Transcript

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

February 27, 2024, 10:00 – 11:30 AM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Sarah DeSilvey, Gravity Project, Co-Chair
Steven (Ike) Eichner, Texas Department of State Health Services, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Ricky Bloomfield, Apple
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Oracle Health
Keith Campbell, Food and Drug Administration
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Raj Dash, College of American Pathologists
Derek De Young, Epic
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Steven Lane, Health Gorilla
Hung Luu, Children's Health
Anna McCollister, Individual
Katrina Miller Parrish, Humana Health Insurance
Alex Mugge, Centers for Medicare & Medicaid Services
Kikelomo Oshunkentan, Pegasystems
Rochelle Prosser, Orchid Healthcare Solutions
Mark Savage, Savage & Savage LLC
Shelly Spiro, Pharmacy Health Information Technology Collaborative
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Jim Jirjis, Centers for Disease Control and Prevention
Aaron Neinstein, Notable
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian

ONC STAFF

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

PRESENTERS

Maria Moen, MyDirectives

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

Seth Pazinski
Good morning, everyone, and welcome to the Interoperability Standards Workgroup meeting. I am Seth Pazinski with ONC, and I would like to welcome everybody and say thank you for joining today. I will be serving as the designated federal officer for today's call on behalf of Wendy Noboa, and as a reminder, all workgroup meetings are open to the public, and public feedback is welcome throughout. Members of the public can type their comments in the Zoom chat feature throughout the meeting or take advantage of the time on the agenda at the end of the call for verbal public comment. I am going to start the call with a roll call of the workgroup members, so when I say your name, please indicate that you are present. Sarah DeSilvey?

Sarah DeSilvey
I am struggling to find the mute, but I am here.

Seth Pazinski
No problem. Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Seth Pazinski
Good morning. Ricky Bloomfield?

Ricky Bloomfield
Good morning.

Seth Pazinski
Good morning. Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Seth Pazinski
Good morning. I did get a message that Hans Buitendijk will be joining, but he will be late to the call today. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Good morning. Christina Caraballo?

Christina Caraballo
Good morning.

Seth Pazinski
Good morning. Grace Cordovano?

Grace Cordovano
Good morning.

Seth Pazinski
Good morning. Raj Dash?

Raj Dash
Good morning.

Seth Pazinski
Good morning. Derek De Young?

Derek De Young
Good morning.

Seth Pazinski
Good morning. Lee Fleisher? Hannah Galvin just messaged that she will be joining late as well. Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Seth Pazinski
Good morning. Jim Jirjis? Steven Lane? Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
Good morning. Anna McCollister? Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski

Good morning. Aaron Neinstein? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Present. Good morning.

Seth Pazinski
Good morning. Mark Savage?

Mark Savage
Good morning.

Seth Pazinski
Alex Mugge?

Alex Mugge
Good morning.

Seth Pazinski
Good morning. Fil Southerland? Shelly Spiro?

Shelly Spiro
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. So, that completes our roll call for today. I have just one quick administrative item before I turn it over to the co-chairs. We recognize that some members have a conflict for the March 12th Interoperability Standards Workgroup meeting. Could you just let us know in the chat if you anticipate not being able to make that call on the 12th? I am trying to figure out if we will be able to have a quorum to have that meeting or not, so I would just appreciate it if you could mention it in the chat or send us an email if you do not think you are going to be able to make that call. With that, I just want to thank everybody for joining again, and I would like to welcome Sarah and Ike for their opening remarks.

Opening Remarks (00:04:09)

Sarah DeSilvey
Good morning, friends. It is great to be here. I am very excited to keep on working through review of data elements. We are really honored to have another subject matter expert (SME) presentation today. As noted in the homework, we really are trying to get those draft final recommendations going, so we are hoping to get going on that as well, and we look forward to a productive call. Ike?

Steven Eichner
I echo what you said. We are going to touch on, and just as a friendly reminder to folks, this is going to be the last call for Level 2 data elements, so think about any requests that you have not put on the spreadsheet yet, and we will focus a little bit as we get to that point in the agenda. As Sarah said, we have a great presentation lined up, and we have some good work to do before that.

Sarah DeSilvey
Just as the agenda for the day, again, someone with well-known ties to the IS WG, Maria Moen, is here to talk through advance directive observation and orders. Then, we will be working through Draft USCDI v.5 elements and hopefully get to those Level 2 elements in time, and then, we are going to public comment at 11:25 AM ET, as usual. Next slide. So, before we get into Maria's presentation and welcome our SMEs, I just wanted to make sure that we ground ourselves per protocol, as always. In the charge of IS WG, again, our overarching charge is to review and provide recommendations on Draft USCDI v.5. This includes those new data classes and elements from Draft USCDI v.5 that should be considered for the final USCDI v.5 release.

Again, part of our job as IS WG and our charge is to make sure the expertise from each of our perspectives is included in those final recommendations, so, please pay attention to what is happening in that working group discussion draft final recommendation area so that we can try to move some of those things forward. And then, our charge also is to elevate any Level 2 data classes and elements not included in Draft USCDI v.5 that should be considered. Again, we need to put a timestamp on that just in order to complete our charge and get the final transmittal letter in time over to HITAC, and today is the day for that deadline. Next slide.

And so, we are very honored to have Maria. I am going to pass the mic to her very shortly, but I just wanted to ground us in the versions of the elements that are in Draft USCDI v.5 or otherwise before we head to Maria's conversation. Last time, I did it flipped, but this time, I want to land on what we have and what we are working on, and then we can hear on how our subject matter experts' presentation builds off of and reflects on that. Next slide. So, these are two data elements that we are going to have Maria reflect on today. Advance directive observation is a statement of presence and properties of patient- or provider-authored documents that record a patient's goals, preferences, and priorities should a patient be unable to communicate them to a provider. This is something we have discussed in past IS WGs.

There was a usage note of reference, which may include whether a person has one or more advance directives, the type of advance directive, the location of the current source document, and whether it has been verified. Examples include, but are not limited to, indications that a living will is on file, reference to or location of durable medical power of attorney, and validating provider. So, this is the first element, and then,

on the next slide, because Maria's expertise is robust, we also have her speaking to orders, which is the provider-authored directive for the delivery of patient and care services. The data element is orders, a provider-authored directive for the delivery of patient care services. Examples include, but are not limited to, diagnostic imaging, laboratory tests, interventions, referrals and consultations, and do-not-resuscitates. You can see the connection there between those two data elements. And now, I am honored to welcome our esteemed expert, Maria. Thank you so much for coming to join us, and we really look forward to the conversation and your expertise.

SME Discussion – Advance Directive Observation and Orders (00:08:31)

Maria Moen
Thank you very much. I appreciate that. Do not be honored for me to be here. I am honored to be amongst all of you, so, thank you for giving me some time to give you a little insight into what we have been doing within the Health Level Seven International (HL7) standards world, informed by an incredibly robust community of clinicians, policymakers, health systems, EHR vendors, etc. So, I just did a really bland, vanilla deck. I thought perhaps the pictures would speak a thousand words, and so, thanks for bringing that slide up for me. Go ahead and go to the next slide, please.

In an effort to level-set where this experience and where some of our thoughts are going to be sourced from, the initial work that we did revealed sections of the Clinical Document Architecture (CDA) or Fast Healthcare Interoperability Resources (FHIR) document that were important to bundle. We have had a lot of questions about bundling, and so, what we want to do with USCDI in support is ensure that we do not lose context of information that has been recorded in these person-authored documents or these practitioner-authored documents. In addition to creating guidance to move from paper forms to interoperable electronic access, we needed to accommodate not only structured ADI, because in the world of HL7, we dream of a future where data is structured, it is actionable, systems can respond to it through clinical decision support, but as many of you know, this is one of the last vestiges of paper. It has been a difficult climb to go from a completely paper-sourced environment to one that is emerging in the world of digital utilization.

However, we have Electronic Medical Record (EMR)s, Electronic Health Record (EHR), and clinical record systems that have stored and housed scanned images, and those unstructured documents need to be released to the general healthcare ecosystem so that they can be accessed to inform care. The third bullet is just talking about person-authored data, and while I know that there is a lift on the part of the clinical record vendors to really go from data that is sourced within my application to accommodating data that is sourced from outside the application, specifically that information that is authored by an individual, we really have to start the march to having an appetite for hearing what the individual has to say, and that hearing may be accommodated through a verbal expression or, in this use case, through existing forms and documents.

So, the following graphic was just provided to show the maturation of understanding that our entire community has really benefited from as we walk down this road. We are over two and a half years into this project, and have worked very hard to learn, accommodate, and respond to the needs of clinicians, vendors, and people like you and I, who really want our care to be very personalized and customized to what matters to us. Next slide, please.

I know this is a busy one. When we started in 2020, on the left, you can see the things that we thought that we knew, and then you can look at a refined understanding, because none of these projects happen without a significant amount of learning. I thought I was going to do this, and I ended up doing this, because through discussion, where we landed was much more useful, usable, and accommodating to the healthcare ecosystem than where we started. So, you see the refined understanding in 2021. Certainly, we weighed in on USCDI v.4, and we were so grateful to all of you and the people at ONC who really want to pivot and have this Copernican shift within our healthcare system from the healthcare system, the EHR, and the vendor being the center of the system to the patient, the individual, being the center of the system, and it is from that center that all of that care is planned, and so, thank you very, very much for all of the initiatives that are in flight around the US that appreciate the inclusion of these data elements.

On the right, you will see where we have landed based on that understanding, and I tried to color-code. My husband is colorblind, so he tells me that this is a failed attempt all the time, but for those of you who are not colorblind, you can sort of follow, say, in green. We knew we needed a data element for those jurisdictional elections of who will speak for me when I am unable to speak for myself. In fact, the Uniform Law Commission, which is that body of lawyers that has really accommodated the Healthcare Decisions Act from 30-some years ago, recently revised the recommended national standard, and that healthcare agent designation is the only section that requires a witness or a notary. That is how important it is. If I cannot honor the rest of your decisions because of whatever your physicality is, I just cannot honor those decisions. At the very least, tell me who to talk to. Who do you trust, who do you have discussions with, who can inform your care?

So, you sort of see the green to green across the line. You see that teal care experience preferences, you see what we started with, which was living will, which is now not right, priorities under certain health conditions, which nobody knows that that is, and then we landed on treatment intervention preferences, which resonated and had meeting, and there were distinct concepts associated with that. Please know that we do understand that these data classes are merely organizing concepts. You could put any of these data elements in any organization that makes sense to you. You guys are the experts. But for purposes of grouping them, because the human mind seeks to make order of things, this is how we listed it. Priorities upon death is something that we will probably ask for in the next version of USCDI. It supports information to organ donor registries. Do you want to be an organ donor? Do you have funereal/burial/celebration of life plans, etc.?

Again, looking at the right-hand box, in the data class advance directives, to-may-o/to-mah-to, we have recommended that an advance directive data element be promoted to Version 5, and I put in sort of a soft gray italic that this enables those person-authored, nonstructured data or documents housed in these EMR/EHRs across the country to be released and liberated to be accessed by providers in a time of need so that they can perform care, and a personal advance care plan is a different topic than an advance directive. In the lower middle of the right-hand box, you will see the advance directive observation, and I will go a little deeper on that in the next slide. I love that you guys have created a data element for orders.

Here is my ignorance. It never occurred to me that out of all the data these EHR systems are to make available to ease transitions of care, to inform the next care provider, to provide a robust picture of the person who they are treating, that the orders themselves were not a part of those requirements. So, once I realized that the pieces, the parts, the quality measures, and all the things that we do that are so important

to measuring the outcomes and the quality of care, once we get over that shock, we definitely need to see that orders data class.

And then, with some data elements in similar way that advance directives and advance care plans are person-authored documents, we have the same subject matter. This is an advance statement of my goals, preferences, and priorities. However, these expressions are authored by practitioners, and they are formal, legal order sets, and there is a very distinct dividing line between those two form types, if you will. So, if we are going to open the floodgates to getting the person-authored documents that are housed in these walled gardens of EMR/EHR files, because I do not know what good it does anybody to check a box and store it in their system when somebody is going to present for care down the road and they trusted you to make that information available, I want to see the portable medical orders as well as the advance directives so that we really have released these documents. Please go ahead and go to the next slide, which is the last one, I promise, and then I will be done talking, and I can answer questions.

So, I took that most recent box on the right from the prior slide, and I laid it over here, and again, if you are colorblind, I am very sorry. I tried to at least lay them on the same row, if you will. Again, we do understand that data class is an organizing element. There was discussion about if an advance directive could be a self-assessment. “I am telling you what I want. I am going to make it available in this data class. You will do your clinical validation and hopefully inform your treatment or your care plan from that.” I have talked to the community at large. They understand that it is an organizing concept. I would never tell you guys how to do your job, so I am going to focus on the data elements and the meaning of them. You guys decide where they belong that fits the desired purpose the best.

Again, going back to the green, this is the healthcare agent. If people do nothing else, then they should designate someone to speak on their behalf in a time of need when they are unable to communicate, for whatever reason. This is one of the most critical things that you can do. So, we would like to see the healthcare agent given credence and move on up through the chain to approach that USCDI formal data element set. Durable medical power of attorney is a very narrow term. It refers to a specific set of jurisdictional instruments, and our guiding light, our compass, throughout this project has been to scan exhausting amounts of existing jurisdictional state health system forms and deconstruct every last one of them into Lego pieces that we can then align with interoperable concepts with a goal of enabling anybody who wants to go from paper to digital and has a form, a bunch of forms, or a state’s worth of forms. Our goal was to create the guidance to be able to do that, no matter what the document. So, I speak from an exhausting number of form reviews, and we believe that healthcare agent is a more overarching, more inclusive term.

Now to care experience and treatment intervention. All I can say on behalf of all the projects that I work with, all the clinicians, and all the skilled nursing facility quality groups is thank you. This was incredibly meaningful. Care experience is those moments before and after you need to make very specific treatment intervention preference decisions, so, thank you very, very much. In the middle, you see the advance directive, which is currently at a Level 2, and the personal advance care plan, which is at a Level 1. Again, there are a couple of motivations here. So, for scanned or unstructured documents, if all we have promoted to USCDI v.5 is the observation, then we have not really released those documents to inform care. We are starting at a particular point and saying, “This is the observation. I saw the document, I validated that it was

still accurate, the most current, and authentic, and it is viable for me to provide care, or not viable." The observation is not always to the positive.

And so, releasing the forms and creating an expectation through USCDI, the certified EHR technology systems to open the floodgates and make those documents available is Step 1. Once I have access to them, I can then use them in terms of an observation to inform care. The teal is the portable medical order. You have person-authored documents, and many jurisdictions will follow them and give them heed. There are safe harbor provisions in certain states where if a care team renders care based on a jurisdictionally appropriate person-authored document, if there are issues with that, such as maybe they accessed one, and there was one tucked in a drawer somewhere, and the family comes in and they are angry, there are safe harbor provisions that they did the very best they could with the treatment they had, they validated the document, and they validated who is to speak for that person. And so, you have the advance directives and the portable medical orders. Both are important to honoring what is important to the people that we treat.

And then, the very last item is the care team members. Proxy decision maker is yet another set of terms. It has been my experience working in long-term care, acute, and all over the place in healthcare IT technology that we keep coming up with new terms. We have a resident representative that is required to be identified in skilled nursing facilities. Who is that? How do I align that with well-known terms? We have an emergency contact. We have medical decision maker, health care proxy… We need to land on a term, it needs to be overarching, and that is the term that we use to represent this thing, this concept, this notion. And so, "proxy decision makers" simply introduces yet another term, and I will tell you that I do not believe I saw that term used more than once or twice on over 350 jurisdictional documents that I reviewed, deconstructed, and got extremely intimate and uncomfortable with. I have some notes here that I can speak to. I think I have spoken enough. I hope that that was helpful for a framework or a landscape. Hit me with what you got. I am so glad that you guys have asked.

Sarah DeSilvey
Great, Maria. Thank you so incredibly much for that very expert review of the possibilities. In this instance, I actually feel like for our conversation, if we could go back to that last slide, it is such a lovely summary of the expert evaluation of the opportunities we have to possibly get this right, and then we can facilitate our discussion. We have until 10:40, I believe, for this discussion, so there is lots of time to make sure that Maria advises us in leveraging her expertise toward this critical task. Any thoughts or questions from the workgroup on Maria's presentation or how to build off the existing USCDI elements in referencing her presentation? Mark?

Mark Savage
It would help me to know what our starting point is, and by that, I mean the opening slides showed two data elements, advance directive observation and orders, and we are looking at a lot more than that on this slide. I guess I am wondering what the hope is that we would be recommending going forward. Is it what ONC put into Draft v.5, or is it going beyond that?

Sarah DeSilvey
I think akin to past IS WGs, if the workgroup feels like the additional details and data elements that are presented as such are required to represent the element, then that could be our recommendation. It reminds me of the diagnostic imaging conversation we had last year, where there are just so many more elements

that are required to get it right than were in that Level 2 presentation. Understanding the consensus of IS WG in moving forward with what was originally presented in draft USCDI v.5 and integrating Maria's thoughts would be helpful for me. Ricky?

Ricky Bloomfield
This was a great presentation, and I appreciate the detail and clarity here with respect to what we need to do and what the long-term goal is. I had a question similar to Mark's, which is that it would be helpful to understand from the technology vendors which of these data elements are commonly collected today in structured form versus simply written down somewhere, and I think that is partly a workflow question with respect to each individual health organization, and also partially a technology question where each technology vendor may or may not support the ability to record each one of these data elements in a structured way. So, I do not know if you have done any exploration on that or have thoughts on the current state.

Maria Moen
I do and thank you for asking the questions. Connecting the dots is something I probably did not do very well, and I apologize for that. If you look at just an advance directive observation, which, in my own language, I call the activation point, anybody can walk in, waving a piece of paper at you, or your EHR can query-retrieve from your state HIE, CommonWell, eHealth Exchange, etc. You can be presented with a document, but for the majority of practitioners, it is outside the scope of their licensure to immediately read something, pivot, and render care based on that document, so that observation is a critical component to activating what has already been captured. Very often, could that observation contain a link to the source document? Absolutely. It could. It should. One hopes that we are not just checking a box, and then going off and rendering care.

But if you do not have an advance directive data element and a portable medical order data element to make those documents accessible, then what is the observation going to be based on? Only what I have in my system. Only what the person comes in and tells me that they have. Maybe they have uploaded it to their patient portal. Maybe I am connected to three hospitals within my health system. My available pool of data is extremely small, and you have caught the advance directive not at the point of origination, not at the point of being available, but right now, in the context of care. I think that is sort of opening the barn door after the horse has escaped. So, I think if you look at our desire at some point to actually formulate quality measures, I want to send some quality measures into place. I want to make sure that the practitioners made an effort to access it. Was it available? Did it inform care?

Logically, we know that when you eliminate unwanted overtreatment, you are going to reduce costs. Was there some type of observable cost reduction? You cannot have an observation without having the forms available to base that observation on. So, to me, if there were a minimal amount of data elements that really take this entire use case and this concept to the next level, I would look at advance directive, portable medical order, and observation, the activation point. If orders is as much as we can get into v.5, we have still taken a huge leap forward. It is probable that that will be a big burst of information. I do not know if portable medical orders would make the cut, but if we were clear in the description, we might get there. So, the rest of it is background, and I apologize for not having connected the dots.

Sarah DeSilvey

I think you have done a great job. Ricky has another question. I feel like there is general consensus for the inclusion of the elements as presented in Draft USCDI v.5. I see Maria offering refinement on what might be the elements within orders, understanding that the original draft included advance directive observation under observations, and then orders itself. What I hear Maria laying is a glide path towards improving the granularity of the additional elements that would be required to accurately represent this concept. Some of that might not be in Draft USCDI v.5, some of it might be in future versions, but we do a lot of iterative work in IS WG, so I just want to hold space for that. Ricky?

Ricky Bloomfield
Thank you. That was fantastic. I have two more questions, and then I will be done with this section. The next question was related to the provenance of the information, what has been your thinking and research around how we could make sure that when that information is passed through, we understand who the authors were? Was it the patient themselves or the healthcare power of attorney? How can we make sure that information is not lost in association with the other data elements here? After that, I will ask one more.

Maria Moen
Thank you, because if you asked them both, you know I would focus on the second one because I would have completely forgotten the first one. In the way of thinking, I try to cross-pollinate with everybody within the HL7 standards world because I am always in a process of learning and trying to understand. In what I understand to be the truth, USCDI is about the data elements and making sure that the right information is made available at the point of care. For the how issues such as author, where, believe me, I can go down that rabbit hole with you, that should be dependent on standards. If the CDA standards for personal advance care plans, advance directives, and portable medical orders, and I say "if" because we actually tuned up the standards recently and aligned them with the FHIR IG, those standards carry the offer. Those standards carry the data enterer. Those standards carry the custodian: From whence did this document come?

All those standards carry those very critical identifying elements. We even have sections within the CDA document and the FHIR bundle that accommodate witness, notary, state/county of commission, and all of that good information. So, when the HL7 community does what they do so incredibly well, we can take that placeholder, that overarching concept within USCDI, and we can bring it to life and make it compliant, appropriate, and valid in the way that standards do. Ricky, we have worked very hard to do that.

Ricky Bloomfield
So, what I am hearing you say is we just need to make sure we take that into account when the data is modeled by the teams that are doing this work and make sure we cover those details, which already happens in a robust way. That sounds fantastic. The last question is something I think we discussed a little bit last year. For health systems that do not yet have this information in structured form in their systems, is there any value in addition to what you have proposed here in asking health systems to expose any of these documents if they have scanned-in PDFs, for example, because that is all they have ever had? Maybe it came from the EMT, maybe it came from the patient at home, and all they ever had was a paper copy.

They could include that, as an example, as a clinical note with the appropriate LOINC code, which is a model that US CORE already supports, and we have already discussed doing that for op notes and ED notes in earlier calls this year. Could we also make this available that way as a short-term solution to make

this available sooner to more people while other organizations are building up the ability to offer fully structured documents?

Maria Moen
Next time, you have to do my presentation, because that was so much better stated than I could have said it. Ricky, that is exactly what we are looking at with that advance directive and portable medical order data element. I have spoken to different vendors, and I have put in my notes that there are hundreds of thousands. I have had a few vendors represent that I need to go bigger and add one more zero to that. There have been documents completed, prepared, created, and then housed in a document management system or scanned. There are so many unstructured documents. That does not damage their validity. That does not damage their potential to inform care.

When you go from paper to digital, you have to have a glide path. In fact, in our IGs, especially our STU2 IG, we are creating a requirement that not only does structured data get sent from system to system, but also, a human-readable PDF version of the source form accompanies that data set. We have to have a crawl-walk-run. If the human knows where to look on the form they are so familiar with on paper to say, "Where is the selection? It is right there," then regardless of how the machines talk to each other, fire off clinical decision support, and all those magical things that these clinical systems do, we have to meet the human where they are, and we are going to provide structured data where the machine is. Sometimes, all we have is an unstructured scanned form, but we have to start making those available. That will support going from crawl, to walking, to running, but you said it so much better.

Ricky Bloomfield
Perfect. That is really helpful. I think this is something we as a workgroup can consider, because from an implementation perspective, I think that would be much easier from a need-to-do, and maybe something we could consider in addition to the orders piece that is also being considered. Thank you very much.

Maria Moen
You said a mouthful there. We were in ballot for a year and a half. For any of you that know HL7, I hope you got goosebumps like I just did. I think I have PTSD. We started the FHIR implementation guides with this pie-in-the-sky idea that everybody was going to be structured and we were going to go digital, and then we had a cold stop from the vendors who said, "I get it, I am there, I will do it, but right now, I need to release interoperable documents, and your guidance on unstructured scanned forms is not strong enough," and we had to go back and accommodate it. So, this outcry comes from the very people who were looking to release those documents. Sorry if I interrupted.

Sarah DeSilvey
Ricky, before I go to Shelly, can I just ask you to clarify? I think what I hear you saying is a way to address the desire for the advance directive element that is written here in the absence of advance directive data class, which does not exist right now in USCDI. Can you reiterate just so I can hear clearly what your thought is there?

Ricky Bloomfield
Absolutely. I left a comment about this in the spreadsheet as well. So, what I am saying is these documents exist as PDFs today in many cases. Can we use the existing clinical notes data elements within US CORE,

which come through as document reference, usually with an attachment, with a LOINC code that defines that document type, just like we did for ED note and op note, and do that for advance directive? It would simply add another required LOINC code that would be selected as part of this modelling. I offered an example code; I know we have language around that for earlier ones and proposed that this year in addition to what is here, given the ease of implementation for something like that.

Sarah DeSilvey
That makes a lot of sense. I am just echoing because I had to cross-check with ONC on this one. There is no current data class of advance directives, so it is also about how we bring forward the expertise and the granularity that we see in the chat regarding the three top things that may be coming out of Maria's presentation, but work it into USCDI as it stands right now, pulling into what Mark was saying in the beginning. So, if these are the three that we are elevating to the top, we have our advance directive observation, advance directive, which could be structured as a clinical note in that method you are talking about that we already have going for emergency department and operative note, and then the portable medical order in referencing under the orders data class. I am trying to conceptualize how we might make a current recommendation. Is that correct, Maria, or am I wrong?

Maria Moen
I do not think clinical note is viable at all. Again, a clinical note would mean that for all of the documents that are out there that are available for data exchange by simply wrapping a CDA or a FHIR header on them, all of a sudden now, I need to make a clinical note for those documents to go. How is that person-centered? How do we take and move from a paternalistic system where "it is accompanied by a note, therefore it is valid" to making sure that these documents are made available without the intervention of a clinician? There are HIEs out there with patient-facing front ends. People have loaded their documents in there. There are state advance directive/advance care plan/portable medical order registries. A clinical note was not necessary to create and make those documents available, so I am a little bit opposed to that. Sorry, Shelly, I see your hand.

Ricky Bloomfield
I just want to clarify one thing there. When I said "clinical note," I was referring to the guidance within US CORE to make clinical documents available. I am not saying that any additional work needs to be done by anyone to make those documents available. It would be like creating a new note for this. There is current functionality that allows PDF to be conveyed through these FHIR APIs as a document reference with a LOINC code, and that is what I am referring to here. So, I definitely do not think that any new notes should be generated as part of this, and I think that is something that we can clarify in our language.

Sarah DeSilvey
Thank you, Ricky, for that clarification. I am sorry if I confused things. I just wanted to try to figure out a path forward with these three elements and our existing data classes. Shelly?

Shelly Spiro
Thank you, and thank you so much, Maria, for an excellent presentation on this very complex topic. My question is more of a discussion. I know of the PACIO project, which is where advance directives live within the HL7 environment. I know the advance directives have gone through connectathons at HL7. Can you

talk a little bit about how you used nonstructured data and more PDF-style data, but still exchanged that within the connectathon?

Maria Moen
I sure can, and thank you for saying that. In actuality, the Advance Directive Interoperability Project is sponsored by the Patient Empowerment workgroup, and then, the technical framework and a lot of the expertise happens within the PACIO workgroup, so Patient Empowerment owns this one, and for a very good reason. When we did connectathons, and some of the connectathons that we did were really past the initial stages, we had an EMS provider, and the EMS provider was able to query and retrieve a scanned image of a portable medical order. EMS can only respond to doctor's orders. They cannot honor person-authored documents.

So, for them to do a query-retrieve at a make-believe emergency point in time when our target individual was found laying on the floor and unresponsive, for them to be able to query-retrieve that unstructured document and see an image on their device, that was a glide path that they could get their heads around. Again, looking at scanned advance directives, I have two witness signatures, I have a notary signature, and I have a healthcare agent here who is telling me, "Mom wrote everything down. Go find her document, and I will work with you to devise a treatment plan." We did a lot of work on scanned documents, Shelly, because that is what is out there. The structured documents are few in comparison to the unstructured documents, but vendors are building up a head of steam, and they are coming. I hope that was helpful. I know I am running short on time.

Shelly Spiro
Thank you so much. That was very helpful.

Sarah DeSilvey
Maria, thank you so much. First of all, it is just so wonderful to see the thought, care, and vision in this presentation. I think this actually lays out a lovely ideal future state that we can hopefully iterate on over the course of our years in IS WG, so what we try to do is leverage moments in time, like "What can we do right now?", and also ensure that we create recommendations for where we want to go, and I do not think we could do it so elegantly without this presentation. It was really very powerful. Are there any other thoughts on Maria's presentation before we pivot to go into the review of the Google sheet and Level 5 elements?

Maria Moen
I just want to offer one comment. Our project was born during the firestorm that was COVID, and we have so many clinicians involved in this project, and they will back away when you get into data standards, but they will give you all of their passion, and they said, "Please, never again. Never again have us delivering care at an extremely rapid pace, doing the best we can, knowing logically that the person I am working on would not want me to do this. Give me the ability to honor the people that I treat." So, that is the passion from which these requests are based. I want to hold good to our promise to them. Thank you.

Other Draft USCDI v5 Data Elements Recommendations & Level 2 Data Elements Recommendations (00:45:57)

Sarah DeSilvey

Thank you so much. I believe we are pivoting now to the Level 5 elements. Next slide. Thank you, Maria. It is so hard to pivot. We have a few recommendations that we are trying to get our final draft recommendation and progress for. That is all happening in the workgroup discussion column. Eventually, it will be moved to the final recommendation column, but right now, it is happening there. We had a lot of people step up to lead those elements, and so, we really are trying to make sure we are driving to that recommendation, and these are the ones we have so far. So, we had emergency department note, operative note, lot number, test kit unique identifier, route, sex parameter for clinical use, pronoun, name to use, and interpreter needed. Again, there is lots of activity happening in the workgroup discussion column, so, thank you all for leading those. If we can keep on refining those and the person who took lead on drafting can keep trying to integrate the other comments that are happening afterwards, that would be great. Next slide.

We do have another SME presentation coming on the 5th, and that is the care team experts across the NIDDK HRQE e-Care Plan Initiative, the MCE e-Care Plan, and also ensuring we had representation from CMS, given the use of care plans across CMS activities. They will be here on the 5th, but again, Mark, thanks for helping us identify those SMEs.

Mark Savage
I am glad to help.

Sarah DeSilvey
There are also a few other elements in Level 2 that SMEs were asked to be identified for, but we asked that members of IS WG get back to us really quickly on those, and I do not believe we have heard any other recommendations, so if we do not have guidance on the SMEs that we need to do outreach on, we are unable to schedule those presentations, so that leaves us to work it out and try to see if we can figure it out ourselves as the IS WG. Next slide. This is where we stand on review of all the elements so far. As of today, the only things that we have not discussed in our Draft USCDI v.5 are author and author role. We did address advance directive observation and orders today, and then, you can see that correlates very elegantly with the final recommendations in progress. So, these are things that we have discussed and refined, and we are hoping to get to final recommendation on those as we refine those comments going forward, and we are hoping to get to author and author role today. Next slide.

I guess we can go to Level 2 before we go to the Google slide. Next slide. Just as a note, this is the current list that we have so far. This is the last day to establish Level 2 elements as a recommendation. If you want to elevate them, they have to go now. We do note the comment that Pooja made before she went back, but for care plan, we do have that planned SME presentation. For health literacy status, we have thought about this one and have a little bit of a thought on how to address that. For laboratory specimen collection date and time, substance food and allergies and intolerances, family health history, a host of insurance information elements… This is one of those that was identified as possibly having a SME be helpful, but we did not have a SME identified, so if you have an idea for that, please let us know. And then, we have a request for clinical note regarding SDOH note.

Steven Eichner
This is Steve. One of the things that Sarah and I were talking about a little bit this morning as we were looking at the health insurance information was that we realized there is not an individual identifier and identifier type that is just there in general to support something like a medical record number or something

like that. Is that something that there is a Level 2 data element that is related to that that we could include? Is there interest in the group in including that? Is that worth discussing?

Sarah DeSilvey
It seems like the best way to address that is maybe just putting it on there, and then have the discussion as part of our work, and then we can do it collectively and center your idea as something to put in Level 2. Does anyone else have a different thought?

Steven Eichner
That sounds like a plan.

Sarah DeSilvey
All right sounds good. I believe now we are ready to go to the share drive to try to work through some elements. If it is okay to start with the reflection, because this is where we put these things to action, we can start with revisiting the advance directives and orders comments that Maria just presented on after we revisit the Gender Harmony elements that were presented on last week. Mark, I believe we have an update to some of the recommendations from Gender Harmony in the definition and in a usage note that might be helpful, so, once Al gets the Google doc open, it would be great to touch base on that.

Mark Savage
Sure.

Sarah DeSilvey
All right. If we can start up at the Gender Harmony element, if we had a SME presentation, I would love to anchor us in reflections on that SME presentation, both in the meeting and in the following meeting, so we can move toward a final recommendation, and I did want us all to take note of the definition that evolved in the sex parameter for clinical use, so, if you can go over to the workgroup discussion element, that would be great.

Al Taylor
It is a hard cell to read, Sarah, because it has become so long.

Sarah DeSilvey
This is one of those Google slide elements that is very hard.

Mark Savage
Maybe widening the column will help for purposes of visualization here.

Sarah DeSilvey
Sounds great.

Mark Savage
Do you want me to jump in?

Sarah DeSilvey

Please do jump in. I just wanted to note that one of the things we were looking to our SMEs to do is, if we agreed, help us refine the definition for sex parameter for clinical use and some of the accompanying recommendations in reference to HTI-1, and Mark, you were such a great lead on this, so I would love to have you show us where we landed, hope we can put this into the final rec, and go from there.

Mark Savage
Thanks. So, on the presentation, I think there seemed to be consensus from both the SMEs and the workgroup about the three elements, but where we spent some time talking was about the definition for sex parameter for clinical use. Hans and others raised the question of if it could be simplified. So, working with the SMEs, what we have is a revised suggested definition. As we reflected on the workgroup conversation, I think it does meet the desire for something simpler, and some of the additional language that had been in the definition, we switched to a usage note about where the observable observation might come from as examples. It is there in front of you, a revised shorter definition, and then the usage note, and then, the last thing, which will be new, unless people have looked at this spreadsheet for today's meeting, is that we did discover that the regulation refers to a LOINC standard in 2.72 that is sex for clinical use, not sex parameter for clinical use, so we have included a note that we recommending including so that ONC can figure out how to avoid confusion as we go forward, as this hopefully gets added to USCDI v.5. That is a quick summary. Thank you.

Sarah DeSilvey
Thank you so much. Any questions or concerns with moving forward? Mark is going to take lead on drafting the final recommendation statement for this and the associated Gender Harmony data elements. Are there any concerns with moving forward with recommending the revised definition and usage note and accompanying recommendation as they were crafted in the guidance of our subject matter experts? Does anyone have any questions? All right, speak now or forever hold your peace. Again, Mark, thank you so much for facilitating leveraging the expert guidance of the Gender Harmony SMEs into IS WG. Mark is going to take lead ever so capably in drafting that final recommendation, including the recommendation to update the definition for sex parameter for clinical use and the recommendation and reference to HTI-1. So, thank you so much. Now, I would love to, again, go back to the advance directive observation element.

Mark Savage
Sarah, do you want to do name to use and pronoun as well, or do that later? I am just checking.

Sarah DeSilvey
Oh, were there updates there as well? My apologies.

Mark Savage
It just is to state that people wanted to go forward. It is not really an update, I just put it in language.

Sarah DeSilvey
Oh, sorry, my apologies. That is my fault for feeling like we were there.

Mark Savage
I think so, yes.

Sarah DeSilvey
Are there any concerns with moving forward with name to use and pronoun with an IS WG recommendation, understanding that we had a really robust conversation regarding differentiating name to use from preferred name and legal/administrative name… No, it was some other element. It was last week, and I am trying to remember everything. Are there any concerns with moving forward the associated elements from the Gender Harmony Project as referenced in the last presentation from the SMEs? If we go over to workgroup discussion, the next column, Derek is still on the call, so we can make sure that the name to use elements contain the conversation and documentation concerns that Derek was referencing in the presentation last week. Derek, sorry to call you out.

Derek De Young
No, not a problem. It is not a hill I am going to die on. I was just more confused about the difference, so I think the conversation helped, and if we get the documentation out there… I think there will be confusion once it comes out about "Hey, if we capture preferred name today for all these patients, is this different?" As long as we have that documented somewhere, I am okay.

Sarah DeSilvey
Fantastic. Mark, I am hearing no concerns and seeing some nice comments in the chat. I do want to honor the fact that moving forward with these three recommendations is a many-year IS WG recommendation, and I feel that. I am very, very grateful that ONC put these in Draft USCDI v.5 because they are of a critical nature, and I am very grateful to Gender Harmony for coming to discuss those elements with us with all their expertise. Mark, thank you for your leadership on these. This is one of those "This took many, many years, and here we are" moments, so, thank you so much.

Now, just because I want to move forward on there, I am going to have us land with a little bit of a buffer back to the elements that we addressed today because I believe most of the concerns we have had or details we have raised in other recommendations or elements so far are happening through our workgroup discussion element, details on whether or not to reference specific LOINC codes, details on "at a minimum," so that conversation should be happening in the workgroup discussion on, for instance, the emergency department note and operative note. We can always elevate it back here into the meeting, but I do want to keep that discussion happening asynchronously in the workgroup discussion if possible.

So, to reference back, we have this wonderful presentation from Maria, and thank you so much for that, Maria. The original recommendation in Draft USCDI v.5 is for the advance directive observation and for order. There were refinements, as presented by Maria, in the SME presentation. I did not hear any concern, amendments, or adaptations or see anything in her presentation regarding any change to advance directive observation. I am going to start there. Any concerns with moving forward with advance directive observation as it stands right now? I do want to note that Ricky's conversation and Maria's conversation talk about other ways to represent the information which was in a structured document type. Shelly?

Shelly Spiro
If we agree with putting advance directive up in observation, does that not then allow us to have an advance directive data class with other components, maybe now or at a later time? Does it have to go into observation when advance directive has many other data element components that could fit into their own class?

Sarah DeSilvey
Shelly, that is a really good question. This is partially why I just queried. So, maybe Al can speak to this, but right now, the core components of advance directives are put across many different types of data class. There is no unique data class, and I heard that very strongly in Maria's presentation as being a really future-forward way to go. That would be a recommendation for the future, as far as I understand. Al, do you want to help us understand current state and possible future state?

Al Taylor
Yes. So, the recommendation certainly could be to establish an advance directive data class to capture all of the concepts, especially the ones that Maria went over, and looking at that list, it covers a very broad array of concept types. All those data elements are very different data types, so organizing them into an advance directive could be helpful to just be able to visually package those data elements so that there is an understanding that ONC, through USCDI, is addressing advance directives as a concept area. The recommendation certainly could be to organize or reorganize the data classes into a single data class. We did intentionally separate them out and not identify or establish an advance directives data class in the first place when we started adding components like treatment intervention preference and care experience preference because those are primarily goals and preferences.

We did it the way that we did it just because it made sense to categorize them in that way, but categorizing all the advance directive related concepts into a single one is another way to go, and it would certainly be okay, but I think that one of the things that we try and project about USCDI is that the data classes themselves do not convey specific meaning to the data elements. They do not indicate the method of use, the care settings in which they are used, or any other characteristic about the data element. I call it a visual organizer, and we are kind of capturing things in this concept area. For that reason, having an advance directive data class could be useful to visually organize all of the advance directive data elements into a single data class. That was a very longwinded way to say sure, go ahead, make a recommendation for the advance directive data class.

Sarah DeSilvey
Even in Maria's presentation, just to call it forward, some elements are included in an advance directive, but also used in other use cases. I think the presentation that you had, Maria, had an advance directive data class, but it is not like every single element was included in that because some of the elements are included across other purposes, such as care team members or preferences. Shelly?

Shelly Spiro
I am just going to be in support, along with Lorraine, of moving to an advance directive data class, and then we can fit the right elements in there. Mainly because of the way that we have worked on this through HL7, this is named as a data class, although whether we put it in as a data class or it is all around in different places in other data classes, I think it is more confusing, and this is such an important piece, so I am going to vote to make it a data class and have other data elements under advance directive.

Sarah DeSilvey
I love it, okay. Steven?

Steven Lane
As I just put in the chat, when we went through this with adding the SDOH data element to Version 2, in that case, they got spread around into different data classes. As Al said, this is really just an organizational schema. It does not change the presence or the meaning of any of these new data elements, but for those of us who are constantly dipping in and out of USCDI, and making talks about it, and trying to explain it to others, with SDOH over these past few years, it has been a little difficult because we always have to go and find them in each of the data classes, bring them together, and copy and paste them from different places. So, it has been awkward, but I get the idea of keeping new data elements in with other related data elements. So, I do not have a preference whether we lump or split across data classes, but I think we should be consistent. I do not think we should have SDOH one way and advance directives another way.

Sarah DeSilvey
That makes sense. I just want to make sure. The original question was on the elements themselves, not the data class, so if we can just revisit and go back at some point to the elements and talk about data class and time, that would be great. Shelly?

Shelly Spiro
Yes, the advance directive observation data element is important to be added at this time. The ADI and Maria have done quite a bit of work to make sure it is part of the HL7 FHIR resources. I think that what Steven is saying is also very important. I believe there needs to be a restructuring of the data classes. Look at medications as an example, which is where my expertise lies. We could have put medication all over, in almost any data class, but by having it in its own data class, it gives it its focal point. Wherever you put advance directives now, I think it is important, but for the future, we need to recognize it as a data class, and I agree with Al that it might not be the time to do it now, but I think we need to look at that for the future.

Sarah DeSilvey
Okay, and I am just going to ask if we can step back from the data class question for one moment and just make sure we are in agreement on the elements as stated and moving forward with that, and then we add recommendations for an envelope data class on top of that. Hans, do you have a thought? Hans, we cannot hear you if you are speaking.

Hans Buitendijk
Sorry, I just rushed back onto my laptop from the phone, so I apologize for not being here earlier. I got a little bit of the tail end of the discussion about a half an hour ago, after Maria's presentation, which I did not get. I think data element and data class are somewhat related, and I heard Shelly and Steven's feedback on that respectively as well. In order to understand the data element and purpose better, which makes sense to advance in this space, then actually, the data class helps as well because putting it under observations, orders, care plan, or clinical notes are all uncomfortable in one way or another, and it makes it hard to understand what we are really trying to achieve with an advance directive observation. When you look at an advance directive, it has elements of a plan, of goals, of preferences, of potential actions that are allowed and not allowed, so I think it goes together. Maybe that is inconsistent with what is happening in other areas, but I would argue that what is happening in other areas is actually not helpful either, so I would rather change those as well to make USCDI much more clear in intent and focus.

As Al indicated, whatever the name or grouping is in USCDI, that does not limit you as to what you can do in FHIR US CORE or C-CDA to then express it, which is where we still need to have some conversation, but I think the data element plus the data class helps clearly articulate what we are trying to move forward to, whether that is initially PDF, scans, unstructured, which, in many cases, will be the only thing that people can really do, and then move our way to fully structured, coded, and computable. That is the path that we are on, and that is a good path to be on. There are just a few more steps to take, but I think that would be helpful. So, I would support the principle of the data element, which is what we are trying to get to. Maybe we can argue a little bit more about the implementation of it, but that is a different story, but we can do it together so that the relationship is very clear on what we are trying to pull together.

Sarah DeSilvey
I hear no concerns with the recommendation for moving advance directive observation forward as an element. I hear thoughts on whether it belongs in the observation class or in a unique new data class. Does that seem fair? Are there any concerns with that statement?

Steven Eichner
This is Steve. I would call it a different data class, not necessarily a unique data class.

Sarah DeSilvey
Okay, and we can figure out what that different data class might be.

Steven Eichner
When I hear the word “unique,” I think of it as a standalone element with its own data class, as opposed to a separate data class that may or may not contain multiple elements. I am not trying to name it now, but I could see offhand something around patient-generated documents or something like that as a class. That would include advance directives or something in that space.

Sarah DeSilvey
We are holding space for the actual class itself.

Steven Eichner
Yes.

Sarah DeSilvey
I do not hear any concerns for the element. Actually, I hear support. I am going to say it positively. I hear enthusiastic support for the inclusion of advance directive observation, and I was going to leave space.

Mark Savage
Yes!

Sarah DeSilvey
Thank you, all right.

Steven Eichner

I have one thing to add on in that space. Perhaps there should be a friendly amendment to look at following some of the work that has gone on in developing the IGs to not swallow preferred method of implementation.

Sarah DeSilvey
That sounds wonderful. We can include those details in our final recommendation. And then, I want to build off of this third element that Maria was mentioning, which is the advance directive document itself, pulling forward what Ricky was speaking to. And so, we have advance directive observation and advance directive. Where are we at with that? If we are saying full force that we need a new data class for advance directives, this type of document or guidance on that document with the LOINC code that Ricky is mentioning in the member recommendation could go into that section, but I want to make sure I understand where the IS WG is in case it needs more time to reflect on that additional advance directive element as suggested by Maria. It could just be that we need more time, and we can come back to that next week. Mark?

Mark Savage
Sorry, I may have missed this, but is there a way in which that document can be attached to the advance directive observation, or does it have to be a separate data element? I am wondering if it is simpler.

Sarah DeSilvey
Simpler than we are making it out to be? Maria, what are your thoughts there?

Maria Moen
I am listening intently. Again, the observation is the point at which it is activated within the healthcare ecosystem. If you do not have an advance directive data element and/or a portable medical order data element, your ability to formulate quality measures is going to be confounded. You are just going to look at the observation, which may or may not create a document. We are looking to create an opportunity for these hundreds of thousands and millions of forms without any further clinical intervention, some of which are introduced by the individual to their state HIE. We are looking for data elements to allow those forms to be liberated and made available. The observation is what happens once they are available, whether they are handed to me or I query-retrieve them from my EHR. In my way of thinking, you cannot do QMs without an asset and what you observed, and we cannot open the floodgates to all of these documents that people really think we are providing care from until they are accommodated as a concept. I think observation is further down the line, in my way of thinking, and I could be wrong.

Sarah DeSilvey
Thank you so much. Hans?

Hans Buitendijk
Thank you. An additional thought is that on the data element itself, currently, the definition is using the term “patient- or provider-authored” as part of the recommendation, and I believe it would be more appropriate and encompassing, recognizing where we are at with actual patient-authored directives, for the term “patient-expressed” to be very helpful because it can cover both, whether it is expressed by the patient and transcribed by somebody else or actually authored by the patient. There are some transitions in place where we are at where “patient-authored” would imply, as the term “authored” implies in other areas, that the patient directly creates into the system the component that is at hand rather than somebody else, though

the latter is more likely. So, “expressed” would maintain flexibility, and “authored” would effectively indicate that the patient has to be the one that wrote it in the system, and that could cause challenges.

Sarah DeSilvey
That makes me think about the two remaining USCDI outlines we have not addressed yet, which we will get to very shortly. I see Mark smiling on that one. I do not know if that answered the question, but what I am going to hold space for is the fact that we might need to talk further on the additional element as presented by Maria, just as we did with the subject matter experts from Gender Harmony. So, I hear us voicing support for advance directive observation with some considerations on how to refine that definition, and Hans, that makes a ton of sense to me. Is someone willing to take the lead on drafting that working recommendation, including possible refinement in the definition, before we come back next week? That would be helpful.

Hans Buitendijk
I would be happy to join, perhaps lead, but either way, I am happy to join.

Mark Savage
Sarah, I will work under Hans’s leadership.

Sarah DeSilvey
Mark is volunteering. Mark, thank you so much. That is very appreciated. I just want to make sure we are moving forward in our process. That is appreciated. So, we do not have a ton of time before public comment, and so, I want to make sure we are landing in a place of action. Can we go to the orders recommendation as well, please? As presented by Maria, her recommendation was building off a Level 2 comment, the portable medical orders. Shelly, do you have any comments before we volunteer?

Shelly Spiro
I did not get my hand up in time to say that I will not lead, but I will help with Mark and Hans on the advance directive.

Sarah DeSilvey
We have a collaborative effort between Mark, Hans, and Shelly.

Shelly Spiro
Hopefully, Maria can feed me some info too.

Sarah DeSilvey
Great. So, I am just trying to make sure we reflect on the SME presentation and reference directly to Draft USCDI v.5. So, as presented, the element was orders, and it was under the orders data class, and then, as it was presented by Maria, there was a recommendation to move forward with the portable medical orders data element that is currently on Level 2, as expressed and defined, which is slightly different than here. Any comment on that before we head to public comment? Someday, we will get to those Level 2 elements. Shelly?

Shelly Spiro

I am in total agreement with Maria on adding portable medical orders.

Sarah DeSilvey
This is a slight refinement of what we have here, so, thank you so much, Shelly. Hans?

Hans Buitendijk
I would like to see some clarification that these are in the states that are in USCDI, that they are reflecting what is documented in that regard, but it is not necessarily initiating and managing the workflow of such an order. "Order" is typically a term that is being used that then manages the entire workflow from ordering to results. In this case, I think it is focused on sharing the presence of that, and then, the right parties can then take that and work with it at that point in time, but it is not meant to be a workflow management tool at this point. We need to think about how we can clarify that to avoid setting an expectation of what it is not.

Sarah DeSilvey
Any thoughts on what Hans said? Steven?

Steven Lane
I think portable orders are so important, complicated, and new. It seems pretty clear to say, "These are the pending orders for a patient," and to make those interoperable, and I really support doing that. It does seem a little odd that it sort of came in in our discussion about advance directives because, of course, those are very unique orders. There are so many other orders, such as labs, imaging, etc., and there is so much value in making those portable, such that a patient can take their orders, shop around, and find the services that are most appropriate for them. But as Hans says, there is a lot of workflow in that, and getting those results back to the ordering provider and CC providers and to the patient when the orders transmit across an ecosystem or across geographies. So, I think there is just a lot to be said about orders, and I do not have the sense that we have really dug into those in detail, and yet, I would love to see them move forward. I just wanted to share that.

Sarah DeSilvey
I am hearing us maybe needing to continue conversation on this. We do have time. We can think on this, think on Maria's presentation, and come back next week. Shelly?

Shelly Spiro
I totally agree with Steven, but I think what we are missing is there has been a lot of work taking place within HL7 around transitions of care, and this is where the portable orders really come in, during that transition of care. So, there are several use cases within the PACIO project that deal with transitions of care, and the portable orders are an important piece of that. Now, whether we put it in a data class of advance directives or leave it in orders, I still think those data elements need to be called out because not every order actually is pertinent for transitions of care, but of course, the portable orders are.

Sarah DeSilvey
So, because there really are two elements here, Maria was bringing to light the portable medical orders Level 2 element that is directly aligned with the advance directive mission, and then there is this general concept of orders, which is far more expansive. Maybe we can keep on talking about this next week, just to make sure, as Steven has mentioned, that we lean into this fairly new, but very critical, thing for us to

reflect on, and maybe it has to be parsed out into different subtypes so we can make sure we get it right, given the various use cases. We are almost at time. I just want to scroll down for a second to author, just so that we can prep ourselves. I want to ask that we start there next week. I just want us to see the last elements for Draft v.5. So, we have author, and then we have author role. I want us to start with this conversation next week after we resolve any ongoing SME conversations so we can make sure we develop a plan for these, as these are the only Draft v.5 elements we have not addressed yet. Mark?

Mark Savage
During this meeting, I quickly dropped last year's IS WG recommendation in so there is something to react to. I am just saying that because it will appear new if somebody has not been tracking it in the middle of our conversation right now. I tried to adjust for some things that have changed over the year. I will go back afterwards and see if I have missed something, but I am just pointing that out. Thank you.

Sarah DeSilvey
Thank you so much, Mark. So, just because it is our charge to review every single v.5 element, if we can review what Mark put in during this meeting, reflect on what IS WG has said in the past, and make sure we come in ready this week to look into these two elements, I would appreciate it. So, I hear we are moving forward with the Gender Harmony elements. Mark is leading some of that work on the final rec. We have a clear consensus on the advance directive observation element. We are working on trying to figure out how we represent a possible new data class for advance directives, and really hear a need to revisit and lean into orders uniquely in the next meeting, and also, we are trying to figure out what to do with that additional element that Maria elevated, which is the advance directive document type, and Ricky was talking about solutions that have been offered for similar elements in past conversations.

So, there is limited real estate, but we are still working in workgroup discussion. We will all discuss with the co-chairs, Ike, and ONC whether it is time to move into the final recommendation column, Mark, just because it is very complicated to keep having these conversations in workgroup discussion. It is getting tight, as you cannot even see it all, like in sex parameter for clinical use, so that will be part of our homework that we disseminate after the meeting. I believe we need to go to public comment. My apologies for being a little bit late. Again, thank you for the robust conversation. Maria, thank you for coming to help us. Seth, back to you.

Public Comment (01:26:55)

Seth Pazinski
All right, thank you, Sarah. We are going to open up for public comment at this point. If you are on the Zoom and would like to make a comment, please use the raise hand function, which is located on the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press *9 to raise your hand, and once called upon, please press *6 to mute and unmute your line. We will give folks a minute to queue up if there are any public comments. Okay, I am not hearing any comments on the line and am not seeing any on the Zoom. I will turn it back to Sarah and Ike to close us out.

Sarah DeSilvey
All right. That was another robust conversation. I do want to say I feel like we are at that inflection point, as we are at an appropriate slide to discuss it, where we really need to start moving forward with final recommendations on some elements, putting them behind us, and putting that little green tag on them in

order to begin final recommendations on March 26th, especially if we are thinking about not having the March 12th meeting because of HIMSS. So, again, we will try to lean into more specific guidance on that in the homework, but do try to finalize those recommendations so we can be really clear on what we have to discuss again. Can everyone also just review the Google drive, just to make sure they are comfortable with the draft recommendations that are in progress so that we can, again, make sure we can facilitate a consensus final recommendation from the group? Ike, any other final thoughts?

Steven Eichner
I think we may amend the 26th item from beginning finalizing recommendations to be a little more aggressive in finalizing recommendations and finalizing the transmittal letter on April 2nd.

Sarah DeSilvey
Thank you so much, Ike. Another robust, great meeting. Maria, again, thank you for being the resident expert and advocate. I think in the elements presented, it is important to note the advocacy element in there. We are so glad to have you. Thank you for the robust conversation, and we look forward to coming in next week with our further conversations.

Maria Moen
Thank you so much.

Adjourn (01:29:30)

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

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Grace Cordovano: I will not be able to make the 12th

Derek De Young: I will not be able to make it.

Kikelomo Oshunkentan: I will not be able to make that meeting.

Medell K. Briggs-Malonson: I will not be available on 3/12 and will also be leaving early due to ViVE.

Keith E. Campbell: I may not be available during HIMSS

Anna McCollister: I missed roll call, but I'm here!

Kikelomo Oshunkentan: Couldn't agree more that "priorities upon death" are included

Grace Cordovano: The time to do this is now.

Kikelomo Oshunkentan: @Grace - +1

Rochelle Prosser: This is fantastic.

Shelly Spiro: @Grace +2

Grace Cordovano: Maria, thank you for this presentation and for your passion in advancing this critical work.

Sarah DeSilvey: noted, Pooja!

Shelly Spiro: @Pooja I recently added a data element “Medication List Type (codified in LOINC) includes a medication administration list and would be a better way to add identifying medication (using Medication FHIR resource in a medication administration list

Shelly Spiro: @MarieMoen excellent presentation and for all your ADI efforts around the PACIO project.

Donna Doneski: Agree 100% @Shelly

Grace Cordovano: Apologies for needed to drop early; conflicts with ViVE meeting.

Mark Savage: For example, do not resuscitate.

Rochelle Prosser: Agree Maria. allows for Clarity in confusion.

Lorraine Wickiser: Great clarification Maria

Katrina Miller Parrish: So if we had a priority order for the 3 - would it be 1) Portable Medical Order, 2) Advance Directive Observation and 3)Advance Directive?

Rochelle Prosser: @Katrina - My understanding is the order would be if patient driven 3, 2 1

Katrina Miller Parrish: Yes @Rochelle, agree on that from the patient perspective.

Kikelomo Oshunkentan: @Ricky +1

Katrina Miller Parrish: It's like a shell to convey the document

Sarah DeSilvey: we are almost at time so anyone who wishes to ask questions of Maria please elevate them at this time

Kikelomo Oshunkentan: and the passion! Thank you, @Maria!!!

Katrina Miller Parrish: Thank you!!

Shelly Spiro: @Rochelle +1

Anna McCollister: Agreed!

Rochelle Prosser: Medical record numbers will change based upon facility.

Rochelle Prosser: Great job team

Steven Lane: Fully support moving forward these data elements.

Shelly Spiro: @Steven +1

Rochelle Prosser: @Steve +2

Rochelle Prosser: I fully support moving Advance Directives foreard

Katrina Miller Parrish: Agree to recommend along with Data Class, ADs and Orders

Lorraine Wickiser: I support AD data class with the data elements in that class

Shelly Spiro: @Lorraine +1

Kikelomo Oshunkentan: @Lorraine +2

Steven Lane: When we added SDOH data elements they were sprinkled around in multiple data classes. This has been somewhat difficult to manage and reference since. Now this is being suggested for these AD elements. This is really an issue of the usability for readers. I would suggest consistency for AD and SDOH, whether this is spreading them around or lumping them together in dedicated data classes.

Rochelle Prosser: @Shelly +1

Katrina Miller Parrish: Yes, agree Sarah

Shelly Spiro: @Sarah YES

Maria Moen: I would love to help in any way I possibly can. I don't want to intrude, I am certainly happy to support your good work though. Consider me a resource please.

Shelly Spiro: @Thanks Maria

Hans Buitendijk: I like the term along the lines of "pending", i.e., other actions are needed to "activate" them.

Rochelle Prosser: I thought this was for advanced directive only

Steven Lane: My reading of the Orders definition is that it includes all sorts of orders, NOT simply AD.

Hans Buitendijk: POLST seems to be more on the clinician care planning side, which would informed by an ADI, but not part of ADI.

Rochelle Prosser: Thank you

Steven Lane: Perhaps Al or others could enlighten us regarding how ONC sees the Orders data class and their motivation for including this element in Draft V5.

Lorraine Wickiser: there may need to be separate data elements,; Orders and an Order

Mark Savage: Which column gets the draft "final rec"?

Albert Taylor: @Steven ONC's intent with Orders is to be able to represent a provider's intention to treat as a separate data element and the first data element is intentionally very generic as a first step into this realm.

Steven Lane: That makes sense, @Al. I do think additional discussion next week makes sense, as this can have HUGE value, but I am sure will have a significant impact on HIT developers.

Albert Taylor: I can restate this during next week's discussion.

Katrina Miller Parrish: Thanks!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

IS WG Webpage
IS WG - February 27, 2024, Meeting Webpage

Transcript approved by Wendy Noboa, HITAC DFO, on 3/6/2024.