Transcript

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

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VIRTUAL

Speakers

Name	Organization	Role
Sarah DeSilvey	**Gravity Project** **Larner College of Medicine at the University of Vermont**	**Co-Chair**
Naresh Sundar Rajan	**CyncHealth**	**Co-Chair**
Pooja Babbrah	Point-of-Care Partners	Member
Shila Blend	North Dakota Health Information Network	Member
Ricky Bloomfield	Apple	Member
Hans Buitendijk	Oracle Health	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Raj Dash	College of American Pathologists	Member
Steven Eichner	Texas Department of State Health Services	Member
Nedra Garrett	Centers for Disease Control and Prevention	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Steven Lane	Health Gorilla	Member
Hung Luu	Children's Health	Member
Meg Marshall	Department of Veterans Affairs	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Miri	Baptist Health	Member
Aaron Neinstein	UCSF Health	Member
Kikelomo Oshunkentan	Pegasystems	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Shelly Spiro	Pharmacy HIT Collaborative	Member
Ram Sriram	National Institute of Standards and Technology	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead

Name	Organization	Role
Joel Andress	Centers for Medicare and Medicaid Services	Discussant

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

Michael Berry
Good morning, everyone. I am Mike Berry with ONC, and I would like to welcome everyone to the Interoperability Standards Workgroup. I really appreciate everyone joining us today. All of our workgroup meetings are open to the public, and our feedback is always welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about 11:55 Eastern Time this morning. I am going to begin rollcall of our workgroup members, so when I call your name, please let us know if you are here, and I will start with our cochairs. Sarah DeSilvey?

Sarah DeSilvey
Here.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Here.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Here.

Michael Berry
Shila Blend?

Shila Blend
Here.

Michael Berry
Ricky Bloomfield is not able to join us today.

Ricky Bloomfield
Actually, I was able to join, so I am here.

Michael Berry
Oh, you are, Ricky? Great, thank you. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Christina Caraballo?

Christina Caraballo
Good morning.

Michael Berry
Grace Cordovano? Raj Dash?

Raj Dash
Good morning, here.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Nedra Garrett?

Nedra Garrett
Good morning.

Michael Berry
Raj Godavarthi? Bryant Thomas Karras? Steven Lane?

Steven Lane
Hello.

Michael Berry
Hung Luu?

Hung Luu
Good morning.

Michael Berry
Meg Marshall? Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Clem McDonald? Deven McGraw is not able to join us today. Aaron Miri? Aaron Neinstein?

Aaron Neinstein
Good morning.

Michael Berry
Kikelomo Oshunkentan is also not able to join us today. I think a few people are coming back from the conference in Tennessee. Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Shelly Spiro?

Shelly Spiro
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
All right. Good morning, everyone, thanks so much, and now, please join me in welcoming Sarah and Naresh for their opening remarks.

IS WG Charge (00:02:26)

Sarah DeSilvey
Welcome, everyone, and thanks for your patience with me as I got my audio set. We have a very big day today as we try to wrap up a review of all the elements in USCDI V.4 and Level 2 elements, carrying over some conversations, really trying to move a few things that we did not address last time, so I will not delay us any further. You can see we have a whole set of cleanup, and then, again, we will close the meeting by formally urging everyone to try to take a stab at final recommendations in the share drive if you have not already done so. Next slide, please. Actually, Naresh, any further comments?

Naresh Sundar Rajan
No, I think that is pretty much what we were planning to do for today, and like Sarah mentioned, your comments are going to be really valuable for us in drafting our final, so please make sure, whenever you get a chance, to update that as soon as possible.

Sarah DeSilvey
Thank you so much. Next slide, please. The charge is now well known. We really are at the level of working through the Level 2 elements. We have formerly reviewed all of the draft USCDI V.4 elements. There are a host of Level 2 elements that we have to wrap up today, and we are really grateful for folks leaning in and carrying that forward. Again, thank you Steven, Mark, the CDC, CMS, and everyone who is going to be leading us through the next Level 2 elements review over the course of the next few minutes. Next slide, please.

So, here is what we just mentioned. As of now, all of the draft USCDI V.4 elements have been reviewed and disposed of. We are trying to capture the nuances we discussed in the IS WG in our final recommendations, so, again, if you can volunteer to synthesize that, that is great. You can always reach out to people who had comments in the workgroup discussion element for clarity. Next slide, please. And then, I think we are going to wrap up… We had very strict time limits on each of these sections because we have a lot to discuss, but as we know, last time, we had an initial presentation of DI, and there was some really important conversation. There has been a lot of work happening in the interim, so we are hoping to make a disposition in short order of the DI data elements, the three elements that were discussed last week. I will turn the mic over to Steven Lane to help catch us up on where we are so we can carry through the discussion, again, noting that we do have time constraints, and I will be holding us to that in order to complete the objective today.

Diagnostic Imaging Data Elements (00:05:15)

Steven Lane
Thank you so much, Sarah. I really appreciate it, and I appreciate, as you say, all the work that has been done in the background. We left off at the end of our last call where the workgroup generally felt that the three diagnostic imaging data elements that had been discussed, the imaging reference, the requested procedure identifier, and the accession number, could all add value as components in the final USCDI Version 4. Hans and Ike both raised some questions as to how ready the industry was to be able to support all three of those data elements.

I think the requested procedure ID and the accession number are really not a super high lift, as these elements do exist and can be readily exchanged today. The imaging reference, which was really the main focus of our discussion, which provides the path and other technical metadata information required to find where the image is, is the main question as to whether systems are really ready to exchange those because this path data is sometimes kept within the EHR, the certified health IT systems. It really derives from the imaging systems themselves. As we heard last time, the folks who are actually moving vendor-agnostic image exchange forward, both within Argonaut and Carequality, were quite supportive of the inclusion of this path data, feeling that it did support and advance the work that they are doing. Hans went back and discussed this with the EHRA and has identified some specific concerns, just that, again, this data is not often in the EHR, and questions about what the right sequence is to be able to advance image exchange in terms of where adding these elements to USCDI will have the most benefit.

What I did was try to synthesize these recommendations in the spreadsheet. I do not know if we are prepared to display that, but basically, I do think that we are in a good position to recommend as a workgroup the inclusion of all three of these data elements from Level 2 into USCDI Version 4 with an acknowledgement that not all health IT systems currently capture or maintain this information, but that the requirement to exchange it when it is available would really advance the ability of both individuals and providers to access, exchange, and use diagnostic images and the associated DICOM data files, and that this builds on available technology, knowing that over time, between now and when USCDI V.4 will be required through rulemaking, that there will be time to see the fruition of both the Carequality and the Argonaut initiatives and see this really advance diagnostic imaging going forward. So, again, I know Ricky and Hans have both really been involved in this. I leave it to you to call on others who might want to speak to this.

Sarah DeSilvey
I believe Al is navigating us to the share drive so we can see the draft of Steven's recommendation as a synthesis of this. Was Ike first, or Hans?

Steven Lane
It looks like Steve was first.

Steven Eichner
I would flip the coin, but thank you. That is great to hear, Dr. Lane. I really appreciate that, and that part sounds good. I think the second area that we were concerned about is not so much… The other part of the lift is really looking at the utility of access and concerns about broadband deployment to enable actual access to the data in many parts of the country that are not urban or close suburban components, and while that is not directly in the sphere of the taskforce, something in me wants to think that we need to address it or comment on it somewhere in that space. That is another dependency in actually looking at the successful exchange of this information.

Steven Lane
Yes, it is a really good point, Ike, and we know that if you are viewing an image in a viewer, that does not require nearly the broadband capability as downloading a full DICOM image file. It is clear that DICOM, like genomic files, are large files that are going to be challenging to move around in rural areas. As you say, I do not know how much that bears on whether or not one includes the path information, for example, in USCDI, but it is worth acknowledging the challenges that we face in many areas.

Steven Eichner
Yes. To me, it is a textural note in a recommendation acknowledging that as a framework that, again, this is one of those… Yes, the data standards should be included, however there may still be some functional implementation issues. It is not that you cannot exchange a low-res image pretty much anywhere in the country, if not anywhere in the world, but when you start getting into clinical-quality images, it becomes a bit of a different story. I just think we could figure out a way of noting that in our recommendation so that ONC can acknowledge it down the line, and maybe it will feed into other pieces later on.

Sarah DeSilvey

Would you mind taking a stab at it in the final recommendation, building off of…?

Steven Lane
I am happy to do that. It looks like Ricky and Hans both have their hands up.

Sarah DeSilvey
Ricky?

Ricky Bloomfield
I think Hans was first.

Hans Buitendijk
Somehow, my hand got unraised. I probably hit the button. I appreciate that, Ricky. I have a couple of thoughts to clarify the discussion there, and I really appreciate Steven pulling a number of these topics together, but they are in line with some of the considerations that Ike is bringing up as well. First of all, there is no argument that these elements are valuable. Just to make sure that is clear, it is about the dependencies and the readiness to move forward. So, I have a couple of clarifications, and I am looking at the proposed recommendation as well. There is good work going on, particularly in Carequality, among image service providers to advance it, and that is really an important part to help address, if you will, the public or easy accessibility of the images as they are being shared. I will come back to that in a second.

The second part is that Argonaut is in the process of starting to work and focus on that, so, current implementation is a little bit challenging to call that. It is trying to figure out what the gaps and barriers are that we need to overcome, and between now and when USCDI Version 4 would be published, Argonaut may or may not have recommendations and considerations around that, and may or may not, at that point in time, have an indication that this is more viable in Version 4 already or not from a standards perspective in particular on what is needed to do that. So, I think the recommendation should further acknowledge that Carequality has progressed further with actual implementations among **[inaudible] [00:13:17]** service providers, not yet really with EHRs, and Argonaut is working in the progression to better understand and identify opportunities to take steps.

But, it is all in the context of where we are at. The critical part is, indeed, the image reference, and that means that given that EHRs are typically not storing the kinds of image that you would access through an imaging study, simple images are already addressed in USCI Versions 2 and 3, and FHIR US CORE has the ability to support that. Simple images are **[inaudible]**, but it is those complex diagnostic images where you rely on it being somewhere else, so it is a reference, it is the data on how to get there. So, the issue at hand there, which is similar to what Ike is bringing up with the bandwidth challenges and broadband issues, is that we need to make sure what the incentive or driver is for services to provide that information consistently with the reports and otherwise. USCDI typically is not focused on that set of HIT, it is typically focused on EHRs that are, in this case, on the receiving end of it. So, what do we need to highlight to indicate that work needs to be done to ensure that that is being picked up?

The second part is that as that is being made available today, and not considering Carequality, where there is the opportunity to advance it, but if you are not in that kind of environment yet and as they are building it out, that information is now shared with an EHR or from that EHR to somebody else, like a patient. Can

they use that information and actually access it? Today, that is based on point-to-point business relationships, trust frameworks, and otherwise to make it work, so, yes, the technology and the standards enable that to be done, but how do we make sure of that, from a patient perspective receiving that image reference in their environments, going from one provider to the next, etc.? They do not have that original business relationship and that connection there. Carequality is a way to help expand that to have it sitting under a common trust framework if you are part of Carequality and want it expanded into that area.

So, from an implementation perspective, I think we need to include a couple of caveats that while the underlying technology and the standards would enable it and that initial implementations have demonstrated that that can work, only putting it into USCDI Version 4 is not solving those other problems, and it needs to be recognized that before it can be picked up and deployed widely, made consistently scalable without point-to-point business relationships, and that a trust and security framework has been agreed to, that this will be problematic. Yes, I can share it, but I cannot do anything with it. I think that is the challenge that is a rationale why, in a discussion with the EHRA, there is hesitancy. Is this the right time, or do we need to get some of those other things addressed first or as well to ensure that the full end-to-end process can work?

In the way USCDI is currently used and applied to certified HIT, where it would impact actual HIT to make it work, sits on one side of the equation, on the receiver end of it, not the source end of it, and not with the other aspects in place. That is the concern that has been raised, and if we can clarify that as part of the recommendation to say we recognize that that needs to be addressed, and ONC should work with the parties on how we can advance care quality, how that fits with TEFCA, and how we can make sure that it is a scalable framework within which you can do it, then I think we can have the traction that we want to get, but without that, we have a good probability of implementing something on one side of the fence where the other side of the fence is not quite providing the information consistently across the board for everybody, and that the trust framework is fully scalable, so I do not need to negotiate another business relationship with that source, be it as a patient or somebody else, to do that.

That is a similar kind of concern to what Ike is raising on the broadband side as to whether it is going to be scalable. Will enough people have access to it when we do that on day one? That needs to be part of the context of the recommendation, to recognize that, because otherwise, we are probably implementing something that will have some of the data in there, but what is it going to do?

Sarah DeSilvey
Steve, any thoughts or responses to that, or should I move on to Ricky?

Steven Lane
Moving on to Ricky's comments would be perfect.

Sarah DeSilvey
Okay, Ricky? Steven, think fast and furious in the recommendation.

Ricky Bloomfield
It is clear that this is a topic that has a lot of nuance, and I appreciate Hans's feedback here, and I thank Steven for herding the cats. I think what I have heard is that we are all pretty consistently saying that we

need to figure out a path towards making this data available via API. It sounds like that is a pretty clear goal. The questions are around the implementation details, which are completely valid. As we have been chatting, I have been trying to solicit input from Brett Marquard and Josh Mandel from the Argonaut perspective to understand a little bit more around some of the implementation considerations from that perspective to make sure that we are not putting something in USCDI and then throwing it over to other organizations to do work that may not be feasible.

I will try to summarize the feedback that I have gotten from them, which is that it seems like the accession number and procedure ID should be relatively easily accessed, and I think they would defer to Hans as to whether smaller EHR vendors have the capability of providing that information, whereas, pretty clearly, the large ones would, but based on Hans's feedback, it sounds like those would be relatively feasible. Brett and Josh did share some concerns as well about the image reference, particularly whether the radiology information systems or PACS vendors can provide that reliably today, as well as the motivation and requirement for them to do so, very similar to the feedback that has already been shared. I think the biggest concern they had was that they do not want to have some sort of image reference that leads to a dead end that is not usable, and so, I think that is reasonable.

The high-level question here is what is the right path to indicate publicly that it should be a priority to make the imaging files directly available? What I am hearing here is that maybe USCDI has some role, but not the complete role, in doing that, and are there other things that ONC may consider to indicate that this is a priority in order to get the right stakeholders in the ecosystem to get involved in the Carequality initiative or Argonaut so that this work can be done on a voluntary basis rather than using the brute force of USCDI? I am trying to summarize what Josh and Brett have shared, but I think that is the gist of it.

Clem McDonald
This is Clem. There are some other aspects of the images, like a chest X-ray is often 12 bits, and you have to have transforms to 8 bits to make it visible to people, typically, and with scaling. Have we talked about that at all or how it is going to actually show up to the user if you do not have a full DICOM? I guess that is what I am really asking.

Steven Lane
Clem, I do not really think that is the issue here. Including these data elements in USCDI is not going to dictate whether and how an end user system actually displays the image.

Hans Buitendijk
Also, to clarify, I think we want to be clear that we are talking about references. I do not think the expectation is that the system receiving the reference will ingest the full image and render it themselves. They will use the reference with a viewer of their liking or that is available in combination with the reference data to access the data somewhere else in the PACS system with whomever actually has the image, and as part of that, those viewers and the capabilities there have a variety of opportunities to then render it appropriately for the context that they are doing. So, it is not really sharing the image, it is enabling somebody to access the image in a meaningful way.

Clem McDonald
Okay, thanks.

Steven Lane
So, this brings us to time, and I want to thank Sarah for the opportunity to work on this together. I have crafted a recommendation here. Hans, I think you have offered to wordsmith this a bit, but it sounds like we are coming to a place that we will be able to move this recommendation forward.

Sarah DeSilvey
That is my feeling as well, so, as long as we capture the concerns and the levers, such as the work going on in Carequality and Argonaut, while we have already tried to capture some of the broadband and rural perspective, do I hear that as being the consensus of the group at this time, understanding that Hans has some editing to do?

Unknown Speaker
Yes.

Hans Buitendijk
I am going to do that in a separate cell next to it to work with it so that I am not changing Steven's language which is in the box right now.

Steven Lane
Thanks, Hans.

Sarah DeSilvey
Thank you, Hans. Thank you for the incredible effort on this rapidly over the last few weeks. We are very, very grateful for all the effort that went into this. In the name of keeping on time, I believe we are segueing into Pooja representing medication elements, some of the Level 2 elements that she took the lead on, along with some other colleagues in the pharmacy world. Pooja?

Medication Data Elements (00:24:51)

Pooja Babbrah
Thanks, Sarah. I am hoping this will not take the full 10 minutes because for part of this, I am actually going to turn it over to others that had recommended these, but I think we have four Level 2 data elements that our colleagues at CMS and CDC had brought forward. So, starting with Row 36, the discharge medications, briefly, I know that NCPDP has a task group that is always looking at regulations that come out, and so, they did have a chance to review all the Level 2 data elements, and they did not have any additional ones to bring forward. There was the discharge medication that CDC and CMS recommended to include.

I know Shelly and I had a chance to review that, and we agree with the recommendation to bring that forward. And then, if you go down to Rows 48, 49, and 50, there were additional Level 2 data elements that CMS and CDC had recommended to bring forward. That included medication administration, medication route, and medication-prescribed code, and again, Shelly and I had a chance to review those and agree with the CMS and CDC recommendations to have those included. So, I am going to turn that over to Shelly. I know she had one additional comment on those, and then, I think if we do not have any additional discussion, we will actually turn it over to Michelle when it is her time to talk a little bit more about that.

Sarah DeSilvey
Thank you so much, Pooja. Shelly?

Shelly Spiro
Thank you, and thank you, Pooja. What we did was work with the NCPDP task group that Pooja had mentioned, but we also went back to the pharmacy HL7 workgroup and got their comments on it also. The pharmacy workgroup has agreed in the future at HL7 to begin to look at this in more detail, especially around the definitions and the standards that are named under the HL7 pharmacy workgroup. We want to respect what CDC and CMS are using today, and the need for these data elements are important, and that is why we agree with them. Under prescribe code, we did add additional information from NCPDP comments about using NDC for that prescribed medication code because both RxNorm and NDC are used as prescriber codes in the e-prescribing script standard. And so, we agree with what CDC is putting out, and if they and CMS feel it is important to move forward, we believe we can work with their request to move this out of Level 2.

Sarah DeSilvey
Before we shift to the CDC and CMS section, I wonder if either Shelly or Pooja can address Aaron's question in the chat, which seems appropriate, regarding whether the definition of discharge medication includes the full list that is reconciled at discharge, or if it is only the medications prescribed at discharge.

Shelly Spiro
Well, that is an interesting question because we do not talk about it in USCDI as to the source of the data, so it is going to still have to be interpreted by those who are creating that discharge list. I assume it is whatever in the discharge summary as the discharge medication list. Again, that is interpreted at the generated level. I do not know if I answered your question.

Pooja Babbrah
Yes, as written, it looks like it is what is prescribed as discharge. That is what we have as written.

Aaron Neinstein
Okay, then I might add a comment that, then, in the notes here, just saying that if we are talking about coordination of care, what is prescribed at discharge does not necessarily reflect true coordination of care because it may only be a subset of the current medication list at time of discharge.

Pooja Babbrah
Yes, that is a great point, Aaron, and I think I put that comment in, so we will make sure to take that out of the recommendation.

Sarah DeSilvey
Before we shift, Al Taylor?

Al Taylor
This is sort of related to Aaron's question. As everybody knows, medication, which includes the RxNorm code for a medication, is already a data element in USCDI. I just wanted to suggest that the final recommendations take a stab at differentiating between medication administration code, which I believe is

the code for the medication that was administered, and the code for the medication prescribed, to differentiate between those particular kinds of medication and the one that is already in USCDI.

Pooja Babbrah
All right, I have that noted. Thank you, Al.

Sarah DeSilvey
I believe it is the desire of Pooja and Shelly to move on to CDC and CMS to carry the torch on these concepts, as they are part of what CDC and CMS originally presented. Is that correct, Pooja?

Pooja Babbrah
Yes. If that group is okay with it, I yield my time to them.

Sarah DeSilvey
Michelle, are you okay continuing the presentation of these Level 2 elements, which include the ones Pooja and Shelly commented on from the perspective of the pharmacy workgroup?

Various Data Elements (48 – 56) (00:31:24)

Michelle Schreiber
So, I have just a couple of comments first. Thank you. We put in around facility information and facility identifiers. We formalized those recommendations and put them into the spreadsheet, and I do not think we will go through those now. As was outlined already on medications, I think you have see what is there, and then, we had a couple of others, but I am going to turn to Joel Andress to go through the rest of the spreadsheet, so, thanks. Joel?

Joel Andress
All right, thank you, Michelle. Can everyone hear me all right?

Michelle Schreiber
Yes, thanks, Joel.

Joel Andress
Excellent. Okay, thank you. I think a lot of what we were wanting to say has already been discussed to some extent, and we have covered medications many times already in previous versions. Our arguments for these have not substantially changed. I think the comment about wanting to capture true care coordination versus just the medications that are **[inaudible] [00:32:31]** on discharge is an interesting one. Ideally, you would want to be in a situation where you are capturing medications on discharge at all points and encounters. From a practical standpoint, obviously, that is not the case, and I think that is something we are going to need to think about exactly how that fits and what we are looking at.

The medications at discharge is particularly critical for our work on quality measures because it defines the point at which medications are being prescribed to patients, allows us to orient responsibility for receiving prescriptions from care providers, as well as being able to identify the timing for those prescriptions. Clearly, this is relevant to the work that we are doing on medication management, and this entire area has been a source of difficulty for documentation for us because of the complexities involved, and that is why there are

so many particular data elements associated with medication. We are trying to get at a lot of the complexities that have come up as we look to develop measures, and so, that is why you see so many pieces of the puzzle here, and as we talk through those, it only seems to become increasingly complex. I think we have already essentially said everything we plan to say on discharge medications, so I will not belabor it too much.

Below that, we have the medication administration and medication administered code. This is a part of our desire to look for greater specificity in the data class. Specifically, for medication administration, the completion of that administration provides important clinical information to ensure appropriate care and is used in our quality measures, as well as public health reporting systems including vital records, in order to manage medication assessment and provision. The current concept of medications in the USCDI does not differentiate among the medications that are currently active, ordered, and actually being administered or prescribed to the patient, and this is a point of contention that rises with some frequency as we are developing measures and trying to get at precisely what has been administered versus what has simply been prescribed. I think all of you are aware that those do not always equate to the same thing.

And so, for that reason, we are recommending that this Level 2 data element be pushed forward to Version 4 of USCDI to allow for greater granularity of data capture. Nedra, do you want to comment on this data element specifically now, or do you prefer to come in after we have gone through the various data elements?

Nedra Garrett
I am basically concurring with everything that you said. We work together on our joint justification and support of these data elements, and so, basically just concurring with what you are saying, it is important clinical information for us for some of our public health reporting systems that include vital records, electronic case reporting, for example, routine HIV and TB surveillance, and antibiotic resistance. So, we just continue to be supportive of what you are saying, and we concur with those recommendations for the medication administered code as well as medication administration. We have joint priorities on those. Over.

Joel Andress
All right, thank you. I assume you all want me to go through the full list before we open up for further discussion. Is that correct?

Sarah DeSilvey
I think we should complete the medication elements, then pause, and then have comments on that, and then we can segue into the nonmedication elements. Joel, does that sound good?

Joel Andress
Certainly. That is fine with me.

Shelly Spiro
Sarah, this is Shelly. I want to just make a comment that might help Joel, the CDC, Nedra, and Michelle understand where we are coming from the standards standpoint. We do not have a code for defining which medications are discharged. We do not even have a FHIR resource for the different types of lists, and so, I am wondering if that is the intent, that you want a specific code for a discharge medication or an active medication, that is not necessarily available today. What is available is put into FHIR resources on how that

list is actually used and identified. Whether that is in a care plan or discharge summary, you have a list there, but I do not believe it is codified as to this particular medication, which would be what Al was talking about, that that medication already has a code using RxNorm or NDC, but we do not have a code that is going to say this RxNorm or NDC code is for discharge, med administration, or active med list, if that makes sense.

Joel Andress
I think I understand the distinction that you are making. I think the question is that it is sufficient to simply say we have the list, and these measures come from this list, and so, because they come from this list, then they are considered to be discharge medications. I think that is probably not the final ideal state, but I think it is a reasonable starting point. I think something that CMS and CDC can do jointly is pursue whether or not additional coding to identify whether a medication is being provided on discharge is something that we can develop for future consideration in the standards, if that makes sense. So, the idea would be to capture the representation in the list now, and then develop the FHIR resources to get access or specific, granular listing at a later date.

Sarah DeSilvey
I am just noting we have until 11:20, and then there are a lot of things to discuss, so I am wondering if we can just move through the medication elements completely just to be able tog et one disposition for those elements, and then we can move on.

Joel Andress
Yes.

Sarah DeSilvey
Sorry, Pooja. We are holding just because I figure we can at least… So, I believe everything went down to Entry No. 50. We have medication administration, administered code, and then we have the next one, which is the…

Joel Andress
The prescribed code.

Sarah DeSilvey
Correct.

Joel Andress
And then, we start getting into immunizations, I believe.

Sarah DeSilvey
The full set of medication elements… Have we discussed them all at this time yet? I think so.

Joel Andress
Yes, I think so, broadly, and generally, the rationale for these pieces is they represent the metadata around medications that we think need to be captured within the USCDI, and I think the rationale for that is largely consistent across the pieces of this, so I think we can probably leave them there.

Sarah DeSilvey
Okay. So, I am going to hold for a second, take comments just on the medication elements, and then see if we can dispose of those and then transition to the other elements. So, Ike and then Pooja, quick comments, as we only have seven minutes left for this whole section. Ike, you are on mute if you are trying to speak.

Steven Eichner
You got me. I was muted, sorry. Great work by all. I do think that there is value in including comments, observations, or recommendations around extending the information about the status of medications on the discharge list as a future modification or what ONC and folks might look at to the future. I think as a related issue, we may also want to make a comment about some issues about drugs that are not included in medication lists because they cannot be coded with NCPDP codes because they do not exist.

Specifically looking at medicines currently in trials that have not yet been approved by the FDA, they do not appear in the NCPDP, which means they cannot get coded, so they do not appear on the lists, and that is a real problem when you are looking at comprehensive information about patients, and that data does get stuck in a patient note somewhere, but it is not included in any lists generated out of the medication lists for that patient out of the EHR, so that is an endemic issue that is probably worth a note that says, “Hey, look at this and figure out a way of extending code sets to include drugs that are not yet FDA-approved, but are in trial.”

Sarah DeSilvey
Thank you, Ike. I am going to have Pooja speak, and then we are just going to have a moment to dispose of the medication elements as recommended by the CDC and reviewed by Shelly and Pooja. Pooja?

Pooja Babbrah
I did put this in the comments. I apologize for the discharge medications. I brought that forward pretty early in the process. My understanding is that we did have FHIR resources for this. We can decide as a group if we do want to move this forward, but I just wanted to make that note. I am not sure if we should be recommending that, then, if it is still in development, so I will just open it to the group on that particular data element.

Sarah DeSilvey
Given that Shelly is commenting directly in reference to that, we can entertain them. I do want to make sure we move on to the other CDC/CMS elements as quickly as possible. Shelly?

Shelly Spiro
I put two links into the chat. One is from the confluence page at HL7, and the other is from US CORE at HL7 related to medication list guidance, and I would recommend looking at that. I know that the pharmacy workgroup at HL7 had decided not to create FHIR resources for medication lists at this time. There is also work that is being done under the EHR burden reduction task group on medication lists, and NCPDP has some work that we are doing under a joint task group in relationship to defining the medication list more definitively. So, if it is the intent and I misunderstood what CDC and CMS was asking for, there is no

codification that I am aware of at this time that is going to distinguish a type of medication list. We will be developing it, but it is not ready for prime time.

Sarah DeSilvey
So, I hear two different pass-forwards. There is the idea of moving forward all of the elements as written, and then there is one of moving forward, but keeping the discharge medication at Level 2. Thoughts on moving all forward? It looks like Al lost his connection, but he will come back. We can do it without that. Any thoughts on whether to move them forward collectively, or should we pause and hold back discharge medications at this time, given Shelly and Pooja's clarification, and move forward all of the others? It seems like there are concerns with moving all of them forward, so let's first move on everything but discharge medications. Do we have consensus for moving forward all those Level 2 elements to USCDI V.4? Okay, and then, discharge medications: What is our disposition for that?

Pooja Babbrah
I recommend we keep that as Level 2 for this go-around.

Sarah DeSilvey
Do we agree that, pending clarification of how it is built in FHIR and understanding how to differentiate discharge medications at this time, and Aaron's comments earlier, that we are going to hold this at Level 2 for now? Okay, great. So, everything but discharge medications is moving forward. Discharge is held at Level 2. We are hoping to finish the last elements from the CDC/CMS presentation. We have vaccine event record type, orders for end-of-life care, etc., so, moving back to Michelle, Joel, or Nedra.

Michelle Schreiber
Joel, let's start with vaccine event type.

Joel Andress
Sure. This simply captures whether or not the vaccine event that is being captured is the delivery of a vaccination, or if there is a report of the vaccination or documentation of prior vaccination. This is an issue that comes up with our documentation of immunizations quite frequently, provides additional detail on how the vaccinations are being provided and when, and helps us distinguish between the provision of services versus confirming that the care has been provided. This is a critical distinction not just in quality measurement, but also in surveillance and providing for surveillance of vaccination of the population at large until we recommend that this be included in Version 4 for USCDI. Do you want me to pause, or do you want me to run through the remaining data elements here?

Sarah DeSilvey
Let's just review them as a set, even though they are not incredibly related. Actually, Hans has a question.

Hans Buitendijk
I have a clarification question. I understand that it may not be the current immunization data that is being captured in USCDI Version 3 and below, but it is not clear yet what it actually is, and therefore, the clarity can give us good sense of where we would have to look when we develop the standards to support it, whether there is something already there or whether that requires a fair amount of work to still pull it together. I am not sure how to scope this.

Sarah DeSilvey
Any comments from CDC and CMS to answer Hans's questions?

Clem McDonald
Along the same route, though, there is not an accepted standard, at least for vaccinations, and, I think, medications in HL7. Are these consistent with that?

Hans Buitendijk
Well, with the immunization data that is currently in USCDI Version 3 and below, expressed in FHIR with the immunization section in C-CDA, they all correlate to the Version 2 vaccination and immunization messaging to report on an immunization that has occurred. In that sense, it is historical because it describes exactly what was provided. Other information is not about planning for it or not, and that is going to be much more of a question to understand what we are looking at. Is this a kind of immunization plan? Is that really what the event is, because we are looking forward in some areas? What is it really that is being looked at to understand how to translate that? Because I am not seeing a direct relationship yet, other than some vocabulary, into what is the concept that needs to be met to or created to support it.

Michelle Schreiber
So, Hans, let me ask you a question. I think what we are trying to differentiate here is whether or not the vaccine is actually administered during the encounter or whether or not it was actually historic that the patient said it was administered.

Hans Buitendijk
That is part of transactions already as well. It is actually in some standards already. If it needs to be known that I am reporting this as a historical event, and particularly, Version 2 already does that, and therefore, if that is what is meant as clarity on how to progress that into FHIR US CORE and C-CDA as well, that is part of it, versus where it is a "now" event, as in "Today, I administered a vaccine" versus "I am recording that it was done two years ago or sometime when I was a kid." Those capabilities are there in the transactions. If that is what is meant, that helps clarify that this should be more straightforward because we already do it in those transactions versus talking about a new concept.

Joel Andress
It is not just a question of whether or not this is something that I did historically and not today, but it is a question of whether or not it is something that the clinician has provided and has direct knowledge of the provision of the vaccine or if it is something that the patient has reported has occurred, but the clinician does not have an independent record or confirmation of it. That is relevant in a number of places where we collect quality measure data, but it is also relevant for surveillance because it ultimately allows us to get a view into whether or not these reports are reliable and can be confirmed with other data sources of direct provision of the vaccines. I think that is a distinction from what you are describing.

Hans Buitendijk
I would have to check whether that is actually captured and communicated already or whether it is historical or not. I would have to double-check that.

Joel Andress
Okay.

Sarah DeSilvey
Joel, I am just going to change the plan a little bit because we are going to bleed a little bit into our general review time, as we have one other element that has not been reviewed, and I know we just started talking about this, but is it okay to consider this a disposition of the vaccine event record type so we can move on to the next element? Anyone opposed to moving this forward?

Hans Buitendijk
Depending on which part, it might get a little bit challenging. The historical part is typically already reported. I am not convinced that the nuance is there yet, but it needs to be checked, and that would make it more or less complicated to identify how to document that in the standards in the timelines that we are looking at.

Sarah DeSilvey
Any other comments from the workgroup? So, do we move this forward or hold it for further analysis, given that we are final recommendation time? Do we move it forward as it stands?

Hans Buitendijk
Can we indicate that there is more clarity on the historical part?

Sarah DeSilvey
Absolutely.

Michelle Schreiber
Okay.

Hans Buitendijk
So we have consideration around the second part to make sure that nuance is already captured consistently today.

Sarah DeSilvey
That is helpful, Hans, and it sounds like we can and should, as we have in other areas. Okay, moving on to orders for end-of-life care.

Joel Andress
Sure. So, think the argument here is the same as what has been presented previously. I think the utility of this is that it allows for the ready sharing of end-of-life care orders between providers, as well as sharing it with patients and their family and related care providers, and having access to that information is going to be, obviously, critical for coordinating that care, which will involve a number of parties, not just the clinician who is ordering it, and we think that is going to be a critical element for appropriately managing end-of-life care at the end of the day. So, we are maintaining our previous recommendation of moving this forward into USCDI.

Sarah DeSilvey
Any comments on this element? Mark is noting that orders for end-of-life care will overlap with the small-group recommendation of advance directive. Can we ask that the two groups reconcile their dispositions to ensure we do not have duplicate recommendations?

Hans Buitendijk
That would be helpful.

Mark Savage
Sarah, I do not think there is any issue about that, I am just noting the conceptual overlap.

Sarah DeSilvey
Wonderful. We will just cross-check to make sure the disposition and definitions do not conflict or duplicate each other.

Steven Lane
In clinical concept, I think they are complementary.

Sarah DeSilvey
Correct. Any concerns with moving forward orders for end-of-life care as written, understanding the need to clarify distinction from the elements that are contained within advance directive? Okay, moving forward to emergency department note. Thank you, Joel, for your patience.

Joel Andress
Of course, thank you. I think the emergency department notes are here for a couple of critical reasons. One, emergency department visits inherently indicate a degree of care coordination from the emergency department to care following up with the patient, which will likely not be with the emergency department. Information about what was done and what care was provided, what treatment was offered, and what follow-up steps are necessary should be readily shareable, so we think it is appropriate for USCDI for that point. There is the additional issue that ED departments are disproportionately responsible for treating historically vulnerable and underserved populations, and so, it is more likely that you are going to need this kind of care coordination for these groups and not simply rely on memory or conversation between the clinicians and the patients, and for that reason, we want to recommend that clinical notes for the ED department be included as part of the clinical notes data class for Version 4.

Sarah DeSilvey
Any concerns with including emergency department note within the clinical notes data class?

Steven Lane
No concerns, Sarah, but I think it is worth noting that these really are progress notes also, and are really probably already included in USCDI. I know that there are constituents that we want to make sure of, like operative notes and ED notes, for example. All of these notes are critical, they are all really important, and we have previously recommended that we simply include them all. They are certainly all included, like EHI is defined. I have no objection to this, but I think the methodology of adding individual note types to USCDI

is not really something that ONC has been enthusiastic about. I think we can recommend it, there is no harm, but I think we need more than just this.

Michelle Schreiber
We would agree with you that we need more than this, but the fact is when there is just a bunch of progress notes that are coming through, it is hard for people to distinguish one note from another, and we think **[inaudible] [00:59:27]** notes that is really important to be able to distinguish that, particularly operative notes, ED notes, and surgical notes.

Steven Lane
Agreed.

Clem McDonald
There is a document ontology that helps with that. I think we noted that in the box.

Sarah DeSilvey
Wonderful. Ricky?

Ricky Bloomfield
I would just make a comment. I am supportive of this as well, and I also hear the concern about needing all of the data to come through as part of EHI. That is completely valid. Right now, the way the clinical notes guidance is written, it does indicate specific LOINC codes, and the LOINC codes for emergency department progress note and emergency department discharge note are different from a general progress note and a general discharge note, so I think the guidance here would be to add those specific codes, and I am assuming you would want both progress as well as discharge note, or are you asking for all notes related to the ED? Because I think that is part of the conversation: Which notes specifically do you want from the emergency department?

Michelle Schreiber
I think the most important one is the discharge note from the emergency department, so if we had to have one, it would be that.

Ricky Bloomfield
Great. I can put some additional links in the document with that information.

Sarah DeSilvey
And then, I am just going to volunteer you, Ricky, to assist CMS in drafting the final recommendation there, just to make sure it aligns with the necessary included LOINC codes, if that is okay.

Ricky Bloomfield
I would be happy to.

Sarah DeSilvey
Thank you so much. Al? You are muted, so we cannot hear you if you want to speak.

Al Taylor
Sorry about that. When I reconnected, it remuted me. So, the point is well taken about multiple different LOINC codes representing multiple different note types from the ER and, consistent with the pattern of ONC's identifying a starter code or a generic code for these different clinical note types, is something that we could carry forward and might designate one of these ER notes, like the ER progress note LOINC code, as a "starter set" or generic code. That is something that could make its way into the recommendation, but that is likely how ONC would process this if we were to consider adding a data element like clinical note type ER note.

Sarah DeSilvey
Thank you, Al. So, with the clarity on specifics, it sounds like we are in agreement that this is an important note type, and we can edit the existing clinical note definitions and add the specific LOINC elements, just understanding the possible proliferation of all note types, but I hear us saying the necessity for this note is well recognized. As a rural primary care provider, I agree. Moving on to the next one, I want to ask us to consider the next three elements as a set because really, there is a theme here. The recommendation is to expand the data element definition across functional status, disability status, and mental cognition status. So, our friends at CDC/CMS, if you can lead us through these conversations in short order, and then we will try to dispose of them collectively. So, functional status, disability status, mental cognition status over the next few minutes, and then we will try to get a consensus rec at the end of that time.

Joel Andress
Certainly. So, as you noted, all three of these are within the health status assessments data class. The three elements we are concerned with are functional status, disability status, and mental and cognitive status. The ask is basically the same across these, which is to expand the definition of the data element to not only include the specified assessment questions, but to also include the responses or results of the assessments in alignment with the PACIO project IG. The goal here is to be able to include the patient-generated information so that this is something that can be shared not only across providers, but also with patients and with family and friend care providers who are trusted by the patient to support the coordination of care across providers as well as at the home. We think that this kind of detail is necessary for true care coordination, and so, we are asking that the definitions be expanded to incorporate the data centers for the responses as they have been outlined in the existing PACIO IGs.

Sarah DeSilvey
Thank you so much. Any comments from the IS WG? This seems like a fairly straightforward recommendation.

Mark Savage
Make it so.

Finalize Draft USCDI v4 and Level 2 Element Recommendations (01:04:45)

Sarah DeSilvey
"Make it so!" Yes. So, functional status, disability status, mental cognition status, expanding the definition to include the responses in line with the PACIO project IG. All right, so disposed. Again, there is a lot of work here to do on final recommendations. Thank you so much to our friends at CMS and CDC for coming

back and running through these elements. We are very, very grateful. I believe we have one remaining element that we forgot to discuss, which is a Level 2 element. I think it was family health history. Mark, am I correct?

Mark Savage
That is right, and you also have a recommendation on advance directive, but you may be thinking of that as a different category. I can go forward with family health history if you would like.

Sarah DeSilvey
That sounds good, thank you.

Mark Savage
Okay. So, this is basically a repeat of a recommendation to HITAC that the workgroup considered and approved last year. The HITAC, in turn, included it in its recommendations to ONC. The idea is to include some core Level 2 data elements that are related to patient-generated health data that have been a critical part of care, like family health history, so that is why it is under F, "data element," but that is just one of the short list of really important items that we could be using to start getting patient-generated health data going. The one thing I have added in Column K that was not before us last year is spotting that the 21st Century CURES Act itself said that the certification criteria should include the patient's ability to electronically communicate patient-reported information, so, in priorities and alignment prioritization criteria, there is statutory support as well. Thank you.

Sarah DeSilvey
Understanding this is a revisiting of elements we have recommended in prior years, any concerns for moving forward this element, family health history, as a recommendation from the IS WG? All right, so disposed. Again, thank you so much, Mark. Just to clarify, as Grace is not here, I believe we addressed advance directive last week. I may be wrong.

Mark Savage
Sarah, there is a small group that worked together the recommendation…

Sarah DeSilvey
Oh, on the recommendation. Okay, thank you. Mark, can you help lead us through?

Mark Savage
Yes. Grace is sorry she could not be here this morning, so I am pinch hitting. Basically, we have divided the recommendation to a V.4 and a V.5, so, to move forward with advance directive focusing on the narrative description and supporting the documentation, but also, in our small group, we talked about advance directive as really being a type of care plan. You will see in the opening sentences there additional work for ONC to incorporate advance directive with the workgroup's recommendations on care plan and to begin integrating advance directive as structured data in the structured aspects of care plan when we get to USCDI V.5. Just picking a few particular items, we noted that advance directive is actually sort of a range of like documents, including POLST and MOLST, so that was my earlier comment. We were thinking of those and integrating that collectively. And then, also, we provided some justification that the immediate

priority should be to establish the existing onramp for documents as we begin to work on structured data for V.5. Ricky or Hans, anything I missed?

Hans Buitendijk
No, I think you covered it, thank you.

Ricky Bloomfield
Nothing from my end. That covered it. Good teamwork.

Mark Savage
Thank you, Sarah.

Sarah DeSilvey
Of course. Shelly, a question?

Shelly Spiro
More of a comment. I did bring these questions forward about the care plan to the patient care workgroup cochairs to further discuss how the care plan components are represented within USCDI, and they agreed to take a look at it. I do not think it will be ready for this cycle, but I did want you to know that I have reached out to the patient care workgroup about how we would define the care plan data elements within USCDI.

Sarah DeSilvey
Fantastic.

Mark Savage
It sounds like that will be good for the V.5 work.

Sarah DeSilvey
Mark and I are brain-sharing. Yes, that sounds like a wonderful thing to integrate into the V.5 work. So, we generally approved advance directive last week, and so, we are approving of this final recommendation with its subtleties as crafted by the sub-workgroup. Any concerns there? Okay. So, we have approximately 13 minutes now before public comment. Mostly, I just want to say an incredible thank you to the work that went into today and all of the previous works to get all the Level 2 elements and draft USCDI V.4 elements disposed of by this workgroup. It has just been an incredible level of effort, and we are all very grateful, and I am grateful as well.

Our next task is really to put in these final recommendations. Al, Naresh, Mike, and I were working on the template over the weekend and early this week. We have some of the sub-workgroup leads who have drafted final recommendations. There is a lot to do. Remember, we have to focus specifically on anything that is a slight edit, so I am going to ask for volunteers to take time tonight and maybe tomorrow to try to lead into this because we really want to have a draft of the final report for you all to look at ASAP. So, I am hoping that individuals can lean in and craft those final recommendations in short order. Naresh, any comments or thoughts? Again, this is putting your final recommendation, which is synthesizing workgroup discussion and, Al, any elements you heard in the chat into that Column M. Naresh, anything else to add?

Naresh Sundar Rajan
No. We will work on the background to continue to finish these final recommendations from our end, but would definitely like to take any support that the team has to offer.

Sarah DeSilvey
Thank you so much. Any other final thoughts? Again, for the lab elements, Hung, Ricky, and that whole group drafted them all. They are now in the document, and each of the different subgroups have them drafted. Mark, I see you have taken the lead in putting some of the elements in, especially those rollovers from last year's IS WG recs. Again, if we can just consider putting those in as a team over the course of the next few days, I would be grateful for that help.

Mark Savage
Will do.

Sarah DeSilvey
It looks like we are moving to public comment a little early. Ike has a question. I will be happy to go to confirm we want them in Column M. So, anything placed as a final recommendation in the final recommendation column on that Google sheet, that Column M, will then be transcribed by the team, and again, Al, thank you so very much for all your efforts here, into the final recommendation draft that we are working on asynchronously with ONC, so then we can present it back to you. Again, if folks can lean into those final recs to put those in both today, tonight, and tomorrow, we would be grateful. I believe we are moving to public comment. Mike?

Public Comment (01:13:40)

Michael Berry
Sounds great, thanks, Sarah. We are going to open up our meeting to the members of the public if they would like to make a comment. So, if you are on Zoom and would like to make that comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and, once called upon, press *6 to mute and unmute your line. We will pause just for a moment to see if anyone wants to raise their hand. Not seeing any hands raised, Sarah, I will turn it back to you. Thank you.

Sarah DeSilvey
All right. Al encouraged me to do this. If we could go to the share drive and actually just start plugging in names of folks who are going to take sections, that would be great, just to get the inertia over. Again, we have at least 10 more minutes of the meeting, so I am hoping to put those in and at least get ownership of who is drafting what in that Column M before we adjourn today because after all the work to review it, this is really the final step so that we can get our report to HITAC. Al, would you mind sharing again? I am so sorry.

Al Taylor
Sarah, which column do you want us to put our names in?

Sarah DeSilvey

If you put your name in Column M, which is that final recommendation column, then that will help everybody know that that is a work in progress. All right. So, starting from the top, if we scroll over to Column M, I am wondering who can take the lead on the final recommendation for the substance nonmedication data element. Does anyone from the peanut gallery want to nod in, or does anybody want to necessarily call out an element that they feel they are willing to take ownership for? I have been trying to fill in the gaps.

Hans Buitendijk
I will have the opportunity tomorrow to go through a couple of them to give it a spin, plus I had a question around some of the general comments. There is one in there that I will be working on tomorrow.

Sarah DeSilvey
Okay, wonderful. I guess what I will say, given that everyone on this committee has worked so hard, is please put your name in Column M soon so that at least we can see who is working on what so that we spare labor for the collective, and then, we can go forward from there. I realize that there was one other data element that was an addition from the lab group, and there was consensus on the recommendation, but I realize that the IS WG did not have visibility on that, so can we quickly move to discussing the lab test kit UDI? My apologies, it was a late breaking addition in an email that I believe started last weekend. Raj, Hung, or Hans, do you want to discuss the disposition of the lab test kit UDI?

Raj Dash
I will kick it off. I think there is harmonization now on the recommendation that has been stated in the spreadsheet for the test kit UDI. I think there is a recognition that while there is some FDA guidance on universal identifiers for devices, this particular data element is not as well established. I tried to make the argument that it is going to be a requirement for comparability of results, and therefore kind of a foundational data element for laboratory data interoperability, but I think Hans has come up with a reasonable path moving forward, so I will defer to him on how we have constructed this.

Hans Buitendijk
Thank you. It is a question of different pieces of the puzzle fitting together, where we see, when it comes to test kit UDIs, that when you use the FDA definition of UDI, the components that are in there, which would include a formal device identifier, serial number, and manufacturer, it is challenging to obtain that consistently, but if you start with device name and manufacturer, that becomes much more widely there, so that is where, in the recommendation, we thought we should focus on that. At the same point in time, there are opportunities that, as that is being defined and say that this the minimum that we should start to support, we should be clearer about what it really is that we are after. That might not be in USCDI, but with appropriate documentation in the respective standards, and we should start to look at that, we want to see that we can help everybody moving forward so that the entire chain from the analyzer, the test kit used, whether it is a machine in a lab or a manually executed test, etc., that we can start to get it in from the get-go and then begin to ripple that through.

So, it is balancing between if you go for that end goal right now, maybe a step too much, but if you do not take a step, that is not good enough. That is where we thought there is a good in-between to get it going and then start to be able to build on that and get different parties to contribute to making their piece work in order to do this because it is going to be an LIS, IVD, EHR, or other system that needs to fall in place to make this work.

Sarah DeSilvey
Thank you so much to everyone involved in that conversation. I know it was a lot of work to get consensus on that. Any thoughts or concerns from the IS WG on moving forward the recommendation? Again, my apologies for forgetting this. It was late breaking. If we can go back to the workgroup recommendation, under test kit universal device that we ended up moving over, Hans, I believe the recommendation is to… Al, can we scroll over? I think we are missing seeing exactly what the consensus statement was. Hans, can you just say it out loud? It is the device name and manufacturer data, correct?

Hans Buitendijk
Yes, it is the device name and the manufacturer, and then, the rationale has that wider concept that we need to be able to work with everybody to get this done.

Sarah DeSilvey
Great, and moving forward to full UDI in time.

Hans Buitendijk
Yes.

Sarah DeSilvey
Any concerns with that, colleagues? Thank you so much. So disposed. All right, wonderful. I believe, again, the yeoman's work for the next few days is to put those final recommendations in. I am going to keep requesting that folks volunteer and put their names in Column M just because, again, if you claim it, it will make sure that there is not duplicate labor happening, and then, Naresh, ONC, and I will be moving those final recommendations into the final draft of the recommendation, and we will start reviewing that over the course of the next weeks. Any other final thoughts before we adjourn today? Naresh, any other final thoughts?

Naresh Sundar Rajan
You covered everything, Sarah.

Sarah DeSilvey
Okay. I am incredibly grateful for the tremendous work of the last period of time. It is now our job to put all of that effort into the final recommendation, and so, that is our push for the next couple weeks. Thank you so much, friends, and we will see you next week.

Adjourn (01:21:58)