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
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer

Name	Organization	Role
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Brian Bialecki	American College of Radiology (ACR)	Presenter
Keith Dreyer	ACR	Presenter
David Mendelson	Mount Sinai	Discussant
Alan Swenson	Carequality	Discussant
Bill Mehegan	Carequality	Discussant

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

Mike Berry
Good morning, everyone, and welcome to the Interoperability Standards Workgroup. I am Mike Berry with ONC, and I would like to thank everyone for joining us today. We do have a few guest presenters with us today, and I would like to thank them for participating in our meeting. All of our workgroup meetings are open to the public, and your feedback is 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 would like to begin rollcall of our workgroup members, and when I call your name, please indicate that you are here. We will start with our cochairs. Sarah DeSilvey?

Sarah DeSilvey
I am here.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
I am here.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
Ricky Bloomfield?

Ricky Bloomfield
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Christina Caraballo? Grace Cordovano?

Grace Cordovano
Good morning.

Michael Berry
Raj Dash?

Raj Dash
I am here, good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Nedra Garrett?

Nedra Garrett
Good morning.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Bryant Thomas Karras? Steven Lane?

Steven Lane
Good morning.

Michael Berry
Hung Luu?

Hung Luu
Good morning.

Michael Berry
Meg Marshall? Anna McCollister? Clem McDonald? Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Aaron Miri? Aaron Neinstein? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Michael Berry
Mark Savage?

Mark Savage
Hello.

Michael Berry
Michelle Schreiber is not able to join us, but I believe Joel or Bridget will be filling in for her. I do not see either on, but they should be joining. Shelly Spiro?

Shelly Spiro
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Anna McCollister
This is Anna McCollister. I just joined. Sorry.

Michael Berry
No problem, thank you, Anna. Now, please join me in welcoming Sarah and Naresh for their opening remarks.

IS WG Charge (00:02:43)

Sarah DeSilvey
Hello, colleagues, for our next edition of the IS WG. We are really grateful for the coordination to get this kicked off. We are going to deep dive into diagnostic imaging data elements. Thanks to Steven Lane for organizing all of that work today. We have guest subject matter experts presenting on that matter. We will then go into comments and recommendations. We just have a couple of USCDI V.4 elements that we have to just move through that I neglected the last meeting, and then really try to formalize and finalize any of those Level 2 data elements, and we will then go into the workplan and timeline.

I will be saying this throughout the presentation, but I want to remind everybody that if members of the workgroup are able to take ownership of drafting the final recommendations, it is very appreciated. We are very grateful to those who have taken leadership on that so far. Again, we are leaning on the committee, anyone who has a workgroup, or anyone who has presented as a subject matter expert to draft the first stab at it, and then we can all respond if need be. We will then go into public comment, and then we will adjourn. Naresh, any further comments?

Naresh Sundar Rajan
No comments, Sarah.

Sarah DeSilvey
Okay. Now on to the reminder on our charge. Next slide. We have, again, almost completed this element of the charge, which is to review new data classes and elements from draft USCDI V.4 and any Level 2 elements that were not included in draft USCDI V.4. The unstated part of our charge is to craft those final recommendations, and that really is what we need to lean into over the course of the next couple of weeks to ensure that we have something really solid in order to review and finalize in order to get it to HITAC on time. Any questions? All right, next slide, please.

This is just, again, the update on what we have had a final disposition on and things to remain. In a review after our last meeting, like I mentioned, I realized that we had not finally disposed of specimen condition and disposition, and I am wondering if that gets rolled up to the work Hung was leading. We also had not clarified a final disposition on time of procedure. That should not take very long, it is just that they were not disposed of in the previous discussions. Everything else that is green is a USCDI V.4 element that we have moved forward and are crafting final recommendations for.

Again, it is really important that we draft recommendations that note differences: Differences in definition, clarification of purpose, for instance, in the substance use elements is those conversations regarding the difference between prescribed substances and nonprescribed substances. So, if all that subtlety is specific, it is part of what we should include in our final recs. If it is moving forward without any comment or any concern, then we do not necessarily need to lean into them as deeply. Any questions? Again, I just encourage anybody to review last year's recommendation from this committee, and for those of us who are new to understand precedent as we draft our final recommendations. Next slide, please.

It is now my honor to pass the mic to colleagues to discuss the diagnostic imaging data elements. Again, thank you, Steven, for quickly and swiftly organizing a subcommittee to discuss this. We have many experts

to speak to these elements and the requirements for them, and we are grateful for their attendance today. Steven and crew?

Diagnostic Imaging Data Elements (00:06:24)

Steven Lane
Yes, and I do not mind kicking us off. Thank you very much, Sarah. I want to acknowledge the ONC, especially Dr. Al Taylor, for bringing to our attention the fact that there were some very valuable diagnostic imaging data elements sitting in Level 2 that the ONC had not included in draft V.4, and as I dug into them, it was clear that there was a huge opportunity here for us to help to advance diagnostic imaging data and information exchange, so we reached out to the submitters of those data elements, Brian Bialecki in particular from American College of Radiology, who is going to walk us through them, with the additional support of folks from his team, and then, we also reached out to the folks at Carequality, and also at the Argonaut Project. Thank you, Ricky Bloomfield, for connecting those dots. We have a lot of people who want to support this, so we are going to try to go through this as expeditiously as possible, answering any questions and then looping back around and seeing if we can all support it as a group. So, with that, Brian, do you want to take it away?

Brian Bialecki
Sure. Thank you very much, Steven. I appreciate the opportunity to speak to these elements and why we believe they are extremely important to be included. I have with me Mike Tilkin, the CIO of ACR, and also Keith Dreyer, who is our Chief Science Officer and a radiologist as Mass General Brigham. Next slide. So, the three data elements that we are speaking to are imaging reference, accession number, and requested procedure identifier. The accession number and requested procedure identifier really give me links between a diagnostic imaging report and the images themselves. Requested procedure identifier can be a subset of what is ordered under an accession number or a service event, and I may get multiple requests of procedure identifiers for a particular imaging study. And then, again, the imaging references where I can physically see, stream, look at, download, get content, or search for these particular images. Next slide.

So, really, the use cases for imaging reference are the source institution continuing to update these records as a source of truth, such as name change, data that was unmatched, or whatever may need to be corrected. The imaging reports, CDA, and DICOM include references to key images and have places for DICOMweb annotations and hyperlinks that can be built in the report. IAG has profiled an interactive multimedia report, which would then become enabled outside of an institution by providing these references. These endpoints are already resources that are provided by all the VNA PACS and image display vendors. It is called DICOM WADO-RS, and you are able to then retrieve the instances in native or rendered format, streaming them into, say, a browser or things like that.

The DICOM WADO-RS Part 18 was added to DICOM in 2011 and is, again, well supported with, obviously, the ability to render them, stream them, just view them in context on the screen from a link, or retrieve them for something like the continuum of care, such as surgical planning, where I may need that physical image to draw something on it. FHIR does have an imaging study resource, which is at Maturity Level 4 in the current CI build, which does have these same references as part of it, and all of these models are well documented through IAG's web-based image access, which has been tested globally through multiple IAG connectathons, again, going well back into the 2012 timeframe. Next slide, please.

The other thing I just want to bring up is where this really impacts patient care. I do not need to worry about duplicate exams or unnecessary radiation events. If I am a patient, I show up to my referring physician's office, and I do not need to worry about rescheduling my appointment because I do not have a CD there with me, I do not need additional infrastructure at a referring physician's office because I can stream these images across, and the data is immediately made available to consumers, whether that is an ER transfer or a referring physician/surgeon. It is available in the format that is needed by the consumer, whether that is image viewing, exam transfer, whichever is really needed, and ultimately, the creator is the maintainer of the source of truth by just having these references available. So, again, those are the points that I would like to make, and I guess if there is anything that you want to add, Dr. Dreyer, please go ahead.

Steven Lane
Does anyone else from ACR want to comment? We did invite Alan Swenson and some others who have been working on the Carequality image exchange implementation guide, just to add any comments about how the inclusion of these data elements in USCDI would support the advancement of exchange over the existing national framework. Alan, are you here?

Alan Swenson
Yes, I am. Thanks, Steven. This is Alan Swenson, Executive Director of Carequality. So, Carequality has an implementation guide published today. Previously, I worked largely with the RSNA and some work from the Sequoia Project with their RSNA Image Share Validation Program, and the implementation guide that we have is really directed at imaging vendors exchanging the full diagnostic images between PACS systems, and we have a number of imaging vendors that have helped in the creation of that, have even published some imaging journal articles on the work there, and are preparing to roll that out to their customers. So, that is different than the references that were specifically talked about and that Brian walked through here.

However, one of the workflow issues that has come up in the context of Carequality is the provider needing to tell their local PACS system to go get an image from someone else's PACS system. Obviously, there are scenarios where that exchange may not be needed, like just being able to view the external images, as Brian covered, but in many cases, there is a reason why an organization would want to actually retrieve and store within their own PACS system the full diagnostic image. Having these reference pointers in USCDI gives us some steps to solve similar workflow problems, both within FHIR and also within C-CDA, and most of the exchange for treatment purposes today uses C-CDA documents over HIE profiles, and there is a C-CDA document template within C-CDA 2.1 for the diagnostic image report.

It is one of the 12 standardly defined document templates. It is not one that we focus on a whole lot compared to some of the other encounter summary referral-specific type templates, but it is defined. Its only required section today is the findings section, which is a narrative section, but that largely lines up, and I would expect, as we see future work and rollout of USCDI V.2, it already requires the imaging test and the narrative report information, which go well in that diagnostic image report C-CDA template. Within that same template, there is an optional section. It is the DICOM object catalog, and the intention of that section is to include the object information that goes along with the findings, the narrative within that document, including the attributes and IDs and things required to retrieve the objects.

So, having this information in USCDI V.4 for the specific references could give us a way to standardize populating that catalogue information within C-CDA so that the EHR system that receives this diagnostic image report from another EHR system would now have all of the necessary information to just tell the PACS system the specific information about the image that it wants the PACS system to go retrieve without the provider needing to log in and initiate a new query flow with patient-matching finding documents, etc., since the EHR, through this CDA, would already know exactly where the image exists and the references to go get it. And so, again, this is not directly considered within Carequality's implementation guide for the full exchange of diagnostic images, but it solves some of the workflow pieces to help operationalize at scale the exchange of those images.

Steven Lane
Thank you, Alan. Dr. David Mendelson, who is a practicing radiologist, also wanted to share some support for this.

David Mendelson
Sure, thank you. So, I am David Mendelson. I am a radiologist at Mount Sinai in New York, and I am representing the RSNA here as well, and we are strongly supportive of these references that Brian from the ACR has submitted. They facilitate all the use cases. That is the beauty of it. RSNA has focused with Carequality and Sequoia on the actual exchange of the images, and there is large utilization and need for that, as evidenced by the exchange of CDs on a daily basis. I think my hospital alone gets 300 CDs a day. I suspect Dr. Dreyer here gets at least that many, if not more. But also, just the viewing capability is another use case that we recognize as being important, so, yes, I think this is very nice in that it really furthers all the use cases. Thank you.

Steven Lane
Thank you, David. Ricky Bloomfield, are you prepared to speak a little bit to the discussion we have been having with the Argonaut team about how this fits into the work that they are doing?

Ricky Bloomfield
Sure, I would be happy to address that. So, Argonaut has approved taking on a FHIR imaging study project this year. For those that may not be familiar with Argonaut, it is a group that started in 2015, originally created the Argonaut implementation guide for DSTU2 general patient access, and there are other use cases as well, and currently supports the annual updates to the US CORE implementation guide as this group puts forward additional content as part of the draft. So, they have been working very closely with this workgroup.

For this upcoming year, this proposal was based on some early work that Josh Mendel had done as part of the Sync for Science program several years ago, and the goal is to enable patient access to imaging studies using the FHIR imaging study resource via standard DICOM web mechanisms, and the high-level goal is really to leverage existing patient API authentication and workflows so that a patient can authenticate into an existing health system so that individual can query for studies that are available in, perhaps, a parallel PACS system, get that reference, and, using the same authentication with token introspection, access that file directly so they can view it, share it, do whatever they need. I think they are very similar use cases to what has already been mentioned.

So, the goal at the end of the project this year is to have an implementation guide and actually have people come to the table to test this, both on the client as well as the server side, to make sure this implementation guide works as expected. So, that is the current plan. Brett Marquard, who leads Argonaut, was going to try to be here today, but he is unable to make it. He could share more information as well if there is interest.

Steven Lane
Thank you, everyone, for providing that background to this recommendation, and back to you, cochairs.

Sarah DeSilvey
"Thank you" is an understatement. We are incredibly grateful for this deep and really careful work that happened in a very short order. And now, we have questions from the workgroup. I see Deven.

Deven McGraw
Great, thank you very much, Sarah. I just want to clarify, because this sounds great, but I want to clarify that I have this right. If a patient gets that reference number that will be part of the USCDI, are they then able to go and get the image files without necessarily having to open up an account at the imaging service provider so it does not require that additional legwork? We get images on our Citizen platform for users not going through their FHIR APIs, but oftentimes, we have had to make arrangements directly with these imaging vendors, including signing contracts, in order to facilitate the ability of our patient users to get this information. It sounds to me like this would streamline that pathway and that patients would not have to establish accounts with Life Image, etc., but I just wanted to confirm that. Do we know?

Steven Lane
I do not know if any of the true experts are prepared to respond, Deven, but my sense is that including this in USCDI would not automatically make all of that magic happen, but that it would move us in a direction where, if patients had the path information, the accession number, etc., they would be in a position to make those requests with less friction, but others are certainly welcome to comment.

David Mendelson
This is David. There does need to be a governance structure around this for security reasons. You would not want anybody just finding your link and being able to open your exams. However, the burden, I think, would be less than that you described today with the image exchange vendors. So, through patient portals, this is already kind of being introduced at many sites, but it is not as lightweight as this is, so if you were in your local patient portal looking at your record, this would facilitate that viewing on your part without the burden of an intermediate exchange vendor being visible to you. If they are there to help, it is there because they are transparent, then.

Deven McGraw
Right. No, I get that, but we are also discussing pathways of interoperability that are less dependent on patients needing to navigate to each and every one of their portals, such as by querying for their records through national networks or the TEFCA. That is definitely on the horizon, so it sounds like there might be some work to do to get some of these imaging vendors connected up through some of those networks so that there is less legwork that has to be done if you are not using the portal to do this, but undoubtedly, this does sound to me like an important first step, just even knowing where to get them and having the session number.

David Mendelson
It could be lighter than that. You would not necessarily need those vendors. As long as, again, there is a governance model on that national framework you just described, the patient could be led directly to their PACS.

Brian Bialecki
Correct. So, once you have done this, it is really institution to institution. The back-end PACS would already support the streaming of the images, so it is really just federating those back-end calls so that the report you are seeing can… Once you are in that portal, if that portal has access to where that endpoint is, those images are immediately available to you.

Deven McGraw
Okay, thank you.

Steven Lane
So, I will say, Sarah, that the recommendation I have put into Row 47 in the spreadsheet was really just for the diagnostic image reference. I did not include the other two elements that were recommended, but it sounds like our recommendation would probably be to take all three as a package.

Sarah DeSilvey
That is what I am hearing as well, Steven, and I note that for the record. Hans?

Hans Buitendijk
Yes, thank you, Sarah. I really appreciate the update being provided today. Tapping into some of the comments that Ricky and Alan made, there is definitely work in progress to understand how to do this, how to expose it in FHIR. There are different places where the work has been done. We are going to be having some discussion to see how far that adoption and connectivity with respect to imaging modalities or PACS systems have been progressed to enable, when it is good in USCDI, that it is reasonable to expect that all HIT to be certified can support that. I guess that is still one of the criteria here.

So, it is not a statement that this is not a good direction to move forward in, it is going to be more on the line of feedback that I am going to be working through with some of the EHRA members on where we are at, that this is a reasonable step for USCDI Version 4, or if it is better to be done based on the work that Argonaut is doing or based on the work that IHE has done that is in play, that if those systems are going to be required to pick that up, that they indeed have adequate time and connections with other parties to make that happen. They have made substantial progress from where it was. Are we indeed now close enough to take that next step and put it into USCDI Version 4? There is no value judgment at all about the value of it. That is great, but is the timing right, or are we just at the edge of it and will be ready the next time around? That is where I am going to be following up with some folks to get a better sense of where we think we collectively are in practice.

Sarah DeSilvey
Thank you, Hans. Ike?

Steven Eichner
Thank you so much for that. I guess I am concerned a little bit, though it is probably because of a lack of knowledge, about whether we are looking at anything about image resolution information as part of the USCDI in this space. I am really thinking about broadband access issues and broadband capacity issues, and understanding both on the clinical team for rural providers as well as patients in rural environments, thinking back and hearkening back to the day where we had dial-up, were trying to download a large file, and suddenly got stuck because it was going to take an hour and a half to download the file.

Looking at the image side of it, most of us, even as home users, are semiprofessional and only have screens that are incapable of displaying full X-ray or full medical resolution, so I am wondering if we have accounted for identifying resolution or prefacing an exchange for a lower-quality image to meet many needs, which are then backed up with a deeper-quality image when it is medically necessary, or if there is a patient need or interest for the larger file, with the understanding that it may take a bit longer to download and have local storage requirements.

Brian Bialecki
All of those are supported by the WADO-RS mechanisms. Whether I am going to stream the image, I can adjust the quality in my requests, and again, I can pull down the entire diagnostic image and bring it locally to do that.

Steven Eichner
Fantastic. From a taskforce recommendation standpoint, I would want to at least acknowledge not that as a limiter, but that as a consideration in actually operationalizing exchange of that data so we are not creating an environment where somebody has a surprise burden on connectivity or storage requirements.

Brian Bialecki
Correct, and I think one of the reasons that I had mentioned the image reference and the ability to stream is that I believe some providers would not have that storage requirement, and so, now they could see it, and again, based on the requirement, potentially stream it at different resolutions, correct.

Steven Eichner
Right, but even looking at the streaming component, in other words, that is still a matter of looking at what my connectivity is. I am sitting at home and have Google fiber connectivity at some huge rate that I do not really care about in terms of trying to access an image. I am not worried. If I go out on travel as a state employee, I could end up in a space where I have connectivity that is about as good as dial-up, and that would be a challenge. I have a small iPhone to receive it on, but I am also dealing with really low bandwidth on getting the image, so I do not want to stream something at high resolution in that space. Again, I appreciate that the technology is there, but just from a guidance and recommendation standpoint, figuring out that piece of it or making recommendations that that piece of it also gets figured out so we are not breaking or overburdening the connection network.

Sarah DeSilvey
Thank you, Ike. Those are some critical comments, and I want to make sure they get included in a recommendation. From rural medicine, which is where I practice every day, in deep, rural Vermont, I hear that concern. I am hoping to move on to Avinash.

Avinash Shanbhag
Hi, thank you very much. Can you guys hear me?

Sarah DeSilvey
Yes, we can.

Avinash Shanbhag
Thank you very much. Hans and Steve Eichner, you guys hit on the question that I was going to have for Brian from the presentation, and the question was if you typically get a link to the PACS system so your source PACS can connect to the PACS system to issue the transfer. One issue was, from a certified health IT perspective, if it is part of USCDI, whether the link would enable automatic access without further authentication or authorization once that data gets exchanged to providers. From what I understand from your responses, the DICOMweb has that kind of token introspection and the like, so I appreciate that response.

The second question was really what we also have heard is that receiving a full DICOM MH with all the bandwidth in place and the issues that were discussed, it still requires the provider to have a PACS system or a VNA, and typically, what we have also seen, or at least what has come to us, is that providers with the reports may not need an entire PACS system, but would be happy to just view the image if it is at a lower resolution, like a JPEG or one of those lower-resolution images, called reference images, that can be viewed on a simpler viewer. So, I would appreciate if the folks here, the experts, could discuss whether that capability is there and if there is value in having providers that now would receive reports to also get a lower-resolution image in addition to or instead of a full DICOM-quality image, which might require both bandwidth issues and potentially additional software that they may not have.

Brian Bialecki
So, to answer your question, you do get both. You can not only link directly to individual key images or potential images directly in the report, so I could pull up an individual instance or a frame, with no need to pull the entire study, at a lower resolution, or I could pull it at full DICOM resolution, even with individual images, and render them inside of a viewer. Really, the limiting factor is the screen that I am actually looking at it on, so, obviously, if I am looking at a mammography image without a 5 megapixel monitor, I am not really, truly getting it, but I can give you the entire DICOM data down inside of a browser, and with today's technology, that is really just the viewer's capabilities. So, there are plenty of web browser viewers today that are streaming data in this way that are FDA certified, even for mammography primary reads.

Sarah DeSilvey
Avinash, did that address your question?

Avinash Shanbhag
It did. Thank you very much. I appreciate it.

Sarah DeSilvey
Wonderful. We have about three minutes left in our workgroup discussion.

Brian Bialecki
And just to follow up on that, that would not require a referring physician to have any infrastructure to store that image. Once the viewer is closed, the image is gone.

Sarah DeSilvey
Thank you. That is really helpful. Any other further comments or questions from workgroup members? Just to summarize, I hear us recommending not just the one, but the three elements. I hear considerations for noting bandwidth limitations and infrastructure requirements, and I hear the answer to some of those in our final recommendation. Any other final questions or comments for our guests at this time? Wonderful, then. Thank you so much for joining us, and all of your expertise, and again, very deep thanks for rallying in such quick order to create such a thorough presentation today and recommendation as noted in the IS WG share drive. We are very, very grateful. Steven, any final thoughts before we move on?

Steven Lane
No. Thank you very much for that discussion. I really appreciate everybody coming together as quickly as possible, and the fact that we could get all of the experts who know this better than anybody in front of our workgroup is one of the joys of being involved in this kind of an effort.

Sarah DeSilvey
I am going to break precedent a little bit, given that we are so close to needing to get final recommendations present on the document so that we can create that final rec. Usually, what we do is separate a little bit the recommendation from the presentation, but I am just going to see if folks are comfortable with establishing consensus for moving forward with those three elements as recommended by the subject matter experts today, understanding that Steven Lane is going to help fill out those elements on the IS WG share drive.

Steven Lane
Yes, and I already put that in.

Sarah DeSilvey
Okay! Any concerns from the committee on moving forward with a recommendation for these three elements as presented today?

Clem McDonald
Could you repeat them, please, just once?

Steven Lane
Yes. The three elements, Clem, are the imaging reference, the one that I initially proposed, the accession number, and the requested procedure identifier.

Clem McDonald
Perfect.

Hans Buitendijk
But not the image reference, correct?

Steven Lane
Yes, the image reference. That was the first one I mentioned. It is the path and the technical details to know where the image is, whether you are going to just view it or whether you are going to subsequently try to download it, as well as the accession number and procedure identifier, which gives you the details that you need to be able to take full advantage of that information.

Hans Buitendijk
I will maintain the comments that I had earlier, that there are likely some concerns around the practical infrastructure readiness, given the HIT that will be subject to this, not the standards and not the individual items, but to have all three readily available.

Steven Eichner
This is Steve. I agree with Hans that there are some issues in looking at that. My point is about the ability to actually implement them and not overburden anybody. That is more of an implementation guide issue, perhaps, than a USCDI issue, but I am not quite sure we are ready systemically for that to be fully adopted.

Clem McDonald
In Indianapolis, they can pull any image up from any of the sites, so I do not know whether we are advanced or whether it is just not that tough of a problem.

Hans Buitendijk
Depending on what it is, maybe not all three elements are used. It might just be the accession number that is used in order to put something together. Not everybody may have the image reference, so requiring all three and understanding that may be part of the challenge there as well, so that is why I am not sure, not having gone through some of the Argonaut work from an EHR perspective, whether everything is understood about who needs to do what and make sure that there is consistent access across the different providers. So, there are lots of elements there, lots of progress made, but it goes back to my earlier consideration of if we are just at the edge of it and ready to go or at the edge of it and there is still a little bit of work to be done before it is USCDI-ready.

Steven Eichner
Clem, on the infrastructure level, many urban environments have a lot higher bandwidth available for exchange than suburban and rural environments. So, not to take anything away from Indiana or downtown urban environments anywhere, it may not be an issue, but as soon as you get beyond urban core, it could be a real issue.

Sarah DeSilvey
This is Sarah. Hans, can I ask for clarification? There are two different types of responses, or three, really. Is what you are saying a comment on the recommendation, or is not recommending?

Hans Buitendijk
At this point in time, I would be very concerned with a full recommendation to put it at this stage, and as indicated, I am going to have some further conversation to get as good a sense of readiness, what systems actually maintain where they do provide access to images, because they do, there are capabilities, and what it means to get it into FHIR and C-CDA, and where the challenges are with the consistency that is

needed to drive this wider. So, there are some challenges out there. It is not necessarily the standard, but it is the practical implementation, and whether all three elements are necessary for that or are not quite there yet. For example, in one case, the accession number is being used to put the URL together, but there is not an image reference in the way it is defined in the three.

So, what would that mean? You still can get an image up in the current application, but that would not be all that would be suggested to go into USCDI Version 4. What other challenges does that provide? Get it from the source that you can have it because the EHR, if you use that one for this moment as HIT, is not the source of that information. They have to get it from somewhere else. Are those links there? Where are they set up? So, it is more than just this part.

Sarah DeSilvey
What I want to recommend, then, is that we do continue this conversation next week, just to reflect a little bit, because I want to honor those concerns. Hung, before we move on to the next element?

Hung Luu
I just wanted to comment that we seem to be holding these data elements to a higher standard than others, and I wanted to remind everyone that our charge is to identify data elements that are essential for interoperability, not to solve the operational issues, and also, I think that we have been tasked by the ONC to provide our honest assessment of what we feel are essential elements for interoperability and not to necessarily defer what other standard-developing organizations have done or are contemplating, because I seem to hear a recurring theme that we have to check to make sure what HL7 has done or what FHIR has done, and I feel like we are obligating our responsibility to give our honest opinion as to what data elements are essential for interoperability.

I understand that change takes time, and that there will be investments that need to be made, but we are currently on Version 1, and we are discussion Version 4, which is in draft form. So, that is broadcasting, and that is foreshadowing for everybody who needs to be making changes. We are not asking for everything tomorrow. These have been identified as essential for interoperability in the radiology space, and not that we are asking for it tomorrow, but we have identified that these are necessary and need to be included as the floor for interoperability.

Sarah DeSilvey
Thank you so much. We are over time, and we need to move on to our next discussion. However, this is directly relevant to our next discussion, so, one more comment from Ricky, and then we will go into the full comment on all the remaining draft elements and Level 2 elements. Ricky?

Ricky Bloomfield
Great, thanks. I will be quick. I echo the comments of Hung. I was going to say something similar here in that many of the items that are being proposed for inclusion in draft V.4 have not yet been fully modeled as part of an implementation guide, so there are gaps for all of these. One of the things that is unique about this is that there is already ongoing work that was proposed and improved independently of our committee, for example, in Argonaut, to do the same work, so it is actually a little bit ahead of where some of these other data types are. So, from that perspective, I think the goal here could be to include this and then kind

of skate to where the puck is going so that the guides are ready and available at the same time that this becomes a formal part of USCDI and not just a draft, so I would support inclusion.

Sarah DeSilvey
Thank you so much. Again, we have time to pick this up again next week, just letting the presentation settle, and perhaps working through some of our concerns in the workgroup discussion section. This is a new presentation for us, so I look forward to doing that and coming back next week. We can now segue into the full review and comments and recommendations for everything that remains. I just need to understand disposition of those two elements, procedure time and specimen collection, and then we need to continue our review of Level 2 elements. Al, are you with us and able to lead us to the share drive?

Al Taylor
I am, and I am. Just one second, please. All right, where are we going? Right here?

Comments and Recommendations – Draft USCDI v4 and Level 2 Data Elements (00:47:26)

Sarah DeSilvey
You are here, yes. I believe what we were going to try to do, again, because I forgot them, is loop back around to understand the disposition of those two remaining draft USCDI V.4 elements, procedure time and specimen collection. Let's start with the word here "time of procedure." This created a whole cascade of conversations regarding differentiating time of procedure from lab elements. I do not think we formally resolved our recommendation here, so I am just trying to understand what we thought as a final recommendation on this data element so that we can move forward and formally dispose of it. Raj?

Raj Dash
Yes. So, I just wanted to follow up. I talked the day after the last meeting with Dr. Luu, and he reminded us of our small group discussion where we did discuss this, but we had not updated the spreadsheet, so I went back and added the word "not" there. "The date and time of procedure should not be used to accommodate the collection date and time for laboratories."

Sarah DeSilvey
Great. So sorry.

Raj Dash
Yes. I think everything else is coherently stated there, and aligned with the other two date/time elements that are being proposed as renames down below.

Sarah DeSilvey
Wonderful, okay. So, it sounds like this should have been rolled up and might have been neglectful on my part, but any concerns with moving forward with the data element with the definition clarified for the differentiation between procedure time and lab?

Clem McDonald
I did not understand what you just said. Between procedure time and lab what?

Sarah DeSilvey

Clem, my apologies. When we initially started the conversation on procedure time, we took care to differentiate the subtleties between the different times of import to lab collections and processing and a standard general procedure time. Hung, forgive me if I am not stating it correctly, but a subgroup was created to go deeper into those elements of the specific and important requirements for lab collection and lab processing, and the workgroup came back, and we agreed and disposed of those, but in my memory, we had not considered the disposition of the original procedure time. And so, what they have done is clarified the procedure time is not equivalent to the lab times that have been specified by that workgroup, and that part of the definition has been updated, and we would then be able to dispose of it just as procedure time differentiated from labs. Clem, did I do a good job? Does it make sense?

Clem McDonald
Just the word "procedure…" Historically, I think that more **[inaudible] [00:50:26]**. I am just not sure what it means in this context.

Sarah DeSilvey
There are some pretty thorough and lovely definitions within the workgroup, and Hung, Raj, or Al, do you want to help clarify beyond what I stated?

Raj Dash
We are in agreement, Clem. We did not think that the procedure time clearly could be applied to lab, so we wanted to leave it alone so that it could be applicable to a more surgical or some other kind of intervention that would be more procedural in nature, and we wanted to carve out the laboratory result report time and the specimen collection date/time for lab purposes, so that is the discussion, that instead of trying to shoehorn lab into procedure time, we are leaving procedure time to its own domain and carving out the two lab times.

Sarah DeSilvey
Thank you so much. Clem, does that answer your question?

Clem McDonald
No, I think it is a good direction.

Sarah DeSilvey
Thank you so much. Al?

Al Taylor
I just wanted to reiterate that when we added the time of procedure to USCDI draft V.4, it was our initial thought that that data element could be used to provide a timing element to more than just a CPT-coded procedure, and other things that are done, including an IV infusion, which is a procedure which is also medication administration, and vaccine administration, which is both a procedure and a vaccine, that it provides timing elements to those sorts of things that are associated with a procedure that are procedure-related. That was our intent, and our specific request when we published was to get feedback like what has been provided on the lab part of that consideration, whether or not it can appropriately be used or should appropriately be used for adding timing to various ones, including lab, but also other ones, like I mentioned.

That was our intent, and the feedback about lab in particular is valued highly by ONC because it does provide us some additional guidance on where we were heading.

Sarah DeSilvey
Thank you, Al. Hans?

Ricky Bloomfield
[Inaudible – crosstalk] [00:53:22]

Clem McDonald
[Inaudible] a little bit about mixing procedure with administrations of drugs.

Al Taylor
As I said, I would not say it was mixing up, but when something is done as a procedure, like an IV infusion as a generic event, not a particular infusion and administration of a dose of chemotherapy or something related, but the timing of the infusion does not… I was trying to get across that what is infused is not relevant to the procedure of the infusion. Right now, there is no medication administration time for USCDI, for example, nor is there vaccine administration time, nor is there surgical procedure perform time, but they are all procedure-related/oriented and might benefit from one data element as opposed to adding a timing data element for every single thing that could benefit from a timing data element in USCDI, to try and reuse a single data element across multiple different data elements or data classes. That was the intent.

Sarah DeSilvey
Thank you, Al. Any other thoughts on that thread, or are we ready to move on to Hans? Hans?

Hans Buitendijk
I would like to follow up on that comment, related to the question I was going to ask, to fully support the recommendation to add the specimen collection and the lab result date and time, but I am very concerned not to do that in the context of where those dates and times are relevant. If we only document that in procedure date/time and not in the places where they actually are relevant and the specific dates and times that are relevant in that context… So, within lab test results, it is the lab result report date and time of specimen collection, it is in medication, and it is in immunization. The time is what you are really after.

I think trying to do that in one umbrella of time of procedure is actually going to create more ambiguity and confusion in the interpretation and use of USCDI, similarly to the comments made with facility information. Not understanding in what context that is being used and what that means is only going to add to the confusion downstream, and how is that implemented, how is that applied, where did I need to do it, where did I not need to do it? It is going to make that much harder. So, I certainly would recommend and suggest that, as part of our HITAC recommendation, we should consider that we do indicate that these times not only are relevant, but they are defined and clarified in the context of the data classes where they apply, and that can then help further the downstream processes to help align them correctly.

Sarah DeSilvey
Thank you, Hans. So, with those caveats, clarification on what was reviewed by the subcommittee, clarification on how that then affects the original data element of procedure time, and considerations of

application, any concerns with moving forward with this original procedure time, which has been updated just to say that it is not what the workgroup worked on? Any concerns with moving forward with this at this time?

Hans Buitendijk
No concerns with the procedure time to move forward specifically for the procedures that were meant to be included and procedures itself, but to really get the other date/times in the data classes where they clarify what that really means.

Sarah DeSilvey
Okay, that makes a lot of sense. Any other final thoughts? Anybody have their hand raised? I do not see that. Okay, I believe we can now move on, and maybe this is a similar thing to before. Did we dispose of specimen condition and disposition? If we scroll over to the workgroup…?

Hung Luu
Yes.

Sarah DeSilvey
Okay, are we good there?

Hung Luu
Yes. This is a CLIA-required element that if a laboratory has set up rejection criteria, which are based on interference or inability to do the testing, and a clinician asks for the testing anyway, there has to be documentation as part of the result that it was performed despite the specimen not meeting a rejection criteria because that is an important piece of information when a clinician is interpreting the results.

Sarah DeSilvey
Perfect. Hans?

Hans Buitendijk
I am not sure whether I interpreted last week's instructions correctly, but I went ahead with a couple pages to provide some draft suggestions and clarifications based on what was there. On this one, I was wondering, in the way that we talked about separating out the component or concepts of condition and specimen to really focus on that, did the draft capture that, and is the term "suitability" appropriate, or is there also, in addition to that, since I thought the notion was that our main focus is on understanding when a result is resulted and it uses the specimen that otherwise would not be suitable for the test, that that is the main one that I thought was coming out of discussion to move forward. Did that capture that to summarize that from the discussion? I am not sure whether the draft that I tried to put together captured those nuances between that. That probably requires more wordsmithing and clarification than what I intended to do, and I hope I did not overstep the instructions.

Sarah DeSilvey
Hung, I am very grateful for all the work you did in that.

Raj Dash

Well, I do not know what is possible in terms of renaming or if that is the best path forward versus creating two terms, but I can immediately think of issues where suitability does not apply, like if the specimen is lost.

Hung Luu
I think the name might be confusing people because this is only restricted to the fact that testing has been performed on a unsuitable specimen, and that needs to be conveyed forward to all future interpreters of the results. And so, this has nothing to do with whether or not we include with every single result that the specimen was suitable. That is not the intent of this. It is purely that if the testing has been performed despite the specimen not meeting suitability requirements, everyone in the future knows that.

Raj Dash
Or the reason why there was no result or it could not be resulted, right?

Hung Luu
Well, if there is no result, then it would not be performed, it would just be canceled. This is occurring in every laboratory today, that there is a comment that is put with the result that says the specimen was hemolyzed, which would ordinarily cancel the test, but it was performed at clinician request. Hemolysis is a known interference for this test. Right now, that is captured as a result comment that could potentially fall off after a future date and not be conveyed as part of the results, and instead, it should be captured as a discrete element through SNOMED or LOINC that could carry with the result throughout the ecosystem so that no matter whether it is conveyed through an HIE or through interface, that information needs to be preserved.

Sarah DeSilvey
Is that clarity sufficient to come to a discussion on final recommendation? Are we good to proceed?

Clem McDonald
This is Clem. I was on mute. I said some very intelligent things… I think there are some elements in HL7 messaging to accommodate some of these. I think we just ought to make sure we reconcile what we are saying with what already exists in the messages.

Hans Buitendijk
Clem, I am pretty sure this concept specifically would fit with that, and there are elements available that are making sure that that vocabulary is in sync with this, but it is being communicated that it is available in regular messaging.

Clem McDonald
Okay.

Sarah DeSilvey
I hear no concerns, so, in my mind, there were these two hanging elements, so it sounds like we have a disposition for them, so now, we can say the draft USCDI V.4 element is complete and move on. Again, I just want to ask those who were deepest in this work to create the recommendation draft so that we can respond to it, so, for any of those folks who are really and truly experts in this, it would be helpful if you started creating the final recommendation in the appropriate column. I believe, Al, we are now ready to

move on to advance directives, which we saved because, Grace, you were with a patient at the last meeting, and you are with us now. We did not want to discuss the Level 2 elements suggested by you in your absence. Grace, are you with us?

Grace Cordovano
Yes, and the topic could not have been more fitting because this patient had an advance directive, but it was, of course, not on file, and no one had a paper copy, so my life has come full circle.

Sarah DeSilvey
Wonderful. Would you mind leading us through your recommendations, both this one and the next? That would be really helpful.

Grace Cordovano
Sure. Column L?

Sarah DeSilvey
The element is advance directive. Just briefly discuss your justification for recommendation, and then we can have a discussion and dispose of it.

Grace Cordovano
Sure. So, I know there have been extensive recommendations and discussions about this element. I am coming from a patient and care partner perspective as a patient myself and someone who works at the intersection of end-of-life care and the essence of having this document actionable. The end-of-life care information is absolutely critical to patient care, and it really prevents harmful, unnecessary medical treatments. I am highly encouraging everyone that we do our best to include whatever elements we can to push this forward with recommendations to HITAC. It is really also addressing the needs of the underserved communities because people who do not have a voice and who are not introduced to this concept really do suffer and face a plethora of different invasive, unnecessary treatments, and their dignity and wishes are not preserved at the end, or are lost in translation.

Really, a key learning after the COVID-19 pandemic really was that the suffering and inequities caused by a lack of having advance directives available to make these critical end-of-life care decisions is something that is nonnegotiable. We really need to do our best, and I think we have a really good platform here, and enough information to push some things forward. I did have a question that I flagged in red that I did not get an answer for, to confirm if the following LOINC code was applicable. Again, I am not an expert in LOINC codes, so I am deferring to workgroup members on any guidance there that may be helpful.

Sarah DeSilvey
Thank you. Any discussion from the workgroup or comment on Grace's question regarding the LOINC code element? Hans?

Clem McDonald
I would just like to be sure. I do not understand the game very fully, but there are a couple other things that are like advance directives, like living will and durable power of attorney, right? Are they just special cases,

or should we be aware that there are parallel creatures that serve a similar function? Does somebody know?

Grace Cordovano
That is a great question. Many patients do also have a power of attorney, but essentially, when you go into any type of care, if you have a procedure that is in a hospital surgery, most patients are presented and asked if they have an advance directive, and if they do not, they are presented with general forms to fill out their wishes. So, "advance directive" is probably the most commonly used terminology at point of care. That is why I am referring to it that way in my recommendation.

Sarah DeSilvey
It is also noted, of course, from a clinical perspective as a requirement for Medicare annual wellness visits to document the advance directive and the presence of it and clinician agreement to comply. Hans?

Hans Buitendijk
I have a question. We need to consider advance directive and progressive in light of the discussion we had a week or two ago with the presentation from Maria Moen as well. Currently, the way that advance directives, with the PACIO project and otherwise, are progressing is very much building on the concept of a care plan, and therefore, it is not a care plan that is necessarily created by a clinician, but it is effectively created by the patients with the system.

So, what I am wondering is if this should also further help advance the aspect of how to get that in, and as I think Maria indicated, by way of having even PDFs, scans, or structured or otherwise independent comments that we made about how to progress care plan with a type of care plan as a start in USCDI Version 4 and then explore the different elements in a more structured fashion for the next version. Should this be a type of advance directive that we recommend so that it can start to flow along with that and take advantage of the overall advantages in care plan and then have the special considerations for directives being then built on top of that as well? So, it is just a general construct of where we would make the recommendation as a separate data class or as a type of care plan in light of what I think is the recommendation of a care plan on Line 23, and let it progress with that?

Sarah DeSilvey
Thank you so much, Hans. Pooja?

Pooja Babbrah
Sorry, can you guys hear me? I am on my phone.

Sarah DeSilvey
Yes, we can.

Pooja Babbrah
I guess I just had a question about this. I am trying to understand exactly what would be included, and maybe this goes to Hans's question, and I saw Aaron post this as well. Is this the actual advance directive? Is it a notification saying that the patient has an advance directive? I guess I am not understanding what we are including.

Sarah DeSilvey
Grace, I do not know if you have a comment on that, but I know that Ricky has his hand up. I think he had a suggestion in the workgroup discussion. Do you want to lead and then…?

Ricky Bloomfield
Sure. Oh, go ahead, Grace.

Grace Cordovano
No, go ahead.

Ricky Bloomfield
I was just going to echo that and what Hans said, which is I think the most important principle that we are trying to achieve here is to make the information available to those who need it. That is the high-level goal. There are a number of ways to solve that problem. What I had suggested in our previous meeting was one of the most straightforward ways to solve that problem is simply by conveying the document itself in whatever format it might exist, whether it is a PDF, image, or whatever, and code that with the appropriate LOINC code. Separately, there could be other ways to consider providing more structured information, but the most important short-term recommendation we could provide is some guidance around simply providing this as a note to start with, just so we can unblock what is really the main problem we are trying to solve.

Grace Cordovano
I really like all of the suggestions, and Hans and Pooja, I really appreciate, too, recognizing the complexity of what is included. Al and I have also spoken about advance directives in the past, and there are certainly multiple components, and it varies from facility to facility and patient to patient, but to Ricky's point, what is our onramp right now for what is available so that we can set the stage with that, whether that is coding with LOINC. I am not sure what the lowest-hanging fruit is, but I do feel that from multiple conversations, this almost becomes either a care plan or a data class with us specifying what the elements need to be moving forward.

Ricky Bloomfield
I would be happy to draft some language to reflect what I had suggested that the group is in agreement with and work with Grace on that.

Hans Buitendijk
I would be happy to help out with that, again, Grace, if you would like.

Grace Cordovano
Fantastic. I would love that.

Hans Buitendijk
Ricky, part of the thoughts that you have to start out with that, agreed. The care plan, in its current way of FHIR US CORE, may already do that, so I want to look at that, and then, continuing to build off that we are discussing the care plan, to start to type it, start to consider it being more structured than more of a text or a reference.

Sarah DeSilvey
Thank you so much for the collaborative effort here. Just a final thought, do we have any concerns? Oh, Mark is offering to help, too. Any concerns with moving this forward with the recommendations about how to include it that we have heard today, understanding that Ricky, Hans, Grace, and Mark are going to be working on this together? Mark?

Mark Savage
I will just flag a comment I added above on the care and treatment items, which I am just trying to figure out what happens when there is an inconsistency, when something like a personal representative or a durable power of attorney for healthcare gives a directive that is different from an advance directive. I do not think that is necessarily within our purview because we are just collecting the data elements. I am just thinking through how that works out in real life, so I will just leave it there. If I am correct, that is not something for us to resolve here.

Grace Cordovano
It is a great point, Mark, and usually, then, you have ethics, a social worker, and a family intervention, but I think that is out of the scope of what we need to do here.

Clem McDonald
Is there a normal trump order between those things? That is, would one thing trump the other? You do not know? I do not know for sure.

Grace Cordovano
I would be happy to address any of these offline because these can go in a number of different directions, and I want to be mindful of time.

Clem McDonald
And I am not talking about a politician…

Sarah DeSilvey
Thank you, Grace and Clem. So, I hear consensus for moving forward with this. I hear the subgroup still working on the final recommendation. I am very, very grateful. We have a little bit of time left before we go to public comment, so, Grace, I believe you actually have one of the next elements of two. I guess we can go down. Al, we covered reclassification, we covered Mark's reissuing of the Gender Harmony recommendations from last year, and I believe, Mark, if you could just lead…I think it is almost copying last year's IS WG recommendations in the final recommendation, that would be helpful.

Mark Savage
Yes, I am happy to do that. I did note that between last year and this year, ONC has broken down sex for clinical use into discrete elements for the different things like labs and diagnostic imaging. It is a very minor tweak, but it will basically look the same as last year's, with that slight tweak, and I can take care of that.

Sarah DeSilvey

Thank you so much, Mark. Moving on, I believe if we go down to the next Level 2 element, Al, this is your and Raj's comments. They were included, so let's go down again. Grace, I believe you had another one. These are all included in the work the subcommittee did. Was there an operative note one?

Grace Cordovano
Yes, there was an operative note.

Sarah DeSilvey
Yes, and I do not know where that is. It might be higher, actually. We might have skipped it.

Hans Buitendijk
Row 23.

Sarah DeSilvey
Thank you so much, Hans. I am working from memory here. All right, I believe this is another hanging element that we waited for you for, Grace, and I think it is one of the last new Level 2 elements that we have to discuss here. Grace, can you lead us in the conversation similarly to how you did with advance directive? That would be appreciated.

Grace Cordovano
Okay, sure. I think we did introduce this, and then we ran out of time. So, just as a refresher, this was previously discussed and recommended, I believe, to HITAC, but was not accepted and included, so I am revisiting here, and to summarize from a patient and care partner perspective, the operative note is something that is extremely important, detailing, of course, the details of the surgical procedure, but also, it is one of the only sources of truth for patients to have details on any tissue or samples that may be collected that then would allow then to connect with pathology and information that is there, so when it is not shared, it is a glaring, gaping hole in the medical history. While I recognize that all notes are supposed to be shared, operative notes seem to fall by the wayside, so I am advocating if we can find a way to collaboratively acknowledge the importance of the operative note and to have it recommended to HITAC, and I am not going to read all of what I popped in to Column K, but transferred what was previously recommended with any notes that are applicable below.

Sarah DeSilvey
Al?

Al Taylor
Grace, thanks for your work on this recommendation, both now and in the past. I would ask or suggest that as you craft the final recommendation, you frame the recommendation as differentiating operative notes from procedure notes, which is, as everybody knows, a data element in USCDI and the clinical notes. We at ONC have been considering operative notes versus procedure notes for some time, and there are obviously some similarities, but there are also some key differences. So, if you could do that, that would make the recommendation much more actionable.

Grace Cordovano
Thank you for pointing that out, Al.

Ricky Bloomfield
This is Ricky. I would also note that the current version of US CORE also calls out surgical operation note and the LOINC code there as one of the types that systems are "encouraged" to support, so there is already a pretty clear path there to move from "encouraged" to one of the "shall support" data types.

Hans Buitendijk
I support Ricky on that.

Al Taylor
Just a quick historical note, procedure note, but not operative note, was one of the primary note types that were taken on by the Argonaut project, which is what informed our original list of eight clinical notes. So, I just put that historical context out there as the reason that we initially adopted procedure note, and not operative notes.

Sarah DeSilvey
Any other further comments on elevating this critical Level 2 element to USCDI V.4 at this time with all the conversation we have had so far? Thank you for all the links. Any opposed to doing so? Again, Grace, it sounds like you are leading the drafting of another final recommendation. We look for anyone to support her in that work, and also, if it is okay, we are all here to support you in that. We are very grateful. We are very close to our public comment period. There are two other entries, Entries No. 33 and 34. I at least want to make sure we socialize them. I did not want to miss them, at least. One is care team members, presented by Aaron, and then, I believe we have provenance, which we have not discussed yet. I think I am correct in that. Aaron, have we discussed care team members yet? I do not think so.

Aaron Neinstein
I do not think so either.

Sarah DeSilvey
Would you mind leading us in discussion of this, as much as I understand we have limitations of time?

Aaron Neinstein
Yes, this one might be pretty straightforward. I was just skimming through the USCDI website and noticed that as part of the care team member data class provider NPI is not yet included as an item in USCDI, so I wanted to bring that forward. There are very clear and specific standards for it. I do not think I have more to say on this one.

Sarah DeSilvey
That is pretty straightforward. Al, any questions?

Al Taylor
Yes. I think this is probably just review for everybody, but we had also considered adding provider NPI as a specific data element, but elected instead to have a more generic care team member identifier, of which one of the examples is provider NPI and NCSBN ID, one for nursing. So, those were two examples, so care

team member identifier is out there as one that we feel could incorporate both provider NPI, or a nursing ID, or some other ID that is appropriate for the context.

Sarah DeSilvey
Thank you so much, Al. Shelly?

Shelly Spiro
Yes, I totally agree with adding this to V.4. This is an important field for care planning. We need to know who the members are, and I think this is a very, very important one to move forward in V.4.

Sarah DeSilvey
Thank you, Shelly. Al, do you have further comments? Your hand is still raised.

Al Taylor
Oh, sorry. Somebody usually puts my hand down for me. No, I am done.

Sarah DeSilvey
Okay. Hans?

Hans Buitendijk
I would like to support Al's comments. In the definition of care team member identifier, NPI is already recognized. It is also in C-CDA and FHIR US CORE in that construct. So, rather than defining a variety of different identifiers as separate elements, recognizing the types of identifiers and then, where needed, adding that to the definition of NRN, for care team identifier in this case, seems a very reasonable way and a consistent approach with how such data is expressed. I do not think it needs a separate element, but it is great that it is already there. It actually raises the question of if Level 2 or others are already effectively supported in this way in USCDI, not needing an addition to it, as it is already there, maybe not as an individual data element, but as a type on that data element, a component of it, if you will. Then, how do we start to identify it in Level 1, 2, etc., and mark those as already satisfied and something we do not need to look at anymore? It might give the impression that it is not there, but it actually is.

Sarah DeSilvey
Aaron, any thoughts on that? I know we have to proceed to public comment.

Aaron Neinstein
I will defer to the expertise of Al and Hans on this. If people feel like it is already there, then I agree, I think the website is misleading, and maybe that is where we should focus attention. It does give the impression that it is not already included.

Sarah DeSilvey
That seems like a great action item. The recommendation would not necessarily be adding the specific element, but clarifying the importance of this being included in the definition as it stands. Agreed? Okay, moving to public comment. We are almost through, but we look forward to coming back next week and trying to resolve the provenance element.

Public Comment (01:25:02)

Michael Berry
All right. So, we are going to pause our workgroup conversation, which has been great, to open up our meeting for public comment. If you are on Zoom and 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 on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for just one moment to see if any of our members of the public raise their hand. I am not seeing any hands raised at this time, Sarah, so I will turn it back to you. Thank you.

Sarah DeSilvey
Maybe we do not have to wait until next week. Can we return back to the spreadsheet in our last few minutes and maybe start? Mark, you were talking about provenance, which is where we were. That would be great, and we will just use our time until the top of the hour.

Mark Savage
Sure. Al, are you going to show that, or should I just do it on my browser?

Sarah DeSilvey
Thank you, Al.

Mark Savage
The next entry, No. 34, is where I think we are.

Sarah DeSilvey
That is correct.

Mark Savage
Excellent. So, this is repeating a recommendation that the workgroup developed last year. It came up last year, especially around the importance of having self-reported data elements for race, ethnicity, gender identity, disability status, and pregnancy status. We were going through all of those elements. We talked at length about how important it was to know who the author of those elements was. Sometimes it is the individual, sometimes it is the system, and sometimes it is a clinical observation. So, those were the use cases we discussed last year, and we therefore developed a recommendation to add author to provenance data class. It did not make it in, so I am just renewing the same recommendation here.

Sarah DeSilvey
Thank you so much, Mark. Any comments or questions regarding the resurfacing of this element?

Steven Lane
Just a comment that much energy was put into bringing this forward in prior years, much discussion, and much support, and I agree with Mark bringing it back up. We need to stay on these things. Even if they do not make it one year, we need to bring them back because they are important.

Sarah DeSilvey

Yes. As a longtime community organizer, absolutely. Persistence. Any other final comments on re-recommending as a critical data element? I believe I hear consensus.

Clem McDonald
Let me just comment. Family history is a complicated beast. It can be structured, you can do a family tree, etc., so what are we talking about here, just narrative?

Mark Savage
No, Clem. We are talking about adding author as a data element, so this is not necessarily… It would be relevant to knowing that the patient was the author of the family history data, but this is just about the author data element.

IS WG Workplan and Timeline (01:28:22)

Sarah DeSilvey
All right, barring objections, of which I hear none, we thank you so much, Mark, for resurfacing this. I believe we are at time, with a very productive meeting. We can go back to the slides. There is going to be a lag. What I am just going to urge folks to participate in is volunteering and leaning in as much as possible to synthesizing the components in the workgroup discussion into final recommendations. Those sub-workgroup leads are taking leadership on that. Any of us who were not part of those subgroup leads, if we can just please lean into that. What I am going to ask for is some final recommendation starting text when applicable, again, when there are thoughts on the element that require some kind of commentary, for each of the elements prior to our meeting next week. So, if folks can volunteer, again, we are leaning on all those subcommittee group leads to take the lead on the areas that they represented, but if others in the workgroup are willing to start synthesizing the work of discussion in the final recommendation draft, that would be really helpful, and you can just put your name in that column. Naresh, any other final thoughts before we adjourn?

Naresh Sundar Rajan
No other thoughts, Sarah.

Sarah DeSilvey
All right. Thank you so much. We will see you next week.

Mark Savage
Thank you.

Adjourn (01:29:57)