 58% agreement, but this is 59% of the time, when using a particular serum albumen with a particular methodology, they would reach the wrong decision about anticoagulating a patient. Now, anticoagulation is a big deal. If you do not have it when you need it or if you get it when you should not have it, there are consequences of stroke and other things in that case.

If we go to clinical oncology, getting the right results for the patient is key in determining the right therapy for that patient, and this is really a foundation that is needed, not just, again, for public health, not just for regulatory decision-making, but it is really more and more important for the care of the patient, and to this ongoing thing about whether we can really trust the results of laboratory data that are exchanged, the truth is, we really cannot. If we need to solve that, this is a foundation upon which we can do that. So, forgive my passion. I am happy to follow up in any way that can be helpful, but I really just want to amplify what Anna was saying because I have heard those stories from other people.

Sarah DeSilvey
Thank you so much, and we really hope that some of that justification can make it into the final transmittal letter, Keith. So, as we think about moving forward and use the workgroup discussion column to draft our final rec, we really want to make sure that Anna’s and your comments are part of that, so we might tap you again. Steven, and then I hope to get to a point where we can think about moving forward because I hear consensus, but I hear some concepts of refinement. Steven?

Steven Lane

Again, on the refinement side, to Anna's point, obviously, the exchange of lab data is critical, and it happens every single day millions of times, and as Ricky said in the chat, that data is going to patients and amongst providers. For the most part, it should not be necessary for people to hand-carry their lab data from one doctor to another. Again, to Ricky's point in the chat, to determine the reliability and the comparability of the results that you receive, that is where this level of detail is so critical. If we are actually going to get to true semantic interoperability of test results, we need to have this depth of knowledge about what test was done and just how it was done, and that is what this is getting us. This is not adding lab data to USCDI. We already did that. That was in Version 1 and the predecessor to Version 1. This is really getting us to the point where we can truly compare those results from different sources.

Sarah DeSilvey
Thank you so much. This has been a wonderful conversation. One of the things I love about this conversation is it really has pulled from all the different types of expertise we have within the workgroup, patient perspectives, FDA perspectives, pharmacy and laboratory perspectives, clinician perspectives, and standards perspectives. It shows the breadth of the expertise we have, so I am appreciative, and I want to see if we can get to a point where we hear consensus with possible refinement. As we have above, can we have someone volunteer to start drafting recommendations from the workgroup in Column L? Hung? Are the three of you raising your hands as being willing? Is that what I see?

Steven Lane
Yes, willing to work together to draft the recommendation.

Hung S. Luu
Yes.

Sarah DeSilvey
That sounds lovely.

Hans Buitendijk
I do not want to jump ahead of Hung. It looks like you were muted. Go ahead.

Hung S. Luu
I was just going to volunteer, but I was also going to hopefully invite you to work with me on refining the final recommendation, Hans.

Hans Buitendijk
Absolutely, I am happy to. With HITAC and the USCDI in the back of our mind, how can we identify the introduction into the chain where it can be introduced? Typically, with USCDI, most of the certified software applies to EHRs, even though it is applicable to others, like LIS. How do we get that into the chain? What are the steps we take there to make that successful? Otherwise, it sits in the USCDI, there is the catcher, and there is no page.

Sarah DeSilvey

Thank you. I just want to note that for the three people who just mentioned they were going to work together, Rochelle and Keith have all volunteered to come in there and help as well with the discussion and the draft recommendation. Rochelle?

Rochelle Prosser
Hi. I am in transit today, so I hope my signal does not go out. I just wanted to clarify. I am in full support and agreement of this mission and this particular item. I think it is a big kudos. I wish we could go faster for patient sharing where oncology is concerned. That particular point of data sharing, diagnosis, lab diagnosis, and pathology means the difference between life and death and access points to treatment. I know that I was talking from the perspective of women and women's health. I think that with some guardrails, we can certainly be protective, depending on the state that we live in. I know this is a federal mandate, but people live in states. That is all I wanted to say. Thank you so much.

Sarah DeSilvey
Thank you so much. This reminds me of the presentation we had… Well, there are lots of experts on data segmentation in IS WG, but thank you, your comments are very much appreciated, Rochelle. I hear we have a group working on a draft final rec in Column L. Thank you so much for this conversation, and we look forward to seeing what is evolving there. I believe we are now ready to try to move on to the next data element, which is route. If we go over, again, thank you all for trying to touch on all these elements and make sure that we examine them.

So, the next element is route. Can we scroll over slightly just to see the first columns? The data class is medications, the data element is route, the definition is the physiological administration path of a therapeutic agent into or onto a patient, examples include, but are not limited to, oral/topical/intravenous, we have the applicable vocab standard as SNOMED CT. This is, of course, a Draft v.5 element, and we have some initial conversation. We have some members saying they support the inclusion, and then we have some conversation on possible refinement. Any conversation on data element route, data class medications? Hans?

Hans Buitendijk
I think it is a logical progression to start to address route. It is already captured in prescriptions. It is captured where administrations are documented in the administration. In light of some of the discussion, I would be inclined to focus on the prescription and request part for this and make it clearer in other parts of the USCDI, and if it is listed under medication as route in that data class, it is actually unclear which aspect of medication we are talking about, the request to dispense, the administration, giving instructions, or whatever it might be, and that makes it hard to interpret downstream. I would suggest to consider not only that it is on the request, but that it is clearly stated that that is the focus, not just medication in general, because that makes it very unclear as to what we mean. Medication administration per se, as we just talked about in other areas, is actually currently not covered. It is mentioned by an example in another data class, actually, in procedure, and just adds to the ambiguity. I would suggest we are crisp, clear, and focused on medication request at the prescription aspect of it.

Sarah DeSilvey
Here, perfectly cued, is one of our brilliant pharmacy experts. Shelly?

Shelly Spiro
I had this conversation yesterday with the HL7 pharmacy workgroup, and the way they interpret the use of route is in the actual medication resource itself. It is okay in med administration because it is a data element that is used in there, but it is the basis of the actual medication resource itself, Hans, so it is classified as SNOMED as the recommended coding mechanism, and it does not necessarily have to be linked into medication request because if medication request is used there, it is still based on the medication resource itself or the components of the medication resource, if that makes any sense, Hans.

Sarah DeSilvey
Hans, did Shelly's comment help refine your thoughts there?

Hans Buitendijk
I beg to differ with that, and we can pick that up, but I am just looking at the medication resource. It is not there. It is in medication request when you drill down into dosage.

Shelly Spiro
Right. They said it is in the actual medication resource itself.

Hans Buitendijk
Let's discuss that separately, then.

Shelly Spiro
I would bring that to the pharmacy workgroup experts, John Hatem, Jean Duteau, and Frank McKinney.

Steven Lane
I just put the link in Column L if anyone wants to go look at the resource in FHIR.

Hans Buitendijk
Yes, I put it in the chat if somebody wants to investigate. If you go to medication requests, drop that one in, and you will see the difference there, but you need to drill down. I will give the path.

Sarah DeSilvey
Where are we at with this conversation on this element? Again, it sounds like general support for inclusion of it, but maybe some conversation on scoping. Al?

Al Taylor
I just wanted to caution the group, if that is the right word, that I do not think the workgroup needs to get into the modeling of whatever FHIR resource might be necessary to communicate this because in many cases, the FHIR resource may not exist yet, but could be modeled at the appropriate time, should this be part of a final version of USCDI. So, I do not know if digging into current FHIR resources is within the scope of this workgroup.

Sarah DeSilvey
Thank you, Al. Hans?

Hans Buitendijk
I appreciate Al's comments. I would raise the awareness, though, that if USCDI requires new resources in FHIR, it would make it very hard in a three-month period of time, give or take, to turn it from USCDI into an implementable implementation guide FHIR US CORE or C-CDA related to that, so I do believe that as part of our consideration, we need to consider maturity and where it is already available, which is actually the purpose of what Ricky and I put together in the data element mappings to FHIR and Consolidated Clinical Document Architecture (C-CDA) to get a sense of if something is being proposed that does not exist in some manner in the standards that are going to be used to measure certification, that will be a challenge.

In this particular case, actually, we are not debating that there is nothing in FHIR, it is actually that we are in slight disagreement on where it is, which we can sort out, but if we do not consider readiness of standards to support it, then it is going to be very hard to get things done in a timely fashion and have actual experience with it so we know it can work, which is one of the criteria that was set for USCDI, that it is implementable in a reasonable time window, etc. That means the standards have to be there.

Sarah DeSilvey
So, Hans is making both a general response to Al's statement and a specific response because in this instance, it actually exists, but just in a more specific location, which I am sure Shelly is going to help shed light on. Shelly?

Shelly Spiro
I will do my best. Route is a major component of not only the medication product itself, because you can determine by the product whether it is for IV use or oral use, it is in the medication instructions to the patient, it is in the medication requested as a component of the prescription that is being requested, it is in medication administration… It is all over the place, so there are many places where it is codified. For this group, and Al, to answer your question, is it an important data element? Yes, it is in multiple places within many of the FHIR resources, and it is a major component of using this data for sharing information, for capturing information… There is a whole slew of uses for it. I think what is important for us to recognize is that the route should be codified within SNOMED. That is the best way to codify it within terminology, but it is also used in text-based areas and proprietary coding in the directions, or what we call the SIG, of a prescription.

Sarah DeSilvey
Thank you, Shelly. Al, you put your hand up and then took it down. Do you have something?

Al Taylor
Shelly hit on it. There is no question that route is important. It actually was submitted two years ago, I think, as a combination of dose and route, and as most recall, we added dose in Version 3 or 4, though I forget the exact history, but we actually split that out, thinking they were different enough to be separate, but for whatever reason, it did not get added as a separate data element, but by adding it to draft v.5, we are trying to fix that. There is no question that ONC thinks that it is important and separate from dose, and that is why it is in Draft v.5.

Sarah DeSilvey

I generally hear the IS WG agreeing, so, just like some of the elements above, we could start moving toward drafting a final recommendation. I do want to elevate Pooja's question in the chat, though, given what Shelly was saying regarding the different routes in documentation. Pooja, do you want to voice your comment in the chat and see if it needs workgroup discussion?

Pooja Babbrah
Yes. We were talking about the FHIR resources and all that. I guess the point is we should just be referencing SNOMED in the recommendation as opposed to the FHIR resources. That is my thought. But I agree with what Al said. I think we talked about this last year, and I think it is important to move it forward.

Sarah DeSilvey
Hans, and then I am going to ask that we get a volunteer to help draft a recommendation. Hans?

Hans Buitendijk
I do not think we need to reference the specific resource in FHIR in the recommendation here, but indicating that we are not just talking about medication in general, which can be instantiated in three or four different places, but that our focus is on the prescription side or on the administration side conceptually, that would help understand what it is we have to do. If we do not state that, the implication is very quickly going to be "I need to do it in all; are we ready?"

So, I think USCDI being more crisp and specific about what phase of the medication process we are talking about where we start to introduce this will be helpful to recognize that because, recognizing the kind of conversations and discussions that are going to happen and the differences in expectation that you are going to run into, if it is not clear in USCDI that one choice is being made in the subsequent standard, that difference is going to yield confusion for implementers and questions as to what exactly they are supposed to support, and that is what we have seen in a number of examples. One of the general comments later on, and this is an example of it that we will come back to, is that not having that level of crispness in USCDI is a problem.

Sarah DeSilvey
Hans, thank you. I see that those kinds of expert thoughts are part of why the IS WG exists. We have an element that we generally agree needs full support for moving forward, but the considerations from the different points of expertise are really important to put in that final comment in the transmittal letter. I am going to ask if someone would take lead on drafting a final rec in Column L, and we can work from it.

Pooja Babbrah
Sarah, I can take that one on too, with the pharmacy people.

Sarah DeSilvey
Thank you so much. I am very grateful. Again, I really want to make sure that the perspectives that all of you all, in your expertise, have put into the chat and the conversation are included in that, so Pooja is going to take the lead on drafting, and all experts from all of our perspectives in the IS WG can ensure that the breadth of expertise we have is represented in the final transmittal letter. All right, I believe the next few elements are all part of our SME conversations. We have a pending SME presentation for advance directive, and we have a pending SME presentation for sex parameter for clinical use. I know we only have

about five minutes left until we move to public comment, but… Oh, I believe orders was also one of those that had a SME recommendation, as well as name to use. Am I correct that orders was one of those that had a SME? There was a whole swath.

Al Taylor
Yes. Advance directive, orders, name to use, pronouns, and sex parameter for clinical use. All five of those are scheduled.

Sarah DeSilvey
So, we only have five minutes, but we landed on interpreter needed, which we might be able to have an initial conversation on. So, again, we have to move to public comment in five minutes. It seems worthy to try to see where we can get with this in the next five minutes. So, the data class is patient demographics and information, the data element is interpreter needed, the Draft v.5 definition is indication of whether a person needs language interpretation services. There are a couple applicable standards. It is a Draft v.5 element, you have general member support, there are lots of plus ones and additions here, and then, I put a justification in Column K, and then, we have a little bit of conversation. Any thoughts on interpreter needed? Steven?

Steven Lane
It looked like there was a recommendation to have CMS and/or CDC come to speak to this as a SME. I am not quite sure who put that in there, but we might want to revisit that.

Sarah DeSilvey
That was me. I put that in there, but then there was a thought that maybe it was so straightforward and required that, given the breadth of other SME conversations we have on the docket, if we wanted to test whether the workgroup thought SMEs were needed in this instance or whether we could move forward as a recommendation without a SME presentation. Does that make sense?

Steven Lane
Yes, I agree. I do not need a SME to understand this.

Sarah DeSilvey
Exactly. We could have SMEs, but maybe it is not necessary. Mark?

Mark Savage
This probably does not need saying for this group, but just to flag it, “interpreter” does not mean the patient’s children, for example, which is often what happens, so I appreciate the use of the word “interpreter.” It is an important distinction, thank you.

Sarah DeSilvey
Zeynep?

Zeynep Sumer-King
Just playing off that comment, at our hospital, we just got joint commission certified in health equity and had a CMS survey and a bunch of different things that made us look at this, and not only does it not mean

your children, but it apparently does not even mean a provider who speaks your language. It has to be someone who is certified, so it does have implications operationally.

Sarah DeSilvey
We definitely want to make sure that we represent what we know to be the evidence and what we know to be the regulatory drivers in our final recommendation. Again, I hear consensus on this one. This is why we did not even necessarily feel like we needed CMS or CDC to come forward and present. Ricky, do you have any thoughts?

Ricky Bloomfield
Sorry, I was just trying to unmute. I think the commentary has been great. Is there any value in asking who made the determination and modeling that information as well? Is it self-determination? Was it a provider that determined that an interpreter was needed? Is that something we should consider as part of our charge?

Sarah DeSilvey
That is a good question. Hans?

Hans Buitendijk
The question that I have in that regard is are we talking about just a need bullion, or since LOINC and SNOMED are being referenced, we are talking about something more? I do not think we are talking about the actual language that is needed, so I think we want to be a little clearer on what is happening. So far, some of the standards are particularly using a simple yes/no, which will be SNOMED, but I am just trying to understand it because there are a couple different things in play here, and I am not clear what is meant by it.

Sarah DeSilvey
This is where maybe we can have Al try to help, but we do see how it is operationalized, and I read this in multiple CMS assessments and instruments, which is very much a yes/no as it stands right now. Mark?

Mark Savage
To Ricky's question, just pointing out the overlap with the discussion we have had on the author data element, the way we have talked about author, it would capture the source of a value, so, with interpreter need, you would capture who made that assessment and reported that value, so they are important interlocking data elements. Thank you.

Sarah DeSilvey
Thank you so much, Mark. It is time for public comment. I am really glad we teased ourselves and got a little bit into this. Ike, any other final thoughts before I move to public comment?

Steven Eichner
Sorry, I was on mute. I think we did a great job and made a lot of progress. One thing to add with interpreter is thinking about sign language interpretation as well because that is another aspect of interpretation that may be necessary. Though not necessarily looking at oral interpretation, it is another aspect in play.

Sarah DeSilvey
Correct. So, we are going to pick up at interpreter needed when we come back next week. Thank you for a really robust conversation. Seth, over to you for public comment.

Public Comment (01:25:56)

Seth Pazinski
All right, thank you, Sarah. So, we are going to move into the public comment part of our agenda. If you are on the Zoom and you would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are participating today by phone only, you can press *9 to raise your hand. Once called upon, you can press *6 to mute and unmute your line. We will give folks a minute here to queue up if there are any questions or comments. Okay, I am not seeing any raised hands or comments coming in on the phone at this time, so I will turn it back to Sarah and Ike to close us out.

Sarah DeSilvey
Ike, any closing thoughts at first?

Steven Eichner
No. I think we made a lot of progress today, and I am looking forward to the next few meetings with SMEs and to continuing our work. I am very appreciative of all the input from the workgroup members. It is really important for everyone to participate. I think we had great participation today, and I would love to see it in the next few weeks as we close out our work.

Sarah DeSilvey
It was a wonderful meeting today. I really do appreciate the breadth of expertise from the workgroup. It is always an honor to hear from all of you all in your different areas of focus. We just wanted to put this slide up, and Ike, thank you for grounding us in this in our prep. You can see that we are trying to move ourselves to getting draft recommendations so that we can start refining those. We do have a fairly tight timeline, so, by the end of March, we really want to try to start getting that final recommendation set so that we can get a transmittal letter on time over to HITAC, so I wanted to put this slide up there for everyone's reference. We have about five more open sessions, and we have subject matter expert conversations we are plugging into those that will assume part of the agenda for each of those different meetings. Thank you so, so much for all of your presence today, and we look forward to seeing you next week.

Adjourn (01:28:29)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Sarah DeSilvey: Good morning!

Anna McCollister: Anna McCollister is here

Steven Lane: These are all very appropriate suggestions. Recall that we will likely need to make STRONG arguments to convince ONC to make any of these additions.

Steven Lane: Great suggestion, @Grace. We could include in the Justification column.

Christina Caraballo: Good point Steven, and it is also important to note that adding high priority elements in our recommendations does elevate the data element and gets more traction to move it forward as a priority in future drafts.

Medell K. Briggs-Malonson: + Grace and Steven. It is important to add context to the recommendations.

Steven Lane: +1 @Christina. Strong WG recommendations often impact what is included inn theDraft the following year.

Grace Cordovano: Thank you Al, that's very helpful.

Grace Cordovano: Let's add Al's clarifying points to the headers of the titles in our working spreadsheet (Audience: ONC)

Jim Jirjis: Jim Jirjis joined late had conflict for first half hour

Pooja Babbrah: I can move medication administration data element up for further discussion when we get to Level 2 elements

Sarah DeSilvey: thank you, Pooja!

Hans Buitendijk: Agreed that for medications it starts with dispense. A standards discussion is needed on whether the lot number should be present on medication administration if a dispense record is not available or whether relevant. For immunizations that is effectively what is happening as the dispense record is not included in the immunization report.

Raj Dash: Agree. Very supportive.

Keith E. Campbell: I think the lack of UDI was very detrimental during covid. This element is really important to include and support.

Keith E. Campbell: So I strongly support the inclusion of UDI elements in USCDI.

Keith E. Campbell: My experience is that the UDI can support all of the above, including underserved communities depending more on over the counter tests.

Keith E. Campbell: So if we need to help make the broad case, happy to help in that regard.

Jim Jirjis: Lack of UDI was very detrimental during covid

Jim Jirjis: I concur with Keith

Steven Eichner: +1, Jim and Keith

Jim Jirjis: Concerned about this being in USCDI+ and not USCDI

Kikelomo Oshunkentan: +1 @Keith

Jim Jirjis: It is important for a variety of reasons to include this in USCDI.

Kikelomo Oshunkentan: and Jim

Hans Buitendijk: How do we get LIS to adopt as including in USCDI would not drive that as certification would impose support for more data than an LIS needs to support.

Jim Jirjis: And we are not yet at a place where we have enough experience to know how the vendors will or will not support items that are in USCDI+ and Not USCID

Steven Lane: +1 @Jim

Hans Buitendijk: There are no clear drivers yet for using USCDI+, but could see that targeted USCDI+ data sets could focus on different classes of HIT. But at this time USCDI needs to be supported in full to be certified.

Jim Jirjis: Thanks Hans my fear is that pushing items that are important from USCDI to USCDI+ could be the equivalent of that data element not actually being prioritized by vendors..Oracle, EPic, etc

Hans Buitendijk: @Jim: If conformance to USCDI would be based on what an HIT actually manages (as also discussed last round), then more HIT could be certified their area of interest/need, thus pushing less into USCDI+ that has no strong driver to adopt yet. And in fact, USCDI+ PH as an example would on its own hard for a number of HIT to certify to.

Jim Jirjis: @Hans I understand and we are having a lot of discussions at CDC about how we focus USCDI+ into actual uses cases fueled by CDC funding

Kikelomo (Dayo) Oshunkentan: +1 @Hannah

Katrina Miller Parrish: Agree!

Kikelomo (Dayo) Oshunkentan: WOW!

Ricky Bloomfield: Fortunately, labs are required to be shared with patients today via portals and APIs. The primary point of discussion here is related to specific metadata (UDI) for the devices used to result some of those labs (which will help determine the quality and reliability of those devices).

Raj Dash: Agree with Keith that LOINC code (even with method) is not specific enough for interoperability or comparability of results. This data element will be a huge step forward. My recommendation for using LOINC for pre-FDA-approved tests is a separate additional device ID code in addition to the LOINC test code, just to clarify.

Anna McCollister: We can’t let the perfect be the enemy of the necessary.

Hans Buitendijk: @Ricky - are labs required by portal and API, portal or API, other? What standards are they required to support? What data set is defined that can then reflect inclusion of test kit identification that the typical patient would not themselves use?

Hannah K. Galvin: To Rochelle's point, this emphasizes the need for granular segmentation including data elements like UDI.

Kikelomo (Dayo) Oshunkentan: To Grace's point, I believe that we need to illustrate a patient scenario as just outlined by Keith to drive home the impact of adding this data element.

Hans Buitendijk: Agreement and understand the data quality challenges, and appropriate use. Question how we advance this through the chain starting with the source.

Keith E. Campbell: I will help with Column L...

Keith E. Campbell: For the record:

Keith E. Campbell: It won't let me paste a reference.

Keith E. Campbell: Source: A-E van de Logt et al.: Bias between different albumin assays. Kidney International (2019) 95, 1514–1517; https://doi.org/10.1016/j.kint.2019.01.042

Hans Buitendijk: See: https://hl7.org/fhir/R4/medication.html

Sarah DeSilvey: thank you, Keith!

Keith E. Campbell: One clinical example, where incomplete or abstracted test encoding can adversely affect patient-care decisions is serum albumin determination. The nephrologist needs to precisely know the details of the assay being performed and use the performance characteristics of these tests to make a proper decision regarding anticoagulation therapy. One study examined various assays for measuring albumin concentration specifically in patients with nephrotic syndrome caused by membranous nephropathy, and to quantify the risk of misclassification as it relates to the decision to start prophylactic anticoagulant therapy.

Keith E. Campbell: This study found that nephrologists may reach inappropriate treatment decisions using the Bromocresol green assay in up to 59% of patients. Ensuring that each test performed is reported is accompanied by a UDI for the performing device, and a LIDR record that characterizes the test performance characteristics—and to use that information in the processing and interpretation of test results—provides necessary rigor to inform safe and effective treatment decisions.

Hans Buitendijk: https://hl7.org/fhir/R4/medicationrequest.html and look at dosageInstruction that is of data type of dosage. That is where it is.

Pooja Babbrah: so should we just be referencing Snomed in the recommendation?

Anna McCollister: I think route is essential. If you look at insulin, whether or not the drug is administered intravenously, via an injection or via an insulin pump can tell you important things about drug uptake, rate of absorption, etc.

Pooja Babbrah: +1 Anna

Anna McCollister: Are drug classes currently part of USCDI?

Keith E. Campbell: I think drug classes need to be part of the system that encodes the medications... For example RxNorm has drug classes.

Keith E. Campbell: Not all do. NDC codes do not.

Keith E. Campbell: The SNOMED international drug model has drug classes, and RxNorm and SNOMED drug model are converging :-)

Keith E. Campbell: So if they are part of the recommended encoding, then I don't think they are separately needed as a field in USCDI...

Hannah K. Galvin: Of note, there may be state-specific requirements around how "interpreter need" is captured. For instance, in MA there are very specific data element requirements around this. Do we need to do an environmental scan of these requirements?

Rochelle Prosser: +1

Katrina Miller Parrish: Thanks - that was my q.

Hannah K. Galvin: Different ways to capture this may include: "primary language for health care", "English language proficiency," and others.

Hannah K. Galvin: Agreed

Hannah K. Galvin: re: ASL

Hannah K. Galvin: This may be included under "Disability accomodations as well"

Albert Taylor: @hannah, the scope of this data element is only the need for interpreter, not the specific language

Sarah DeSilvey: yes, that would be a separate element! a necessary one!

Hannah K. Galvin: @Al - agreed, but sometimes the need for an interpreter is indicated by the capture of those other data elements

Mark Savage: Is a data element for preferred language, I believe.

Hannah K. Galvin: (that is, a primary language that does not = English may trigger logic indicating the need for an interpreter)

Albert Taylor: I think it's an unsafe assumption that a preferred language other than English would correlate to interpreter needed.

Hannah K. Galvin: That may be true, but in my experience, that is some systems are set up currently.

Katrina Miller Parrish: Sign language

Hans Buitendijk: Agreed with Al, which is what needs to be clarified whether just a Boolean, and/or an actual language.

Mark Savage: Moving to the left lane on the freeway.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

IS WG Webpage
IS WG - February 13, 2024, Meeting Webpage

Transcript approved by Wendy Noboa, HITAC DFO, on 2/21/24.