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Transcript

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

February 20, 2024, 10:00 – 11:30 AM ET

VIRTUAL

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

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
Hans Buitendijk, Oracle Health
Keith Campbell, Food and Drug Administration
Grace Cordovano, Enlightening Results
Derek De Young, Epic
Raj Dash, College of American Pathologists
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Hung Luu, Children's Health
Steven Lane, Health Gorilla
Anna McCollister, Individual
Katrina Miller Parrish, Humana Health Insurance
Alex Mugge, Centers for Medicare & Medicaid Services
Kikelomo Oshunkentan, Pegasystems
Rochelle Prosser, Orchid Healthcare Solutions
Mark Savage, Savage & Savage LLC
Fillipe Southerland, Yardi Systems, Inc.
Shelly Spiro, Pharmacy Health Information Technology Collaborative

MEMBERS NOT IN ATTENDANCE

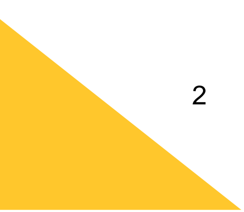
Medell Briggs-Malonson, UCLA Health
Christina Caraballo, HIMSS
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, Centers for Disease Control and Prevention
Aaron Neinstein, Notable
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

ONC STAFF

Seth Pazinski, Director, Strategic Planning & Coordination Division, ONC
Wendy Noboa, Designated Federal Officer, ONC
Carmela Couderc, Office of Technology, ONC
Sara Armson Office of Technology, ONC

PRESENTERS

Carol Macumber, Clinical Architecture
Rob McClure, MD Partners



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

Seth Pazinski
Hello and welcome, everyone. Good morning. We are starting our next Interoperability Standards Workgroup meeting. I am Seth Pazinski with ONC, and I want to thank everybody for joining us today. I will be serving as the designated federal officer for today's call on behalf of Wendy Noboa. All workgroup meetings are open to the public, and public feedback is welcome throughout the call. Members of the public can type comments in the Zoom chat feature throughout the meeting, and there will be time on the agenda towards the end to make verbal public comments for those interested in doing so. I am going to begin the meeting with a roll call of the workgroup members, so when I say your name, please indicate that you are present. I will start with the co-chairs. Sarah DeSilvey?

Sarah DeSilvey
Good morning. I am here.

Seth Pazinski
Good morning. Steve Eichner?

Steven Eichner
Good morning. Present.

Seth Pazinski
Good morning. Pooja Babbrah?

Pooja Babbrah
Good morning.

Seth Pazinski
Good morning. Ricky Bloomfield?

Ricky Bloomfield
Good morning.

Seth Pazinski
Good morning. I did get a note that Medell Briggs-Malonson will be absent today. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Good morning. We also heard from Christina Caraballo, who will be absent today as well. 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?

Lee Fleisher
Good morning.

Seth Pazinski
Good morning. Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Good morning. Raj Godavarthi? I also heard from Jim Jirjis that he will be absent today as well. Steven Lane?

Steven Lane
Good morning.

Seth Pazinski
Good morning. Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski

Good morning. Anna McCollister?

Anna McCollister
Good morning.

Seth Pazinski
Good morning. 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
Good morning.

Seth Pazinski
Good morning. Mark Savage?

Mark Savage
Good morning.

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

Shelly Spiro
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King? Naresh Sundar Rajan? Was there anyone I missed? All right, thank you all. That completes our roll call. Before handing it back to the co-chairs, I do want to mention that Al Taylor from ONC is out today, so we have Sara and Carmela from the ONC Office of Technology who are going to be joining the call today to fill in if there are any questions for ONC during the discussion, and they will also be helping with managing the Google doc and taking notes if needed during today's call. So, with that, I want to say thank you to everyone, and I will turn it back to Sarah and Ike for their opening remarks.

Opening Remarks (00:03:47)

Sarah DeSilvey

Welcome, everybody. It is really exciting to be getting into some of our SME presentations today. We are going to be hearing from Robert McClure and Carol Macumber. I think Rob might be leading the presentation, but Carol is with us as well. I have the honor of knowing the experts from my work at HL7. We are going to be excited to hear their presentation. And then, we will hopefully be diving into some of the other Draft v.5 elements and Level 2 elements, again, pausing anything else that has a subject matter expert presentation scheduled. We will see those later on in the slides. Ike, anything else to add?

Steven Eichner

No, other than my good mornings and welcomes to everybody. I am excited to continue our good work.

Sarah DeSilvey

I know, I know. We are getting there! So, the first order of business is to pass the mic to the esteemed Rob McClure and Carol Macumber. Rob, I believe we are going to be hearing from you on the Gender Harmony Project and its critical work to standardize elements, many of which have been elevated into Draft v.5 today, so, thank you so much for coming.

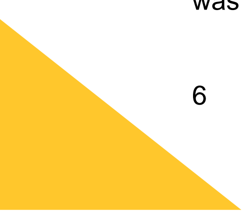
SME Discussion – Gender Harmony Project (00:04:56)

Robert McClure

Thank you, Sarah. Thank you so much to the workgroup for giving us some time to go through this. We are excited about this. This is a long project. I know some of you are pretty familiar with it. Some of you have seen some of these slides. We do have a deck, and we have adapted that deck to focus on the things that I think the committee has asked of us. You will note that I have put myself in there as ex officio. Carol is actually leading the project now. I am trying to retire, and so, I will be spending less time working on the improvements to this standard because it will be improved over time. Next slide. As was noted, Carol is here, and she will be chiming in.

So, I wanted to go over some of the basic things because I know that there are some new folks on the workgroup, and I want to make sure I get everybody started in the same place. We were actually essentially given this use case many years ago to try and figure out how to fix the fact that, in healthcare systems, and to some extent in society, we think of everything as wrapped up into just M and F, a binary view of the world, and that just does not work, and particularly in the clinical world, it does not work. It particularly does not work for transgender patients, but as I am going to get into in a second, it is not just transgender patients, it is everyone that this is important for.

Our particular use case here is one way to show how the various things that you need to know about a person can require different pieces of information, and therefore they need to be separated out. For this particular use case, a female-to-male transgender patient who is presenting to a facility to get imaging and admission for procedures and was an anatomic female, but is undergoing hormone transition, this person has a gender identity of male, and in order to get set up for imaging… This is one of the main use case issues we had. We had a lot of participation from Digital Imaging and Communications in Medicine (DICOM) because they were having issues with this. The imaging system is only set up in a binary way, and what was needed to know was that this patient's anatomy was associated with a typical female.



In addition, for the lab, depending on the lab test, this patient is potentially more consistent with reference ranges that would be associated with the male group, and there are other things, like the operating room (OR) setup and things like that, that need additional information that was also different from the gender identity. So, one of the things that we learned through doing this work was that birth sex, administrative sex, and just the idea of sex and gender identity are not consistently understood or used. Next slide.

The other thing that I wanted to just make sure people understood is that, again, the things that we proposed are not only important for transgender patients. They are important for all patients. So, for example, for a patient who has post-bilateral prophylactic mastectomy, one of the things that we know we need to do is to stop sending alerts to get a mammogram. Additionally, persons who have polycystic ovarian syndrome have atypical hormone levels, and that is something that we need to communicate. We have been working our way around this, and we have been doing it in different ways, and in particular, I would say we have had issues when someone needs to have something done that is outside the typical insurance process, so we need to find a better way of actually communicating this, and I think we have done that. Next slide.

So, obviously, this is a very dense slide, and it is a dense model, but we focused on these five areas. We are going to talk about three of them, what we have identified here with regards the use in USCDI, as gender identity has been a part of USCDI for a while, but we are now talking about the next three that we have there, and then, reported sex and gender, depending on what part of USCDI you are looking at, is not quite ready, and we will not be talking about that today. The other tiny thing down there is I would encourage anybody who wants to do more work on this to take a look at the implementation guide (IG) that we have published. We do have this design considerations document in there that shows something that was very important. Go on to the next slide.

We wanted to make sure that, in creating this, all of the HL7 standards, v.2, Clinical Document Architecture (CDA), which was obviously then Consolidated Clinical Document Architecture (C-CDA), and Fast Healthcare Interoperability Resources (FHIR) all align. That took us some work. We actually had not ever done that before, but we have done that, and so, in doing that, we published four things, which I will get to in a second. First, this group has been working since spring of 2019. We do have a *Journal of the American Medical Informatics Association* (*JAMIA)* publication. It is a little outdated right now, but it is a good document to take a look at. As I noted, we actually had four, or really five, publications that came out of this work. One is the cross-paradigm guide, which you saw a page from. It is an IG, just like a web IG, just like all the other FHIR things. We had a set of CDA templates. We do have our changes in FHIR R5, and then, v.2.9.1, and I will note that when you get this slide deck, if you click on that v2.9.1, it will not go anywhere because v2.9.1 actually had another issue that they needed to pull after the ballot and bring it back for reballot, and they are finishing their work, and it actually has not officially been published yet.

So, there is lots of participation not only from external SEOs, but governments and the lived community. We had strong active participation from Epic and some of the other vendors, etc. As you know, we have to deal with this. Next slide. So, these are the three that we are all looking at with regards to promoting to the next version of USCDI, and so, I just wanted to make sure that you all saw the definitions for these, and we will talk about each of these separately. Go ahead, next slide.

The other thing that I wanted to make sure that everybody understood is that Gender Harmony really is in the house. Everybody is aware that it is a part of HTI-1. We are really excited about that, and are actually named in the regulation, and that actually has a strong influence on what we need to accomplish, which, again, I am sure you are aware of, and I think we will be able to explain how that aligns with USCDI here in a minute. We actually did a presentation at National Committee for Quality Assurance conference, which I am forgetting the name of now, where they have included relevant clinical information in two of their measures that allows for the use of sex parameter for clinical use (SPCU) and other sex-oriented ways of documenting information about patients. This was an update to those measures to make clear that we wanted to focus those measures on patients where it really mattered.

This is becoming more and more important over time, as, again, I think you are very aware of, and we need to do it in a way that aligns with how computerized systems can capture the data and communicate it as opposed to forcing people to figure out how to ignore one piece of information and presume another.

There are international groups that are working on this. Particularly, Canada and Australia have been active in the project, and also plan on using the work to implement changes in their systems, and, as I mentioned before, Epic certainly has been very active in this, Fenway Health has also been active and has also implemented systems to help support this inside their own environment, DICOM has adapted it, and Laboratory Information Management Systems is also trying to figure out how to do this. Again, as you might know, there has been some state work to try and push ahead in order to be able to collect some of this data. Next slide.

So, I wanted to focus on the questions that Al sent. He noted that in terms of the advancement criteria, he wanted us to talk a little bit about Criteria 1, 3, and 4, so I put this slide in here to kind of note how that works with these three elements. I think "name to use" and "pronouns" are probably a slam dunk, if I can be so bold. I hope so. I know that nothing is ever a slam dunk, but I want this committee or this workgroup to hopefully approach it that way. They are pretty straightforward, and we will go over that in a minute. The SPCU is probably not as clear. We think it is clear. We think organizations do understand how this works. It is incorporated in FHIR and, as I noted, the other standards, which is really important to understand, in ways that organizations can easily adopt, and then systems can design and utilize that information without significant burden. I want to add, as we noted on the last slide, that there are a number of places that are already doing this. Usually, in some around-the-back way, Epic has designed a system that supports it already with regards to SPCU. All right, go ahead.

So, we are just going to run through each of these. Again, I think you guys know this, but the Gender Harmony Project defines name to use as a text attribute that provides the patient's name that should be used when addressing and/or referencing the patient. I want to note that, for example, it is not the same as legal name. Oftentimes, you do need to know what the legal name is. It is one of the advantages of having name to use as a separate thing, so that you can keep these things separate. The ability to send this sort of stuff is built into systems already in place if they are following any of the guidance that has been provided already from HL7 or, actually, other systems by just picking the right way of communicating it, and what we did was to make it clear how to say which is the name to use. For example, in FHIR, in human name, we use "usual," in CDA, we use the qualifier Call Me (CL), and in v.2, there is an extended person name segment. Again, if I can be so bold, name to use is a slam dunk. It is already available, easy to implement, and should be promoted. Next slide.

Pronouns are pretty similar. They are not quite as easy, in that, again, I think everybody understands what this is. It is a patient-level datum, although we have had questions about the possibility, and in our original logical model, which was a PDF and which was superseded by the FHIR guide that we published, we actually thought there might be use cases where people would want to use pronouns in a particular context. I do not know that that is going to be something that is important in the clinical world, though it is certainly important in real life, but I do encourage us to move this forward as something that is at least important to capture about the patient.

It is clearly important in terms of establishing a relationship and being able to communicate with the patient well, and in FHIR, that is an extension that you simply add, like many things that are important that you add in terms of exchange, in CDA, it is a new template, which is a similar process and easy to include, and in v.2, it is included the new GSP segment, but in addition, v.2 explicitly included direct information standards on how to use the existing observation, the Observation/Result (OBX) segment, to do this. Again, any organization can adopt this. Next slide.

This is sex parameter for clinical use. I want to give this definition. We are going to talk a little bit about this later on. This is a use-specific sex categorization value that provides guidance on how the recipient of that information should apply settings or reference ranges that are derived from observable information. Now, that is a mouthful. It is something that we have taken a lot of time to craft in order to be able to succinctly communicate what this is intended to do. Maybe you do not think it is too succinct, but it is. The idea here is one that has learned from the community. When we went out in ballot when it was originally proposed and originally added to Logical Observation Identifiers Names and Codes (LOINC), it was sex for clinical use. We had strong pushback from one element of the community in particular. Even though the community participated in creating it, they thought about it more and decided they really needed a different way of communicating this, so, in one of those classic "Nobody was celebrating, but everybody was satisfied" endpoints, we arrived at sex parameter for clinical use, SPCU, so that is the name of the element.

I actually think it is a better name in terms of communicating that kind of definition. The way you get it is, quite honestly, probably most often done, and I would even say better done, through some kind of logical rule, evaluating a set of observations or pieces of information about the patient, and then determining what that particular SPCU is for a particular context, but it could be based on a clinical observation, and a clinician could enter that information if that is the way it ends up being done initially. But I do want to highlight that it may not always be just that way. It can be patient-level data, and as I noted, it was initially thought of that way. I think our community feels very strongly that it should be really focused on contextual use, and we would certainly agree with that, which was why, in the Level 2 context for USCDI, there were a number of different SPCUs which I think really communicate this information clearly.

Based on that definition, as I said, I hope it is clear that this is to be used in an order, a result, or a particular observation. If you think back on that use case, you can realize that it was really about communicating an order, a request, an alert, or something like that. And then, again, our standards are straightforward in terms of how this is implemented in FHIR R5, as an extension. In CDA, it is a template, so it is easy to consume, and in v.2, it is the same thing as before, the same kind of standard way of implementing this. Next slide on SPCU.

So, there are lots of words. Again, you guys are going to get this slide deck. We put a number of things in the slide deck so that you can take your time and review it. You do not have to sit here and read this. It does have the definition that was in the guide. Actually, this comes from the text that we put into the FHIR extension. It is a little different than the definition that I have given you on the other slide and that we are going to talk about here in a minute because we have more space to add more words, and so, it is kind of worded differently, but the focus is exactly the same. The intent here is to say that you are going to use this in a particular case, a particular context of use, and you are going to base what you send on maybe a subset of information about that patient. Your setup may require a female-typical set of information, and that is based solely on this patient's hormone level or something like that. Hopefully that is pretty clear, and we will have the opportunity to answer questions here in a minute. Next slide.

So, associated with this, we crafted a very specific value set. Again, when we originally went to ballot, we had something slightly different. In the logical model, we did actually specify some potential value sets, but the logical model did not actually dictate anything like that. Again, through a lot of discussion in the community, we came up with these required values for this SPCU data element: Female-typical, male-typical, specified, and unknown. So, again, you will see that we are not saying male and female. We think these are better because we think it communicates more clearly exactly what is happening. I want you to think about where we have these issues arise, and this is actually what we are already doing in clinical systems, so it makes it clearer.

What do we mean by "specified"? Again, a lot of work went into picking that word. Nobody was perfectly happy, but everybody was satisfied. What that is communicating is that you need to look for other information. Perhaps you need to talk to the patient, perhaps there is something else in the chart that you can use, but do not just presume, particularly just by looking at the patient, that you can take a value that has not been made available. You need to go in and get additional data to be able to determine something. It could be that a lot of times, this will communicate "specified." This is very similar to what is already going on, in that instead of specifying, they would say "other." The problem with "other," which some folks may understand, is that this community is tired of being othered, and we would agree with that. This is not what this is about. This is about saying that there is something that you need to go and figure out and then use. Okay, next slide.

So, I wanted to get to some recommendations that we have with regards to your considerations. Again, name to use and pronouns are straightforward, in our opinion, and absolutely should be promoted to USCDI. The sex parameter for clinical use is in Draft v.5 as a data element that is being categorized under the data element observation class, and it was not what we had been proposing, but given that it is in the HTI-1 final regulations and we are pointing people to work that gives them more clarity than you would get in a little one-sentence thing, we are satisfied with that being a good way to move forward, but we do recommend that we make the definition that is associated with this data element clearer so that it explicitly states, as well as you can do in a short form, which I know is not as short as what is in the current proposed definition, and provides more guidance to people who are trying to implement it as to what we really want them to do and what it is intended to do. So, we would suggest the definition that I have included here as a better way of making that clear. Again, we are certainly open to conversations about that. Next slide. I think this is my last.

So, HL7 is an open-ANSI process, actually an International Organization for Standards (ISO) process, but we are very much interested in ongoing participation by the community, particularly the lived community. I will have participation, but Carol will be leading the charge going forward. We do have comments against this IG already, and we will be working to adopt changes in a future ballot, but I am very comfortable with the material as published and am comfortable that we can move forward as we have defined. With that, I will close.

Sarah DeSilvey

Thank you so much. So, what we are going to do now is thank you, Rob and Carol, for that excellent work. I am a huge fan of Gender Harmony. In order to ground our discussion, we are going to try to review the draft elements as presented in Draft USCDI v.5, and then pull back a few slides as needed, or just call on Rob and Carol to answer some of the many questions that are in the chat. I neglected to review the IS WG charge. That is one slide, and we will go into the elements that were actually on Draft USCDI v.5 next. So, this is our charge, which is to review and provide recommendations on Draft USCDI Version 5, and this includes elements in Draft USCDI v.5 and Level 2 data classes that were not included that we wanted to elevate. Next slide.

So, we just wanted to make sure that, as we drive our conversation and pull out the wisdom and expertise of Carol and Rob, that we ground it in the data elements as presented in Draft USCDI v.5, and then we will transition to make sure that we are commenting on the elements as presented, and then we can get this into the Google doc whenever we are ready, but I do want to make sure we leave the SME slides up for any questions that can be answered by supporting documentation in the SME slides. So, here is the sex parameter for clinical use, which is currently defined as a category based on clinical observations typically associated with the designation of male and female. We heard Rob's and Gender Harmony's comments on proposals for alternate definitions for that. Next slide.

And then, we have name to use, the name that should be used when addressing or referencing the patient. This information is usually provided by the patient. Examples include nickname,but are not limited to that. We heard some information, and we have Nick commenting on that from a current practices perspective. And then, we have pronoun, which is a word that can replace a person's name when addressing or referring to a person. As a usage note, this information should be provided by the patient, and may be used to identify a person apart from their name. Examples include, but are not limited to, she, her, they, them, he, and his. So, those are the elements as presented in Draft USCDI v.5, and I would love to elevate many of the really critical questions for our SMEs in the chat, so if people want to comment and ask questions of the SMEs, raise your hand as usual, or just elevate your question in the chat. And then, we have some questions to ONC, I believe. Steven?

Carol Macumber

Sarah, I have been trying to answer the questions as they have been coming in in the chat.

Sarah DeSilvey

I saw that, yes, Carol.

Carol Macumber

There are a few that I did not get to as Rob was talking. Steven, I think you raised your hand first, but you also had a question in the chat specifically around the utilization of SPCU being context-specific attached to an order result or an interaction. Sarah, if it is okay, we can start with that one because I did not get to it in the chat.

Sarah DeSilvey

That sounds great.

Steven Lane

Go ahead, Carol. I am all ears.

Robert McClure

I am trying to catch up. There is a long list of questions.

Carol Macumber

Rob, I have been answering them. I will go ahead and introduce this one. Steven Lane has asked Rob about the context of SPCU being either exclusively attached to an order result interaction or data maintained over time at the patient level. This is a longstanding conversation that we have had around SPCU being available at the patient level. The intent is that it would be context/use-case-specific, and that it would be and can be attached as modeled to a specific observation. That being said, one of the changes that was made from the initial informative specification to the cross-paradigm implementation guidance was that you could have a patient-level indicator, though it is not meant to indicate sex in general, nor is it to be confused with gender identity. Rob, do you want to further elaborate on that?

Robert McClure

The idea is this should be something that is very specific to a use context. We are kind of dealing with a couple of things. One is that we are transitioning this worldview and societal view that all you had to do was look at a person, stick them in a binary bucket, and you would know everything you needed to know. Certainly, as clinicians, we have known for a long time that this is not true, but we do not have systems to support that. One of the things that this project did was make us bring together a community to look at figuring how to do the transition. How do we step across that gap?

So, part of the process of stepping across that gap was to acknowledge that for some systems, understanding what we would call a default SPCU may end up being the way that the system can support this, and so, that is what we have done. We have made it very clear that we do not see this as a patient-level piece of information, that it is really a context-oriented piece of information. I really want people to understand that use case as a very typical one in the transgender community, but also, it is not atypical in people that they may actually have more than one SPCU value for a particular clinical scenario. And so, that means that a lot of times, where it is really important and unique, that patient-level piece of information, from a Gender Harmony perspective, should be specified.

That being said, we want all systems to think about using SPCU all the time, and I noted that there was a question or comment about that in the chat. We want people to understand that this is always in play, and I will be honest, I know there are a number of people in the community that I have worked with who would not be particularly happy with me saying this, but given this gap-stepping-across kind of issue, if we have

the ability to have that at a patient level in default and specified in those places so that you went and looked at the particular order to make sure that there was not something unique in that particular order, that would be good. Similarly, for patients for which any test would always follow male-typical or female-typical, you can put that in at the patient level so that, again, a system that is always looking for SPCU would have it. So, I see that as a cautious endorsement of this idea. I hope that is understandable.

Sarah DeSilvey

That is understandable, Rob. There are some really good questions from Hannah regarding implementation, but I want to focus on Katrina and Derek because one of the things that I want to make sure we are utilizing our SMEs for is understanding how their expertise can help us recommend, adjust, or alter the USCDI v.5 elements, since we have them in the house. Katrina?

Katrina Miller Parrish

First off, again, thank you so much for a terrific presentation, and I will admit I am really catching up, just trying to make sure I understand what our IS WG recommendation really should be in the context of all this. So, my main question, Rob, comes from a little bit more detail from what you were just describing. Should SPCU have a field that is specific per imaging, per lab, per whatever the context is, or is it just an open element to be filled in when that order is placed in that context? If I am thinking about a list of demographics, SPCU should be in there, and maybe "for SPCU" should be in there as opposed to just entered every time somebody is ordering imaging. So, could you help me out with that?

Robert McClure

I can. That aligns with what we were just talking about, and this gets to the nuance that I think all of you understand about how we communicate changes in systems so that they integrate them properly deeply within the workflow and that sort of stuff. I also understand that the idea of SPCU, the idea of the work that we are doing, particularly the idea of collecting gender identity, is typically collecting something that likely was a gender identity and never looking at that again, so it was an easy workflow. I think about how, decades ago, when I was working with implementing systems, I remember walking through an ICU and trying to convince a surgeon that we needed to implement electronic health records, and he had his nurse and his chart tables with him, and he said, "How can it be easier than this?" My answer was, "Jeez, it is not. We need to push forward." So, this is going to be some similarity. The idea here is that it is not some other object that you fill out that happens to be brought in in the context of a particular order. This is another element that is specific to that particular order.

Now, I agree that that is burdensome. It means that the fun of filling out orders get just a little bit more difficult, but remember, I think it is also valuable, and Epic has shown us that this might be a good path forward, that one way to implement this is to build logic that basically determines when that is valuable and puts it in. I would absolutely agree that clinicians who do things should review the information that a computer decides for them, but this gives me an opportunity to talk about SPCU as one of the things that is in HTI-1, which not too surprisingly was added to the list of things that patients can review and change. I understand the importance of that.

I honestly do agree that what we worry about is wrong stuff, and so, that is important, and I absolutely think patients should be able to identify and flag when things are wrong, but I would like the idea of SPCU to be seamless and built, to say something foolish, into systems that are smart enough to know that they need

to be gender-neutral, system-aware, and information-aware. So anyway, that is a long answer, but no, it is not a separate thing that you go and grab and attach, but something that is very specific to that particular order, result, or procedure event to which you happen to add one additional piece of information.

Sarah DeSilvey

Thank you so much. I believe we are off to Derek now, and I just want to note that we have these SMEs today. Please ensure that you ask them the questions you need to support our discussion when we return next week so we can create a recommendation on this. Derek?

Derek De Young

First of all, thanks for the presentation. This is really good information, and I want to just add on a little bit. My question is hopefully a simple one, but I wanted to touch on the last topic a little bit because I do think the implementation of how Electronic Health Record (EHR)s like Epic, Cerner, or you name it, will implement that SPCU that will be the most critical part of this to make sure it is not going to be an additional burden for providers, but it is essentially targeted to the people who need it and for the procedures that need it. I do think that is a solvable problem. Rob, you mentioned you are working with some of the Epic people already, so I think we are thinking through that. I think it is achievable to do that, and I think there will be some defaulting in certain procedures and certain cases where it is not needed.

So, I do not want it to necessarily be the limitation to say we should not move forward with it. It is definitely a solvable problem; it will just take some design work on the Health Infromation Technology (HIT) side. So, I think it is solvable. My hopefully simple question is really around the name of the data element "name to use". I put this in the chat too, but I was doing some Google searches just to verify my hunch, since I talk about it with all of our provider communities in my work for Epic, and from my understanding, the general term that is used in the industry today is usually called "preferred name" for this data element. I am just curious how we came to the name "name to use" instead of "preferred name." Was there a reason behind that in the debate, which I was not in? I am just more curious than anything.

Robert McClure

There was a debate. Honestly, I do not remember all the nuances of it, and Carol probably has a better memory of this than I do, but my memory was that it was concern with regards to having "preferred name" having a more generic use, and therefore potentially not specific to this idea of "I want this name to be used," i.e., that it got merged with legal name and some of the other distinct different names, and therefore there were some concerns about that. Carol, do you remember anything else?

Carol Macumber

No, that is accurate from my recollection. There were a lot of examples given for first and last name. You often see "preferred" going from Robert to Rob. One of the examples was in the military setting. There were also examples where the field "name to use" could be "Col. Roberts," versus "Rob," versus "Robert," where this person has reasons why or will react much differently if they are not addressed by a designated name to use that they provided, and it is not necessarily the same, or at least the community at large, when we were going through this, felt that they were distinct.

Derek De Young

So, from an EHR perspective, would we then be expected… So, you said they are distinct from preferred name and name to use. Would we be expected to collect legal name, name to use, and preferred name, from your perspective?

Robert McClure
I think that what I would expect is that you would support the ability to do that.

Carol Macumber
To distinguish between them.

Robert McClure
I have you and Hans, so we are going to cover two big spaces here, but I think that we sometimes get confused about an expectation that we have on you poor folks who are building systems that are used for implementations, and then, what implementers might do. You have the bigger burden. You need to provide a larger set of possibilities, and this falls into that category. I want to be really clear that we are not saying that everyone needs to collect all of those by any stretch, but we are saying that it is possible.

Sarah DeSilvey
Thank you so much. Again, we are going to come back next week and try to think through this further. I do want to make sure that we honor our SMEs' time and the agenda we have, and I just want to make sure we prioritize any remaining questions before we move on to the rest of the Draft v.5 elements. Hans?

Hans Buitendijk
Thank you. First of all, as others have said, thank you for the updates. I am going to echo Derek's comments around the ability for systems, that they will have to work out and work through the easiest way to put in the information, like sex parameter for clinical use, so it can be default where it can, it can be overwritten and set aside, so I think it is going to work itself out. I have a couple of comments. One is related to Katrina's comment, and I was curious for Rob and Carol's input in that.

When we currently look at the proposed definition of SPCU in USCDI and some of the questions that that would raise, would you indicate that if one were to phrase that SPCU is that it documents the sex to be considered for the performance and interpretation of diagnostic tests and/or procedures would actually make it a little clearer to understand what it is? And then, we can determine where in the flow, on the observation itself, on the procedure, as part of the order, etc., different context that can then come into play, but it is providing the proper context within which to interpret the diagnosis and procedure. Is that an accurate, reasonable interpretation that might help us improve on the clarity and guidance of where to use it and where not to use it?

Robert McClure
Hans, I do not know if you are proposing a different definition.

Hans Buitendijk
Possibly. I am trying to understand the current one in the USCDI and address questions like Katrina, Hannah, Derek, and I have about where I put it in the system. Should I put it under all lab or otherwise? It makes it a little bit hard, so that is why I am trying to figure out if there is a clear way to define that to make

it easier for us to understand where that should land. That is related to the last comment after that that I wanted to make.

Robert McClure

I would have to see the words that you specifically said. It was clear to me that you were using different words. As I mentioned, I am very sensitive to the fact that we have to get people across this gap to get them to stop thinking of gender and sex as the same thing and gender identity being able to serve all needs, etc. I know that you said that it is the sex that should be viewed. I am confident that the lived community that I have worked with would not be happy with us continuing to focus on this word “sex” as something that is demonstrably valuable in the context of taking care of a patient. We really need to get away from that, quite honestly.

One of the things that the next set of projects… It is not actually defined as a separate Gender Harmony Project, but anatomic characteristics, otherwise known as organ inventory, is a better way to think about this. Then, you would not be trying to get a sex. I would rather we not use that. My kind of awkward phrasing of use-specific categorization is very typical for me if you know me. The workgroup will do what the workgroup is going to do, but the reason why that phrase is longer than just the word “sex” is because I am trying to communicate and use this as a way of letting folks understand what they are doing as opposed to keeping them in the same old rut.

Hans Buitendijk

I appreciate that because I actually think your feedback is providing some thoughts on how to possibly blend it together to avoid the concern that he raised, yet make it clearer as to the context where it can be used, so that is very helpful, and along those lines, the last comment I want to make is that the types of names in FHIR C-CDA Version 2 are still not totally aligned, and I think we have a little bit more work to do to help clarify the question, particularly, that Derek and Carol got into on when to support either “usual,” “legal,” “official,” etc. You know the ones that I am getting at. So, I think there is a little bit of work to be done that we should consider as well on helping clarify which one or ones we are actually looking for to be consistent in how they map.

Robert McClure

Just a highlight, and then I would like to get to Rochelle, Hans highlights the question of why it was not called “preferred.” Well, in fact, in each of the specific HL7 product family implementations, they do not use “name to use” or “preferred name” already, so it is already a mishmash. Thanks.

Sarah DeSilvey

Okay, I think we are at time.

Robert McClure

We had Rochelle.

Other Draft USCDI v5 Data Elements & Level 2 Data Elements Recommendations (00:51:08)

Sarah DeSilvey

Thank you so much, Carol and Rob, for coming. We are indebted to the work of Gender Harmony Project and to your expertise today. IS WG friends, we will return next week, further discuss these elements, and craft our definitions and comments in the Google doc, and again, thank you so much, Rob and Carol. We are so grateful. Again, if you have any other questions afterwards, we will make sure we get them answered, and I think it was an important grounding for anyone who has not been part of the Gender Harmony conversations prior. Thank you. All right, I think we are moving on now, just trying to keep things moving, into the review of the sum total Draft USCDI v.5 elements. Next slide.

So, this is a limited list of the draft recommendations that have moved forward with some attempt at finalization. We had a move to draft a recommendation for the lot number for immunizations as well, and there were a couple others that members volunteered, like the test kit identifier, to draft as well, so we have a few different recommendations that are forming in the workgroup discussion element so we can move them forward for the final transmittal letter. Next slide.

When we go into the Draft USCDI v.5 elements, it is important to note that we are still going to hold on discussing any Draft USCDI v.5 element where we have SMEs coming to present. We do have Maria Moen coming on the 27th to discuss advance directives and orders, and then we have a plan for care plan conversation, which is a Level 2 data element. That has not been put on the calendar yet, but we do have the SMEs gathering. We are attempting to get somebody from CMS, and we are also getting representatives from the Multiple Chronic Condition e-Care Plan Initiative. Next slide.

Again, this is where we are in the things that have been touched on, so we are moving well through the list of discussing elements, and we are on target to try to make sure we can create recommendations for the final transmittal letter. We obviously have had the initial SME presentation on pronoun, name to use, and sex parameter for clinical use, and we will come back next week and further discuss them, or we can discuss them now as well. And then, again, we do have those elements on hold that we are looking for SMEs to come present on, and I think we are ready right now to move to the Google doc to further our conversation, and if we have time, maybe we can discuss some of the internal thoughts that we have on the Gender-Harmony-presented elements there. I think Sara Armson is leading us to the Google doc.

Sara Armson
Yes. Let me share my screen. I have zoomed out to help you more, but if this is too small, please let me know.

Sarah DeSilvey
Thank you so much. So, I am thinking that maybe it would be helpful to run through some of the questions. We can either continue talking about the Gender Harmony elements or we can have the workgroup think on them, but I do want to make sure that everyone sees the full list of elements again. Let's start from the top, if we can. We have the emergency department note and the operative note that are going into drafting of possible final recommendation, again, in the workgroup discussion section. Please scroll down a little bit. We have lot number, for which I believe Shelly Spiro has drafted an initial attempt at a final recommendation in the workgroup discussion element as well. We have the test kit unique identifier where, again, as I mentioned, a final recommendation is in process with all the brilliant people who volunteered for that last time. Scroll down. I think we had someone working on route as well from the last meeting. Advance directive is on hold because we are waiting for SMEs there. For sex for clinical use, our SMEs came today.

If we scroll down a little bit more, I want to complete everyone seeing the Draft v.5 elements. So, we have orders, and that is planned for a SME presentation, and then, scroll down again. Name to use and pronouns was our SMEs today. We are thinking about a SME for author. What I am trying to state is that for a lot of the Draft v.5 elements, we are either working on a final recommendation or waiting for SME presentations, so that list is quite narrow. I am wondering if folks want to further discuss the Gender Harmony elements or move into Level 2 elements. What is the discretion of the group? What are we thinking? Do we want to reflect on Gender Harmony elements and come back next week, or do we want to keep the conversation going now? I hear votes for continuing the conversation today. So, IS WG members, how do we want to proceed? Any other votes for continuing on sex parameter for clinical use, pronouns, and name to use? How do we feel about the recommendations for changing the definition for sex parameter for clinical use from the definition that is in the current USCDI Draft v.5 submission? That was the recommendation of the subject matter experts. Hans?

Hans Buitendijk

Just based on the comments that Rob made, if you go to the row on the observation SPCU…I still get confused whether it is up or down. There you go. I did make an adjustment, if you go to Column J. What I put in the chat was drivers, but I was trying to figure out whether blending the two would help clarify that because the focus still seemed to be on interpretation of diagnostic tests and/or procedures that you may need to ask for or indicate at time of order or as you record the observation or procedure to clarify what it was based on, but to avoid the term "sex" and reflect on the other words that were in the original proposal there. I had some challenges interpreting that correctly. I understood the intent in the way that was there, but I could not quite make sure from the reading that I would be landing there, so I wanted to make sure.

Sarah DeSilvey

In the workgroup discussion, we have a few, so if you go to workgroup discussion in Column L and scroll down a bit, you can see the definitions from the original *JAMIA* article. If you scroll down, this is the SME definition that was on the presentation. I copied it from the PowerPoint and put it into the workgroup discussion, just for reference. So, where are we landing? I hear us leaning into the question of whether we should support or suggest altering the definition to more closely align with the objectives of the sex parameter for clinical use purpose, both from what you said, Hans, and what you edited, and then, in the SME's suggestions, and then aligning with the previous article. Mark?

Mark Savage

I think what I am hearing is there are a lot of voices for improving the definition, and so, it is good to say that, and what we are working on now is what those words are. I agree that we should be improving the definition. Looking at what Hans put, from the SME-suggested definition, it is that notion that it is not just a category, but it can be really specific to a use case that ends up being particularly important. Wherever we get to on the words, categorization is not quite yet… And now I am looking at what you put in, Sarah. It is the focus on the sex categorization value. I think the value part and how that can vary with the specific situation or context is important. Thank you.

Sarah DeSilvey

Any thoughts on the SME-suggested definition, given that they reflected on the variance between it and Draft USCDI v.5 prior to the session today? Hans, do you feel like the SME-suggested definition addresses your concerns?

Hans Buitendijk
I think it definitely gets closer. I am still curious what Rob's reaction is. Based on his concern, it was using the term "sex" in the definition, not just in thing.

Sarah DeSilvey
[Inaudible – crosstalk] [01:01:28]

Hans Buitendijk
I am trying to see if there is anything that can be bridged there, or if sex categorization is in line with his feedback as well, and then, that certainly would provide more guidance. I think it is a lot clearer than what was in the USCDI draft.

Sarah DeSilvey
I see Rob and Carol on. Part of being SMEs is helping us to work through these questions, so, can you respond to Hans's question on the role of sex?

Robert McClure
I will jump in first because, unfortunately, I am on two calls now. I am on another CMS-oriented call. What I caught from that is that yes, just saying sex as a way of representing this keeps people in the same mindset as they have historically been in, in my opinion. We want to try and move away from that. The word "sex categorization" is something that I push because the idea of sex is a categorization. It is a summary assessment. There is no M or F observation. I hope everybody really, really gets that because it is so true, and it is going to take a while for people to understand that there is not a sex thing about a person.

That is a summary categorization based on discrete observations, and what we are trying to communicate with SPCU is, in fact, we are trying to align with what the receiver has in their system, where they do use this summary categorization for some use, and we are giving you an interpretation, perhaps only one particular observable piece of information about the patient, and translating that into the typical male or typical female. So, it is really not sex. It is this thing that is specific to SPCU. Hence, the values are not M and F.

Sarah DeSilvey
That is helpful. Hans?

Hans Buitendijk
That is very helpful.

Sarah DeSilvey
Carol, I do not want to step over you. Do you have anything to add? My apologies.

Carol Macumber

This is funny because we are terminologists, and we have a very difficult time trying to say that in any other way as far as "sex categorization" goes. One could contemplate, just reading a use-specific categorization, if including the word "sex" confuses folks as to Rob's point about really getting the fact that it is not an M or an F in that more traditional legacy sense. You could read the definition solely as a use-specific categorization value and not include the word "sex." We would have the glossary and definition folks in our terminology standards world reminding us that using the term from the actual thing you are trying to define in its definition is not typically the best practice, but we have belabored over this definition, and Rob was trying even yesterday to provide a more succinct one than what we have in the most recent specification.

If it were to stand alone, having sex there is useful, but I can see why it might also be confusing, and thus the constant terminology conversation around a succinct definition for this. As you will note in the cross-paradigm IG, it is quite a lengthy description along with a usage note, and what we have done here in the suggested definition is include some of the information from the usage note here.

Sarah DeSilvey

Thank you so much. I am going to keep on making sure that we are getting to a point of clarity here. I hear general consensus for altering the definition. I want to make sure we elevate any implementation and burden questions as well. It seems like we might as well use this time until public comment to dive into this, since our SMEs are here. Hans?

Hans Buitendijk

I just want to follow up. I appreciate and support the updates to use according to the SME-suggested definition, but there is one part that I think might still be helpful in the definition. Suggest that, if this is the direction we go, suggest that it should apply, and the question I would then have is to what would it apply? To observations? To procedures? To what does that apply, so we have a better understanding of to which workflows and areas SPCU is relevant? This definition seems to stand alone from that, making it unclear to what it is supposed to apply. Any additional guidance on that would be helpful to enhance the version.

Sarah DeSilvey

That sounds great. Rob?

Robert McClure

I am listening with one ear, but I got you, Hans. Again, this aligns with the change that went from the Level 2, where we had very use context-specific sets of SPCUs, which was promoted and actually pretty aggressively requested by the community that I was representing when I put in these notes in order to communicate that SPCU is really intended for use in these very specific use contexts. By putting it as a single data element under observations, that gets a little confusing, and Hans is reflecting that, and that was one of the reasons why we very carefully crafted this definition in order to reassert the importance of use-specific.

Again, that tied with the HTI-1 expectations with regards to use of SPCU, where, presumably, people will come back to the guide and learn more about what SPCU really means. I kind of wish that was very

explicitly stated in the regulation. Instead, it just kind of pointed to LOINC, which is problematic, but nonetheless, it does get people on the right path, and therefore, I spent a long time trying to correct the right definition, and I think it actually communicates to people in a way that does allow you to put this generic SPCU under observation, with the expectation that it would be used anywhere.

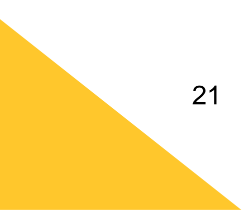
Now, I would be happier, honestly, if you put it under a number of different classifications or classes in USCDI, like we had in Level 2, but one of the things that I think everybody has heard a lot, and which I will reiterate because I believe it is true, is that the intent of ONC is for those classes to be ways of bringing together things for people to look at. They are not intended to be definitional, so those things that are collected under observation are not defined by USCDI as observations, and I hope this workgroup understands that. I hope I am not misrepresenting what ONC expects because it is certainly what I understand. So, that is a nuance that ONC and this workgroup has thrust upon the community, and I am just aligning with it.

Sarah DeSilvey
Thank you, Rob. Again, I am going to step back a bit because we have a little bit of time before we go into public comment, and I want to make sure we are using our time to get to a point where we can start drafting recommendations. There were three elements that were presented by the Gender Harmony experts today. We had name to use, pronoun, and sex parameter for clinical use. How is the workgroup feeling regarding the general statement of the desire to include these elements, even as we work on the definition specifically for sex parameter for clinical use?

Mark Savage
A resounding yes.

Sarah DeSilvey
I want to just elevate some of the burden concerns. Does anyone have any concerns for moving forward with drafting a positive recommendation as we consider things like definition? I am thinking about Derek's comments regarding the difference between preferred name and name to use and some of the either use case or generally applicable considerations for implementation when it comes to sex parameter for clinical use. Certainly, from a clinical perspective, the existence of sex parameter for clinical use will allow those use cases and situations where it is critical for interpretation, safety, and analysis, even before it is applied widely to every single person every single time. Any concerns? It looks like support we can help with is specifics for clarity. We can do that in our final recommendation. Okay, we can also request some of the experts… I see Hannah and Ike.

Steven Eichner
I do not think we are terribly far off. I think there is a little bit more work that we need to do here. One of the things that is a little far afield is to think about how the information may actually be exchanged and what it means as we boil things all the way up from exchanging gender and sex identity for information for things like patient-matching, and in that space, we started to break some of those patterns. We may have some unintended consequences that we need to address, particularly as we are looking at some systems that are certified and some systems that are not. Is a LIMS system going to support a full catalog of sex- or gender-related issues, or is it going to be mainly EHRs, and what are the impacts on that for things like public health reporting?



Sarah DeSilvey
That is important, Ike. Maybe we can make those kinds of caveats in the aligned element final recommendation. Do we feel like the patient-matching concern applies to all three, or more specifically to some and not others?

Steven Eichner
Probably some more than others. I am not sure if many matching algorithms are using preferred name or something in that space. There really is a focus on gender or sex identification. That is a factor that is being used more frequently in matching.

Sarah DeSilvey
We can definitely use our collective wisdom to put that in our draft recommendation. Any other thoughts? Hannah, you have so many good comments. Hannah is asking if legal sex and legal name would still be used for patient-matching. That is a good question. Mark?

Mark Savage
I will just lift something I put in a comment much earlier, which goes to Ike's point. Adding sex parameter for clinical use helps us begin to adjust those algorithms, so this is the important step to be taking. Thanks.

Sarah DeSilvey
Hi, Hannah.

Hannah Galvin
Hi there. This is just my comment in the chat. Our current patient-matching algorithms are based on legal name and legal sex. We are not really addressing any change to a legal sex definition here. These are additional definitions. I think legal sex is already in USCDI, so I think all of the data that we have around patient-matching is based right now on legal name, legal sex, address, and other demographic and very much legal data that we have. I think if we are going to reevaluate patient-matching algorithms based on some of this additional data, that would be a whole additional scope.

To Gavin's point in the chat, maybe the more data for matching, the better, but I am not sure that we have explored the implications of that, and that people may have provided different data to different organizations or different institutions in this regard. They may have provided one gender identity to one organization and another to a different organization. Sex parameter for clinical use, as we see, can be different in different contexts as well. So, is patient-matching in scope for our discussion here, or is that a totally separate discussion, out of scope? I guess that is my question.

Sarah DeSilvey
It looks like Carmela has her hand up. Carmela?

Carmela Couderc

Hi, everybody. I just listened to the last comment and I have seen things in the chat, and I just have a question for the group. I am wondering what legal sex is. I hear that thrown around sometimes, and I am just wondering what that concept is.

Derek De Young
This is Derek. I think the more common thing that we have, at least in Epic, is the concept of sex assigned at birth, but I am interested to hear what other folks think about that as well.

Sarah DeSilvey
It looks like Hannah has her hand up. Is it regarding this conversation?

Hannah Galvin
Yes. I see legal sex as different from sex assigned at birth. Legal sex is not what is on your birth certificate or your driver's license, it is how you are defined legally from a demographic HIM perspective, which may or may not be the same as your sex assigned at birth. If you have legally changed your sex, that may be the same as your sex assigned at birth, or it may not be, and Derek knows that that can result in unreliable sex logic. I was not sure if we were getting into that definition as part of these USCDI elements.

That is a sort of separate element, but from my understanding, typically, what is used for patient-matching algorithms is the legal sex, not the sex assigned at birth, not gender identity, and not SPCU. It is actually legal sex, just like legal name, not preferred name, because that is what is used currently for patient-matching algorithms. That is how my organizations defines legal sex. Now, how is that verified? Is an ID collected every time, is the birth certificate checked, or do you take the patient's word for it? That can be problematic because if I go in and just say I am female, who is checking that in terms of my legal sex? So, that can be questionable, again, from an implementation perspective.

Sarah DeSilvey
Thank you, Hannah. Carol?

Carol Macumber
Sorry, I had to find my mute button, and then I found out I was not actually muted. I am popping an example into the chat, but I would just put a plus one in for Keith's comment in the chat also, but there is specific policy within a state or jurisdiction. We had this discussion around the concept of legal sex and asked many of the folks in the legal realm of informatics if there was a definition we could point to, and there was no universal one that anybody could come up with. There are examples of specific states where a state will refer to something as a legal sex. The one that I just popped into the chat is one that is under discussion in Oregon state law in terms of expanse of student guidance. In the definition of the school systems, they say the legal sex is something that was on your sex designation allowable on Oregon birth certificates and driver's licenses. Now, they do not address here the fact that those can be different. That is their definition for this use case in Oregon for this policy. That is just a comment and example where that phrase of legal sex is not as clear as you would hope it would be.

Sarah DeSilvey

I just want to note that Rob is supporting Carol with some of the comments on the administrative use of the recorded sex or gender in the Gender Harmony IG. We do have only three minutes until public comment. There are a lot of really good conversations that we see that want to represent in our final transmittal letter. I hear general support for the inclusion of these three elements, I hear us wanting to evolve and recommend an evolution of the definition for sex parameter for clinical use, I hear us wanting to center some considerations for the burden of implementation, and I definitely hear us wanting to work on representing recommendations for patient matching. Do we have volunteers to start drafting recommendations in the workgroup discussion column, Column L? There are a lot of details there. Mark?

Mark Savage
Sorry, I do not need to speak. I am just putting my hand up to continue helping here.

Sarah DeSilvey
Fantastic. It sounds like Mark is willing to start trying to get something that we can react to in Column L as a draft recommendation to go in the transmittal letter. I would hope that all the folks who are experts in the different areas will step up to help as well. Are there any other comments on these three elements? Again, thank you to the subject matter experts from Gender Harmony, Rob and Carol. Are there any other thoughts before we go into public comment shortly? Derek is saying, “Just to add what I mentioned, we allow health systems to collect legal sex, sex assigned at birth, and gender identity.” Thanks, Derek. Any other thoughts? Mark, rope us in to help for the draft recommendation. Again, thank you so much, Rob and Carol. These critical elements have been part of our conversation here in IS WG for many years. It is really exciting to see us both move to a Draft USCDI v.5 and to have you come back and help us make sure we get those recommendations correct. Seth, back to you.

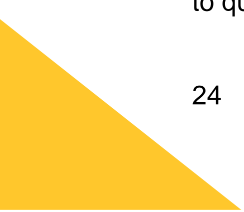
Public Comment (01:22:46)

Seth Pazinski
Thank you, Sarah. So, we are going to move into our public comment portion of the agenda. Accel, please open us up for public comment. Just as a reminder, if you are on the Zoom and would like to make a comment, please use the raise hand function, which is located in the Zoom toolbar at the bottom of your screen, and if you are participating by phone only today, you can press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. We will give folks a minute to queue up. I am not seeing any hands raised in the participants list. Excel, do we have any public comment on the line?

Accel Solutions
There are no comments at this time.

Seth Pazinski
All right, thank you. I am going to pass it back to Sarah and Ike to close us out.

Sarah DeSilvey
Fantastic. Okay, next slide. We are trying to socialize the fact that we are moving toward our finalized transmittal letter at the end of March or beginning of April. We are trying to work on getting some draft recommendations in the workgroup discussion element. We do have subject matter expert Maria Moen coming next week in order to present on advance directives and orders, I believe, and then, we are trying to queue up the care plan conversation. There are a host of other Level 2 data elements. There were



suggestions for SMEs, but we do not have SME recommendations yet, so, just ensure that you are looking at that workgroup discussion element and suggesting SMEs if you have them. We are looking forward to the final recommendations that come before our next meeting in process. Ike, anything else to say?

Steven Eichner
I would like to thank the workgroup members for a really dynamic conversation today, and I would like to thank the presenters for doing a fantastic job, and we are going to start to move forward and are thinking about finalizing these recommendations for the early pieces so we are not facing a mountain of work in the last week and a half. I want to make sure we have lots of opportunities for workgroup members to review the final recommendations.

Sarah DeSilvey
Again, all of us have various blends of expertise, so, once we start a draft recommendation in that workgroup discussion element, we really can pepper in all of our different lenses into that final rec to make sure we leverage all the expertise in the IS WG. Thank you so much. When we come in next meeting, again, we will have a SME, but I really do want to get into some of those Level 2 elements, at least the Level 2 elements that do not currently have a SME listed on them, and we look forward to seeing you again next week. We will see you soon.

Seth Pazinski
Thanks so much.

Adjourn (01:26:22)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Katrina Miller Parrish: Good morning!

Sarah DeSilvey: Good morning!

Katrina Miller Parrish: Nice!

Sarah DeSilvey: Ricky! That is hilarious.

Shay Vaughan: Has the workgroup shared the idea of including the elements of Gender Harmony with X12 & WEDI to include that info in HIPAA/ claims data (since that's being worked on)?

Hannah K. Galvin: SPCU is helpful but needs to be ubiquitous and easily passed through interfaces, for instances between EHR and lab systems. This is where we are seeing most of the patient safety concerns.

Pooja Babbrah: My understanding is that all SDOs (X12, NCPDP, Wedi) were all involved with this work.

Shay Vaughan: great

Pooja Babbrah: Would love Rob or Carol to confirm though

Steven Lane: Yes, @Hannah. This is the value in getting this added to USCDI, as this will drive it into systems, interfaces and ubiquitous use and exchange.

Steven Eichner: Historical information may be needed to support identity matching

Carmela Couderc: Participants in the Gender Harmony Project - https://confluence.hl7.org/display/VOC/Project+participants

Derek De Young: Most people in practice call "name to use" "Preferred Name" in practice. Wondering if there was a specific reason we chose "Name to Use". If not may be good to align with what the industry is calling this today.

Pooja Babbrah: Thank you, Carmela

Sarah DeSilvey: Derek that is a great point to raise in discussion!

Pooja Babbrah: GREAT point, Rob

Steven Lane: Is SPCU exclusively specified and attached to a specific order/result/interaction, or is this data maintained over time at the patient level where it could be attached and used routinely? If the latter, would HIT systems typically default Female-typical and Male-typical based on birth sex?

Sarah DeSilvey: Thank you, Rob. This is an important point!

Hans Buitendijk: A clarification on Name to Use. CDA (global reach) has guidance, but that has not yet been included in C-CDA (e.g., C-CDA E1 in progress supporting USCDI v4) does not include it yet). However, not a big step as the guidance to include is clear.

Grace Cordovano: Thank you for this presentation. Would love to know if there is a blog or publication you could point us to that summarizes this work to share with our communities and networks.

Pooja Babbrah: +1 grace

Shelly Spiro: Thanks for the presentation Rob.

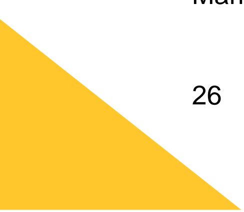
Mark Savage: Thanks so much, Rob and Carol! So much critical work over the years behind this.

Mark Savage: ISWG shows the love! <3

Hans Buitendijk: HL7 v2, use for placing most orders, enables attaching SPCU to an order the the initial flow. The approach is changing from V2.9 to V2.9.1, but the ability has been there.

Sarah DeSilvey: @grace and @pooja https://academic.oup.com/jamia/article/29/2/354/6382238?login=false

Mark Savage: @Rochelle, perhaps adding this data element is exactly what begins to help correct that?



Hannah K. Galvin: I understand the theory behind context-specific SPCU but also think this may be difficult to implement from a usability perspective, especially with consideration of provider administrative burden. How has the group considered this?

Grace Cordovano: @Sarah, thank you. So helpful!

Grace Cordovano: It is critically important for patients and families to understand all these distinctions and the nuances of how sex is used clinically so they too may be able to best self-advocate.

Hannah K. Galvin: +1 Grace

Mark Savage: @Hannah, isn't clinical care always working with granularity at implementation--just time to do so here as well? Context-specific is normal.

Steven Lane: Clem is not here to say this, but we do have to think about the potential for this addition to USCDI and HIT systems could substantially increase provider burden as orders are placed.

Steven Lane: The HIT systems will need to develop UI/UX that makes it easy to do the right thing every time without adding burden to every order.

Hannah K. Galvin: @Mark - agreed, but I do think clinicians and others are used to dealing with sex and gender at the patient level; moving to context-specific is a transition, and one that requires additional consideration. For instance, if I order a lab test with sex-specific reference ranges, so need to provide SPCU when ordering that specific lab test, this is important to understand. As much as this can be moved to the patient would be ideal, though some of this may need to be done in collaboration with their provider. I think the level of granularity at which this would be specified would need to be considered from a usability perspective.

Hannah K. Galvin: @Derek - glad to hear it - and I imagine it is solvable - just wanted to call it out that it will take some thought.

Steven Lane: While I agree that individuals should have full ability to see the SPCU specified for a given event, it does not make sense to me that individuals should typically be specifying this, but rather that this is the responsibility of the ordering clinician, ideally in consultation with the patient at the time of ordering when appropriate.

Steven Lane: @SteveE, it seems that maintaining this data in unique/specified data fields will mitigate any risk to patient matching, and perhaps even provide additional data that could (rarely) be used to support accurate matching.

Hannah K. Galvin: I agree with Steven Lane that this would often need a clinician's expertise.

Mark Savage: USCDI is about capability. Does not require use per se, but makes it available for everyone to use.

Pooja Babbrah: +1 Mark

Hans Buitendijk: Agreed with Carol, but more clarity is needed as the value sets across standards are at least ambiguous as to overlap.

Sarah DeSilvey: Perhaps “name to use” could be a qualifier on either of the existing name concepts? given it is a statement on criticality?

Katrina Miller Parrish: To make it more practical and efficient!

Mark Savage: @Hans, are you preferring what you said as definition to what SMEs put in deck as suggestion?

Rochelle Prosser: +1 Sarah but will that cause confusion on other documents already published?

Hans Buitendijk: "Suggest to clarify the definition that it documents the sex to be considered for the performance and interpretation of diagnostic tests and/or procedures."

Sarah DeSilvey: yes hans, this is in line with the definition in SME presentation. we will pull these into the google doc for ISWG discussion.

Mark Savage: Gender Harmony SMEs also included specified and unknown, which are more than sex to be considered, but a particular range/reference.

Hans Buitendijk: Based on Rob's comment I can see a blend of both to avoid the concern he raised.

Sarah DeSilvey: I have the jamia article and the definitions from the article in the comment section. we will integrate the same definition there.

Mark Savage: Big thanks! For today, and all the years!

Rochelle Prosser: Rob you hit my statement right at the end in that we have moved away form wither choice.

Kikelomo Oshunkentan: Gender Harmony

Hans Buitendijk: I'm hearing from Rob that using the term "sex" is challenging as well.

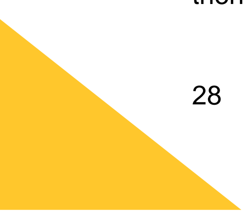
Mark Savage: Yes, "use-specific sex categorization value"

Rochelle Prosser: I was just wanting to know if SPCU and LOINC under Gender could be combined?

Rochelle Prosser: I really think they are related.

Hans Buitendijk: USCDI v5 is post HTI-1, so has an opportunity to make that more clear. "Anywhere" is very broad thus unclear what the next step of focus is. Applying to Observation is a good start. But that should be made clear.

Hans Buitendijk: Leaving it open in USCDI then shifts the discussion to FHIR US Core 8.0.0 next year and then we have a gap in interpreting USCDI vs. FHIR US Core / C-CDA.



Grace Cordovano: Fully support inclusion

Hannah K. Galvin: Support. I do echo Derek's comments re: preferred name as the commonly used term.

Katrina Miller Parrish: Support, we can just perhaps help with specifics for clarity

Keith E. Campbell: Also support...

Rochelle Prosser: 100% Yes, we can clarify as definition later...with some concerns of course.

Hannah K. Galvin: Would legal sex and legal name still be used for patient matching?

Katherine Lusk: I see these elements in addition to Legal Sex and Legal Name for patient matching. The more data the better for matching.

Steven Lane: +1 @Katherine

Katherine Lusk: Legal Sex is as defined on the birth certificate

Keith E. Campbell: I think legal sex varies state by state...

Grace Cordovano: @Hannah, I would see these elements supporting/enhancing patient matching, especially for Individual Access Services (IAS) via TEFCA.

Keith E. Campbell: Different states allow different things to be put on the birth certificate, and I believe some states allow changing of official birth certificate.

Rochelle Prosser: +1 Keith

Rochelle Prosser: We need a source of truth.. Is that what I am hearing Hanna?

Sarah DeSilvey: we have 5 minutes until public comment

Keith E. Campbell: https://www.peoples-law.org/changing-sex-listed-your-maryland-birth-certificate

Rita Torkzadeh: Does HTI-1 define legal sex?

Rob McClure: The phrase “Sex” is usually on documents like passport, driver license. What that means is unclear but it -can_ be used to matching. Given that it is unclear what it means _for the patient_ it would be considered a “Recorded Sex or Gender” by GHP which is just a “templated bucket” to categorize non-GI/SPCU values

Carmela Couderc: HTI-1 does not define legal sex.

Hannah K. Galvin: @Rochelle yes - I think there are different definitions and then different ways that that these are actually being implemented. For instance, even if we have a definition of legal sex as the sex on your birth certificate or drivers license - organizations may or may not actually CHECK the birth certificate or drivers license in order to populate this field. If they do not, are they getting accurate "legal sex" data in

this field or are patients really providing something closer to their SPCU or even gender identity? All of this is very implementation-dependent.

Derek De Young: Just to add to what I mentioned - we allow health systems to collect Legal Sex, Sex assigned at Birth, and Gender Identity.

Rob McClure: So instead of “legal” sex - perhaps driver license sex or passport sex would be best

Hannah K. Galvin: @Rob - that makes sense if someone has a DL or passpord.

Hannah K. Galvin: passport

Rochelle Prosser: @Hanna I would concur form a Legal Nurse Consultant perspective that there are many definitions and remedy's to address legal Sex.

Katrina Miller Parrish: Maybe we need to add "Legal" Sex and Name to USCDI proposed elements. Not sure Recorded Sex or Gender does that.

Mark Savage: @Katrina, even if we thought it worth adding (not sure that's the case, though): because "Legal Sex" is not a proposed data element in ONDEC, not available at this time, as I understand it.

Katrina Miller Parrish: @Mark, understood. Fodder for discussion.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

[IS WG Webpage]
[IS WG - February 20, 2024, Meeting Webpage]

Transcript approved by Wendy Noboa, HITAC DFO, on 2/28/2024.