HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS WORKGROUP MEETING
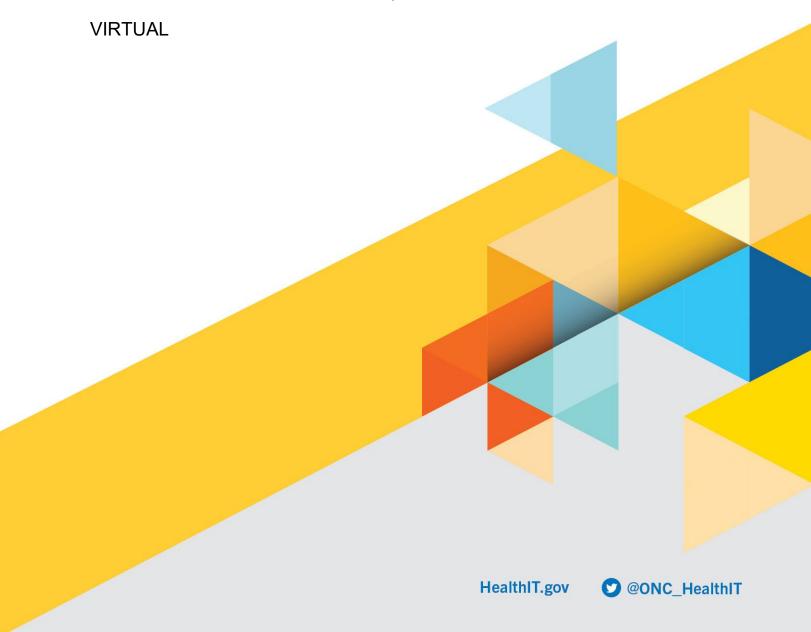
March 17, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Sutter Health**	**Co-Chair**
Arien Malec	**Change Healthcare**	**Co-Chair**
Kelly Aldrich	Vanderbilt University School of Nursing	Member
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Cerner	Member
Thomas Cantilina	Department of Defense	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Steven Eichner	Texas Department of State Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
David McCallie	Individual	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	Baptist Health	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards and Technology	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	ONC Staff Lead

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

Michael Berry
And hello, everyone, and thank you for joining the Interoperability Standards Workgroup. I just want to remind everybody your feedback is always welcome throughout the meeting, which can be typed in the chat feature or can be made verbally during the public comment period that is scheduled at about 11:55 Eastern Time this morning. I am going to begin roll call of our workgroup members, so when I call your name, please indicate your presence. I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Kelly Aldrich? Medell Briggs-Malonson? Hans Buitendijk? Thomas Cantilina? Christina Caraballo? Grace Cordovano? Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Sanjeev Tandon?

Sanjeev Tandon
Good morning.

Michael Berry
Raj Godavarthi? Jim Jirjis? Ken Kawamoto?

Kensaku Kawamoto
Good morning.

Michael Berry
Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
David McCallie?

David McCallie
Hello.

Michael Berry
Clem McDonald? Aaron Miri? Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Abby Sears?

Abby Sears
Good morning.

Michael Berry
And, Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Good morning, everyone. Now, please join me in welcoming Steven and Arien for their opening remarks.

Workgroup Work Plan (00:01:53)

Steven Lane
As always, thank you, everyone, for getting up and getting going wherever it is that you are and joining us today. I know that for some of the people who are not here with us, it is because they are fully engaged to HIMSS, which is a good thing for them, but we will adapt our plans for today's discussions accordingly based on who is here. I know Christina is caught up. For those who did not hear, she is the new VP of Informatics at HIMSS, which is very exciting, and Hans has been very busy. He told us he would not be able to join us this time, as he was unable to last time, so we will make the most of what we have here today.

You are looking at the agenda, and we are going to jump in where we left off and try to work through some more specific recommendations as possible, remembering that our time is short. We have reached out to a number of folks, including Hans, Clem, and others, and asked them to come specifically to represent their recommendations, so, Dr. Hung Luu in particular is going to give us a straight-up focus early on regarding

laboratory interoperability and the opportunities that he sees there. We are then going to turn back to Mark to do a little bit of cleanup on some of the issues that we had left open last time, and then talk a bit about provenance author as a potential data element for consideration, and then also, as we said, clean up some of the other open issues related to health status and assessments, as we have been discussing. Arien, do you want to add to that?

Arien Malec
Let's get into it.

IS WG Draft USCDI v3 Member Recommendations (00:03:45)

Steven Lane
Jump right in, all right. And, just as a verbal reminder to members of the public who are joining us today, we do encourage your participation. You can do that through the chat, as well as at the last five minutes of our scheduled time, we will have verbal public comment and invite you to participate there as well.

So, Dr. Hung Luu, thank you. You are a relatively new member of our workgroup, and you have been making some really great suggestions regarding your area of expertise. You provided some slides regarding laboratory data class for specific data elements within that class that you wanted to comment on. You have entered that, as we invited you to, into the spreadsheet, so why don't you walk us through the changes that you are recommending and the reasons for them? And also, Al, if we can pull up the rows in the spreadsheet as we go so we can make appropriate edits, that would be wonderful, and as you are doing that, I will say that Al made some additional changes to the spreadsheet specifically. We added entry numbers, because you will recall last time, we had a little bit of a challenge with things being inserted or sorted, so rather than going by the line numbers, we are going to go by entry numbers, which are distinct, so, FYI on that. Arien?

Arien Malec
Before we dive into Dr. Luu's recommendations here, maybe a request to Al. Lab tests and results occupy the same position in USCDI as medications, where there is an absurdly complicated meatball, one might say, under a very simple heading. So, in medications, we say medications coded by RxNorm, in laboratory, we say values/results, and then, I do not even know that we say encoded by LOINC and UCUM, but again, we have this very, very complicated structure in lab, so I think we say overall, lab is tests with applicable vocabulary standard of LOINC.

For values and results, I do not think we mentioned SNOMED, specimen times, and result status, so we have a very simple conceptual structure, and as everybody knows who has dealt with laboratory results, tests, analytes, and the whole complex beast, there is a ridiculous amount of complexity here, and I have the same question before we dive in and start adding elements to the lab category as I did when we started contemplating elements to the medication category, just a philosophical question relating to USCDI and how it measures or how it manages these very complex objects as, effectively, one-liners.

Steven Lane
Arien, I think that is a really important orienting question, and I think that labs are quite different than meds, right? In the med space, for those of you who have been with us, we were talking about what all the data elements were that would be required to meaningfully display a current medication list in a way that would make a difference to patients, providers, and other stakeholders. With labs, we have struggled mightily with

discrete lab integration and exchange, and we know the difference between being able to simply view a lab result from another organization versus being able to integrate it into our system and the levels of integration that that might entail.

So, I think the issues are similar, but different enough that we should not say because we made this decision about meds, we should necessarily make a similar decision about labs. I think there probably are some substantial marginal benefits that could be gained in lab data interoperability as we add on additional data elements within that class, so that would just be my perspective, and I think we have some folks participating in the chat already who are weighing in on that as well, but I think it is a really good point.

Arien Malec
I just would love Al's comment on the philosophy of USCDI from an ONC perspective when it comes to these really complicated, hairy beasts on what level of specificity we should and want to go down to. Is Al on?

Al Taylor
I am. Can you hear me?

Arien Malec
Got it.

Al Taylor
Just in general, clearly, from Arien, ONC is aware of the potential complexity or the real complexity of each of these data classes, and the decisions about how much detail and how much complexity to add to a core set of data required by EHRs is something that we revisit with each version of USCDI, with each versioning cycle, and where we have landed in the last three cycles is where we have stayed, for the most part. There are some exceptions. We have significantly expanded on other data classes, but that was to meet a specific need that was addressed by the submissions. So, not to say that we could not expand, just that we have considered it and have not in those examples.

Steven Lane
All right. Hung?

Hung S. Luu
All right. Can I have the first slide, please? First, I would like to thank the cochairs for this opportunity to present on my rationale for including the above data elements into the USCDI Version 3. My rationale comes from both personal experience and also my continuing work with the FDA SHIELD initiative, which is a public and private initiative to promote laboratory interoperability. Next slide, please.

So, I would like to begin by highlighting some personal experience. In the early days of COVID especially, at our institution, there was a need to preserve personal protective equipment and to protect our hospital personnel in terms of being able to keep them safe while, at the same time, trying to safeguard limited resources such as N95 masks. And so, what we came up with is a complex system of alerts and decision support in order to inform the providers as to what level of personal protective equipment they should wear when interacting with patients. Especially for admission and also for surgeries, we required testing for

COVID, and then, the results determined algorithm and determined what level of precautions they needed to take.

And, early on, one of the requests clinicians had of me is that they wanted to be able to accommodate patients coming from far distances by being able to integrate results from outlying sites into our EHR so that the results could be used to clear patients for surgery and admission, and also to trigger the appropriate decision support and what have you, if they were performed within three days of either surgery or admission. And so, the way we accomplished that is there is existing functionality to be able to map these results into our EHR. Once they are fully mapped, they are indistinguishable from locally produced results, and will perform in the exact same way as locally performed results in terms of triggering the appropriate alerts and decision support. Next slide, please.

So, this is an example of the result that I would work with in order to try and determine if it should be fully mapped into our system. A result like this makes my life easier because No. 1, I know the specimen source and I know the platform that it was performed on because in this case, that is included in the comment. Without this information, I really could not determine if the test was comparable to what was locally performed. That was extremely important to our providers and staff, that any result that was mapped from an external source needed to be equivalent to what we were using for admission and surgical clearance.

And so, for me, a result like this is a godsend due to the fact that I know that a nasopharynx has the appropriate sensitivity versus if this was an anterior nares, or a saliva, or oropharyngeal sample, which would be unacceptable to our infectious disease team for clearance. In addition, I know the platform and know that this is a system that we ourselves use, so this is definitely equivalent to what we are performing in-house. And so, once it is clear, not only does it appear in the result view, but we also put this banner at the top so that anybody who is viewing the results knows that this is equivalent to what we performed internally. Next slide, please.

So, unfortunately, only about 20% of results looked like the previous sample. This is what 80% of results look like, and so, there is minimal information here. As a matter of fact, I cannot even tell from the test name if this is actually a molecular PCR test or if this is actually an antigen test, and so, this would be extremely problematic to try and map. In addition, I do not know the specimen, so I do not know if this was a saliva or anterior nares, and so, this would be very difficult. If I make a mistake, that means that a child could potentially not have a necessary surgery because of an exposure to the anesthesiologist or a surgeon, and so, obviously, this is a duty that I do not take lightly, and so, unfortunately, I had to reject about 80% of external results du to the fact that they did not contain adequate information for me to determine equivalence.

In addition, the results were often problematic, not for us, but potentially for public health areas, due to the fact that organizations represented the results in varying ways for qualitative results. So, here, we have "negative" for a negative result, and in the previous example, we had "not detected." So, if you are a human being looking at one result, we have it in two different senses of what represents positive and what represents negative. So, "negative," "not detected," or "nonreactive" are going to pose little issue for us.

But, imagine if you are public health lab and you are receiving thousands, if not millions, of results from different organizations and they have elected to use different terms for representing the results. That can

be very problematic. You either have to invest in human beings sorting through the results to determine what constitutes a positive and a negative result, or you have to develop complex translation tables and take into account all the possible permutations for these results and then map them to either a positive or a negative result. We can solve this issue up front if we map these results to a standardized ontology, such as SNOMED CT. Next slide, please.

So, I am going to switch gears and talk about quantitative results. And so, what I am showing here is actually data from proficiency testing. So, as part of the Clinical Laboratory Improvement Act of 1988, all laboratories, if they perform non-wave testing, have to enroll in a proficiency testing program. So, what that is is about two to three times a year, a manufacturer of proficiency testing samples will send known quantities of an analyte to different laboratories, and have them perform it on their tests, and report it back to the proficiency testing provider. And then, the proficiency testing provider would then grade the laboratory against their peer group, which is the same group of laboratories that use the same instrumentation.

The reason we have to divide them into different peer groups performing on the same instrumentation is that even though these are aliquots off of the same sample with the same quantity of analyte in them, the results that are produced from the different platforms can be radically different, and this can be accounted for in terms of the units of measure, but what I am highlighting here is that even within the same group that are using the same unit of measure, we are seeing radically different, and so, the exact same sample is producing a result of 0.771 in one peer group and 2.109 in a different peer group, and the reason for this is there is variation in instrumentation, and that has to be accounted for, and so, therefore, this is the reason that we break it up this way. Next slide, please.

So, what I am showing next here is the LOINC code for fibrin D-dimer with a fibrin equivalent unit in platelet-poor plasma by immunoassay. And so, this is the LOINC code for this particular class of test. And so, all the tests below would qualify for use of this LOINC code and would be appropriately mapped to this LOINC code, but again, if you look at it, I would argue that these are not all the same tests. For one, we have two different units of measure that fall under the same LOINC code, and even within the different units, there are variations in the results. And so, using the LOINC code to determine equivalency would not be appropriate for this class.

And, in addition, that is why I am suggesting that we need to include instrumentation and kit information in the USCDI Version 3 in order to provide laboratories with the data they need to determine equivalency, and also, we have to consider downstream uses for laboratory data also. Currently, a lot of the instrumentation at my institution, which is a children's hospital, would be considered off-label use by the FDA because they were not FDA-cleared in children, and the reason for that is that children are a protected population, and in some cases, the manufacturers have chosen not to submit the data required to get it cleared in the pediatric population, not because it would not work in that population, but because that is an added expense.

And so, one movement that the FDA is using is to move towards use of real-world evidence in order to be able to perform post-market surveillance and also to potentially expand initial indications to other populations that may not have been evaluated in the initial clearance. And so, this, to me, is a health equity issue, and also, for post-market surveillance, you have to be able to know what instrumentation you are comparing to in order to make any kind of assessment. And so, the test kit information is essential. Next slide.

So, this also has ramifications for clinical interoperability due to the fact that again, clinicians would like to be able to compare results and be able to have a complete history of the patient's lab testing, no matter where the testing is performed, and so, we do try to map externally generated results into the EHR for the patient, and this is the view that most clinicians will use. This is called a result view for a particular vendor, but the beauty of it is that you can consume a lot of information in one screen, and you can trend and see results as they change over time. The downside of this is that there is limited real state, and so, obviously, you have to suppress some essential information, such as, potentially, reference range and other information, such as the fact that it was performed at a different laboratory. Next slide, please.

The practical implications of that are that if I make a mistake and map an external result based solely on the LOINC code without knowing the limitations of that, and without knowing the kit and instrument information, I could inadvertently map the result from an external lab that produces radically different results onto the same line as my locally produced D-dimer. In this case, the D-dimer is used to determine the likelihood of the patient having venous thrombosis. The implications of a high or a positive result above the break point is that the patient could undergo additional imaging to determine the source of the venous thrombosis, and they could undergo additional laboratory testing to determine, and they could undergo prophylactic treatment with heparin to try and stop the clot.

So, this should be of interest to CMS because if this mistake is made, the patient could undergo unnecessary testing, and unnecessary treatment, and unnecessary imaging for a clot that potentially does not exist, and so, as a laboratorian, I am deathly afraid of making this mistake, and I know other institutions are as well. And so, I know Dr. Raj Dash is in the audience, and at his institution of Duke University, he has informed me that they have a committee of four commissions and laboratorians that spend hours on each analyte they plan to map into their EHR, and the reason they have to do this is because the information is limited, and they have to thoroughly vet each one to make sure that they gather adequate data, including contacting the original institution that produced the result to determine what platform it was performed on, and in order to make sure that this mistake does not happen, along with all the potential implications for that.

Steven Lane
Well, thank you, Hung. That was very helpful. Do you have any more slides to go through?

Hung S. Luu
We can go to the last slide. And so, what I am proposing is that in order to make clinical interoperability available to everyone, information needs to be available to the laboratory, and that includes not just the name of the test, but also information on the specimen, source, and type, also the instrument platform, and the same test kit. I want to use the analogy of building a house. So, we are told that if you want to move a light socket, it is very easy in the design phase, but once the structure is up and everything is in place, moving a light socket a few inches to the left is a monumental task.

And so, what I am proposing is that this committee is involved in the design phase of clinical interoperability. USCDI is central to that. And so, none of what I have proposed cannot be fixed on the back end, it just involves a lot of money, and also, I do not know how many community hospitals would have the resources of an academic medical center in order to make sure that the results are adequately vetted. And so, what

they are going to do is either they are not going to map these results or they are going to do the best they can with the information they have and potentially make mistakes and produce patient harm, neither of which are acceptable outcomes to me. Thank you very much for your attention.

Steven Lane
Thank you so much. Arien, do you want to comment?

Arien Malec
I do. Again, I am very publicly struggling with what to do here, and it seems to me that it is hard to add test kit to USCDI test result when we do not have, for example, reference range as a data element under test result. That is conceptually where I am. We do not actually have the numeric or qualitative result in test result, so if I take USCDI at face value as an ontology of data, all I have is that a test was resulted with this LOINC code. If I interpret USCDI to be shorthand for an underlying ontology, then where I think we want to go is more specify the underlying ontology rather than adding specific data fields or data elements.

One of the other commentators pointed out that CLIA has not quite an ontology, but a specific implied data set that is required for validation. The direction that, in my head, we should be going is to point USCDI to the underlying ontologies or underlying representational things that define what a result is with respect to clinical interpretation for interoperability that defines the constraints under which a test result should be communicated for the purposes of interoperability, and I would prefer to go in that direction rather than go in the direction of specifically adding, for example, test kit when, as I noted, we do not actually have the numeric test result or have the reference range associated.

Steven Lane
Thanks, Arien. I want to put a time bound around this discussion because we could easily spend the entire meeting on this. I would challenge the notion that we do not have the actual result because we do have values results as a data element already in USCDI V.2, and you mentioned the absence of reference range, and as far as I can tell, I do not see that at all in the USCDI as a submitted data element, which is interesting. I put my thoughts in the public chat, so I will not spend a lot of time reiterating them. I am going to ask Clem and Ike to comment, and then I am actually going to recommend we close discussion on this topic, move on, and come back to pick it up again next week. Clem? You are on mute. We can see it from our end.

Clem McDonald
It is tough to get these items into the processes, but I would like to ask a specific question. So, the LOINC codes with the cooperative activity by the FDA, CDC, and the industry, every COVID test, as it became accepted, was put into a structure called LIVD and publicized within three or four days of their availability, and they had specimen in them when the vendors, manufacturers, and CDC agreed on that, so I am just curious as to why it was not helpful to the process that you were working on. And, the other thing is when you talk about the D-dimer, were you distinguishing the DDU from the FEU units? Because they are different tests, and clearly will be way different.

Hung S. Luu
Yes. I was on the slide of the LOINC. All of those were FEUs, and so, I do not include the D-dimer units in there. And, Clem, in the June 4th Department of Health and Human Resources requirements, yes, they did include specimen information, but they also included a unique device and kit identifier, and there was

pushback from the laboratories about this, not because we disagreed with their inclusion, but because we knew that there was insufficient functionality in the LIS and EHR systems to capture and transmit this information. So, this was information that was considered vital by the Department of Health and Human Services, but laboratories could not capture it and could not transmit it to public health labs, and so, that is an issue. So, I do not think that we can afford to wait on this due to the fact that we have government requirements to include things that are not currently supported by our current technological ecosystem.

Clem McDonald
Okay, thank you.

Steven Lane
Ike? Last comment on this, and then we are going to move on.

Steven Eichner
Thank you. I will be as brief as I possibly can be. First, I think we probably need to reexamine or re-reconcile laboratory results from labs to hospitals in laboratory reporting from laboratories to public health because things like test kits are included in the standards for reporting laboratory results to public health, and if there is a miss there or a disconnect, that is something that we can probably relatively easily address because it is definitely a requirement on the other side. The second component of that one is looking at the relationship or any relationship between USCDI and what might be USCDI Prime, USCDI Plus, or whatever it is going to be labeled down the line. I want to parking-lot that issue, but I think it does relate as to what USCDI Plus ends up looking at as to whether it is use cases or something else. I think there are some opportunities that have not been well explored in that space to have great alignment between the USCDI and whatever the other thing is, and not create a bunch of confusion about if a data element is in the USCDI and/or the Prime. As we approach that and need to resolve it, I am happy to work on it.

And, the other component of that was looking at routing data and including things and expectations on laboratories as potential middle entities in providing care services. We do need to be cognizant of what additional burden we are creating on the labs for data that they cannot really use for any particular purpose. It does not really make a difference to the laboratory, in most cases, if I went to Aruba last week in terms of their processing, the test sample, from a pure business end of it, but we find they have to spend a lot of effort in modifying their LIMS to include that information because they are serving as a passthrough entity to get that data to the next step. And again, it is a parking lot issue. Are there better ways of doing that, maybe leveraging HIEs or rerouting those laboratory orders so we are not ending up with what is effectively orphaned data or data that is irrelevant to somebody that is receiving it?

Steven Lane
Thank you, Ike. I really want to thank the subject matter experts who have taken the time to submit public chat comments. We will include all of those in the notes from this meeting. We will try to turn those notes around as quickly as possible and get them out to folks before the weekend, hopefully, so that you can review those in anticipation of our further discussion of this next Tuesday. I want to point out that ONC did include two additional data elements in draft USCDI V.3 in this laboratory category. V.2 includes just test and values results; draft V.3 also includes specimen type and result status. The specific recommendation here is to take a couple of additional data elements from the Level 2 for laboratory, and also bring them forward into V.3, and I think our relatively simple and bounded challenge is to identify which additional data

elements that have been leveled at Level 2 warrant being brought forward into USCDI Version 3. With that, Arien, do you want to add anything before we move on?

Arien Malec

No, I think the comment that I put in the chat really covers it.

Steven Lane

Terrific. Again, we will try to get all the chat comments copied and out to everyone for review, and thank you all for your participation. Thank you, Dr. Luu. All right, the next areas we are going to turn to are all things that Mark Savage has spent a lot of time thinking about, and I have asked him to tee them up. Mark, I am sure you have an order in mind, but we are going to try to look at health status, sex and gender, health insurance, and provenance author, I believe. If we can get through as many of those as possible, that would be great. How would you like to proceed? It looks like author is what is on the slide deck.

Mark Savage

Sure, I can go in whatever order you would like.

Steven Lane

I know you have given it a lot of thought, so you tell us what entry item you want to start on.

Mark Savage

Why don't we start with 53? I will pick up on your comment at the beginning of this hour that there was a little bit of cleanup. We covered sex assigned at birth last time, but on Row 53, there was also a recommendation that Abby and I put forward and Arien supported as well about the Gender Harmony Project's proposal.

So, on Entry 53, we are strongly recommending alignment with the Gender Harmony Project framework and the five data elements, gender identity, sex for clinical use, recorded sex or gender, name to use, pronouns, and the value sets, which work together collectively to represent sex and gender diversity for better care and outcomes for gender-marginalized people. There is a slight tweak on the Gender Harmony Project's presentation to us on February 8th around gender identity. You will see in Row 53 that with the four elements listed under Gender Harmony Project gender identity, we are recommending keeping two additional ones from USCDI. Additional gender categories are "other/please specify" and "choose not to disclose." And, I have been in consultation with folks at the Gender Harmony Project and looked at some of the drafts on their website, and they, too, are drafting a proposal that would do just this, that would keep these two additional items from USCDI for the six collectively.

Lastly, as the Gender Harmony Project recommended, we would recommend that gender identity be in the patient demographics data class, name to use and pronouns there as well. Sex for clinical use and recorded sex or gender might be clinical values as well, so, as Arien tees up a little bit with the provenance and author item to come, we recommend that we track the source of the value and the method of capturing it. So, with that as a broad summary, maybe I should pause in the interests of time.

Steven Lane

Al, can you get us over to Column…okay, good, you can. So, if there is any way for people to scroll down to the bottom part of that column, which is tough because there is a lot of text there, so it is not displaying well. Let me do this. I am going to temporarily cut out the stuff that we have talked about before, and now we can see what it is that Mark is talking about, and I will put it back when we are done. So, the recommendations then, Mark, just to be clear… Say it again. Say specifically what you would like to add to the recommendation.

Mark Savage
Align with the Gender Harmony Project's proposal that we saw on February 8th, which were the four that you have now cut out, which is fine, but to keep from USCDI V.2 the two additional ones that are in gender identity in USCDI V.2, and, as I mentioned, I understand that the Gender Harmony Project, in work since February 8th, is drafting up the same recommendation anyway. But, that is not a guarantee, that is just my understanding.

Steven Lane
Any comments, questions, or objections to that suggestion?

Arien Malec
Help me understand. Did you add in sex for clinical use post this recommendation? Because I believe that right now, USCDI is teed up to better specify gender identity and sex assigned at birth, and that sex for clinical use should be a future element that we would want to contemplate, but we do not have the runway to add sex for clinical use.

Mark Savage
So, to your first question, Arien, yes, this recommendation has always mentioned the five data elements that are at the beginning. It does not change your second question. I did some checking around. This is not my primary area of expertise, but I do find LOINC codes and work on the HL7 FHIR specification for sex for clinical use, also for recorded sex or gender. Those are also outlined in the two articles that are linked there from the Gender Harmony Project under the justification for recommendation that has been there for a while. Others may have something to add on that, but I did poke around and did find that work. I can drop some of that in the chat, if you wish.

Arien Malec
I do not know that we have any interoperability on the ground that is appropriately… Again, Al, correct me, but this recommendation from Gender Harmony is also the same recommendation that came from the federal report that we were looking at previously, the notion that we should be treating biological sex only in context of the clinical decision that is being made is a consistent recommendation. This is an area where I think we are going to need to do work on the ground before we are able to contemplate. First of all, I do not know that sex for clinical use can be in USCDI because sex for clinical use almost definitionally has to be an interoperability-specific data element because it is not a thing, it is something that is specific to, for example, a radiological exam or specific to a lab result, and for many people, it may be the same thing, but for some people, it may need to be tailored and specific for the specific procedure, test, etc. that wants to be performed, and so, it may be malleable and context-specific.

Mark Savage

That was what we heard from the Gender Harmony Project, and I think the framework that they gave us envisions that the codes would be used, and actually, the values might be different for a test or a procedure, but the coding was there. Thank you.

Steven Lane
Okay. So, are we ready to accept this? It will need to be reworded, and we are not going to try to do the wordsmithing here in real time, as a workgroup decision that will turn into a recommendation to the HITAC. Does anybody object to that based on this discussion? All right. So, we have a decision to accept and include, and we will work on the wordsmithing for that between now and the next meeting. Mark, where do you want to go from here?

Mark Savage
Thanks very much. Let's go to provenance then, please, which is 65, if memory serves.

Steven Lane
Provenance for 100?

Mark Savage
No, I am going to go for 200, please. So, this is a Level 2 data element, and provenance is a data class. Author is the data element, and we are recommending that that data element be added to USCDI V.3. We have already had discussions in this workgroup about the importance of this element for self-reported data that is critical, race/ethnicity, gender identity, disability status, pregnancy status, all proposed for V.3, and capturing the difference whether this is a self-reported value, which is important for some federal standards, especially race and ethnicity, or whether it is a clinical value, or even whether it is another source. In a meeting a while ago, I mentioned my own investigation, which found that sometimes, you could have a race/ethnicity value that had been self-reported or clinically observed, but overwritten by a batch file, so, keeping track of that provenance is really important, and really important for health equity here to know how the person self-identifies.

There are also some examples of Level 2 data elements that show how important this could be. Family health history, the thing that we all fill out in the room, problem, the date of onset, allergies, travel information, for example, COVID and Zika. So, I have listed some V.3 elements, some Level 2 data elements that, at the very least, would be really helpful to have this Level 2 provenance author data element, and that would be my recommendation, that we raise author up to USCDI V.3 for those reasons. I will just add that the Social Security Administration, which was the one that submitted it, gave a pretty compelling example of how 3 million disability applicants really needed this result, too. Thank you.

Steven Lane
So, the suggestion is to add author. If you will look down at the bottom of the justification, actually, that last sentence is something that I included and I will speak to, which is that in discussing the challenge of adding the author to provenance with EHR vendors, I have come to appreciate that there could be a lot of work here in specifying what it means to be the author of any given data element, for example, a diagnosis on a problem list or a medication on a medication list. Is the author the original person who entered it? Is it the last person who modified it? Does this require the entire chain of modifications for a data element over time? It can be difficult. So, one way to consider this would be to do it in a limited way, adding the element

to simply specify if the data source was a patient or caregiver versus a clinician or other care team member, as opposed to specifically address this issue of patient-generated data and differentiating it, as opposed to going all the way down to the individual, so I throw that out for consideration as well. Any thoughts?

Arien Malec
David has an interesting comment on source versus author. I wonder if David could comment on that.

David McCallie
Yeah. Thinking on my feet here, I have not looked into this, but many times, you get data through an indirection that would not let you know who the actual author was, but you would know the class of the author. It is a system, or it is a patient, or it is self-reported. So, maybe a working notion might be for some of these fields, where, to take Steven's idea of a gentle start, is maybe consider it to be source instead of author.

Steven Lane
I think Clem has also thrown some support for the idea. I will ask Al to comment, but the trick is that author is Level 2, source is leveled at Level 1, and author role is leveled as a comment, and each of these individual data elements was suggested by different stakeholders with a different use case in mind. I do not know that we can say, "No, let's use source from Level 1 instead of author from Level 2." I do not know that Al and ONC would let us get away with that, so I think if we are going to do this, we need to call it "author" because that is what it was leveled as, and then perhaps make the recommendation that it be implemented in a leveled way initially. Al, can you comment?

Mark Savage
Can I add one thought, Steven? As author, that is especially important when you are considering self-reported data elements that are up there. I think source may be broader, as we saw from the Gender Harmony presentation, so the birth certificate may be the source of the information, but somebody might have actually been the author of that information.

Arien Malec
I think David was thinking about the opposite side of this, where the source is a patient self-reported narrative, but the author could well be somebody transcribing that into an EHR. But again, as long as we agree what we mean when we say the word "author" and include the source of the information under the definition of "author," then we might be okay.

Mark Savage
Sorry to interrupt, Steven and Al.

Al Taylor
So, Steven, to answer your question, we have in the past and we might well in the future take a given data element with a given definition and make changes to it to make it more applicable across multiple different use cases, and so, that could involve changing the scope of any of those three that you mentioned, author, author role, or source, changing the scope to better meet this broader set of use cases. And so, I have not looked deeply into the other ones besides author to see why it is a comment or Level 1. It could be because it was just very narrowly defined, or it could be because there were no mature standards, or it has not been

exchanged as much. So, depending on which of those it is, the things can be modified to meet a broader use case, so that could include something like changing the definition or the scope of "author" to make it a little bit more nonspecific. So, it could be closer to an author role if the intent is to capture things like patient-recorded data, patient-informed data, or provider, or system. So, those are some options that could inform the recommendations. It could also inform how ONC interprets the recommendations.

Steven Lane

Well, I have been trying to capture this in the spreadsheet as we go. There is also some useful input coming in through the public comment. There seems to be a general embrace of this idea of trying to use this initially to capture this notion of patient-sourced data. Arien?

Arien Malec

Yeah. So, I wonder whether the issue here is that we have something called author organization, and to Al's point, the minimum surgery here may be to rename that field from "author organization" to "author/source" and define that the author/source could include the patient, individual, or organization.

Steven Lane

Al, what do you think of that idea?

Al Taylor

That is a different recommendation than what we have been discussing so far and what has come in through the submission system. So, that could be as a separate recommendation because author organization has been in place since USCDI Version 1, and it is currently being enforced as is, and I am not familiar with the test data around author organization, but that is an already established thing, so the impact of changing an existing data element would be different than the impact of adopting a new one.

Steven Lane

Okay. Again, I do not want to burn more time on this than necessary. Does anyone object to us trying to craft a recommendation to add author to the degree necessary to be able to identify data that is sourced from the patient or a caregiver separate from members of the healthcare team, if you will? And, that is always tricky, of course, because we consider caregivers part of the healthcare team, so we will have to get the language right, but does anyone object to this becoming part of our work? Okay. Mark, where do you want to go next?

Mark Savage

I am not sure what you may have, but maybe 26, disability status, mental function, and functional status. So, this is a comprehensive recommendation. I have pulled together some of the different things from our presenters at DREDF. I have talked with them about whether this collective recommendation captured everything that they were saying, and they thought that it did. So, recommending the inclusion of the three data elements, at the last meeting, we talked about mental status, but there was a question about the name, but we did not talk about disability status and functional status, so this is a collective recommendation to include all three in USCDI V.3, consistent with the presentation for disability status, that it go into the patient demographics data class and that it use the seven questions that our presenters reported to us.

So, it is the six questions from the American Community Survey used by the U.S. Census, plus a seventh question on communication issues from the Washington Group on Disability Statistics. I am going to get to some nomenclature in just a second, but functional status and mental function would remain in the health status data class.

Again, to our conversation we just had, the disability status will be self-reported, but functional status and mental function might be self-reported, or there might be a clinical observation, so, author is an important thing.

As we have been discussing, we recommend that we add source and the method of collecting a value. Perhaps the provenance/author discussion will take care of that. And also, adding that we recommend some work in the near future, but not ready for USCDI V.3 right now, on five other categories of questions: Learning disability, mental health disability, autism/social disability, healthcare accommodation, and caregiver's disability status. And also, the data element on accommodations, which was, I believe, at Level 1, if memory serves, but as our discussion with our presenters highlighted, that work, improving outcomes, was really important.

In closing, I took on some homework on Tuesday's meeting, I did talk with the presenters, they affirmed that "disability status" is the nomenclature that they recommend using and is fine to use, and they did recommend "functional status" and "cognitive status" rather than "mental function" as wording for the other two data elements. I think I have captured everything, in the interests of time.

Steven Lane
Arien?

Arien Malec
I believe that last meeting, on Monday, what we talked about was that we should add disability status as an assessment, and that we should contemplate that the disability status, as an assessment, should have a minimum vocabulary, which would include the ACS Washington Group survey, and I also thought that we discussed on Monday that the disability status is more like a vital than it is like a demographic in the sense that demographics are or want to be permanent or semipermanent characteristics, whereas vitals are important observations that can and do change, and where the change is important and material to clinical care. So, I want to characterize that I think in the space of a few days, we have had discussion that has at least encompassed both of those positions. I clearly have a preference for the assessment approach, but I just want to note that we talked about this a couple days ago, rather than being in demographics, as being an assessment, and rather than specifying a particular instrument, specify that it is an assessment with multiple instruments with a value set that is inclusive of the ACS Washington Group instrument.

Steven Lane
Mark?

Mark Savage
Just to repeat, I did check with the people at DREDF about that. They did strongly recommend that it be in demographics. One of the things that they pointed out that I had not realized is it even has implications for clinical workflows. Often, those questions get asked in the patient registration. This is outside my swim lane,

but for some reason, that works significantly better as a demographic item than it does as a clinical item, which I think they were saying assessments in the internal workflows were viewed more that way. The other thing, I would say, is if the placement in a data class depends upon whether it is static or dynamic, this is going to be an issue for a variety of things. So, gender identity is not static either, and my instinct here is that whether it is static or changes, it should not really be the driver of where it belongs, and the advice that I have heard is that disability status should be in patient demographics, such as sharing…

Steven Lane
Just to be clear, in a certain sense, it does not matter and we should not spend a lot of time on this. Getting the data element into USCDI is what is going to change the world. Which class it is filed under really does not matter. I would encourage us not to spend a lot of time on this and just do what is most expeditious. You did ask the key question in your recommendation as to whether the source and method of collecting needed to be specified as a data element, or subdata element, or metadata related to this element, or whether, as we have just discussed, that can be captured under the provenance data that would travel with this, and it seems to me that we have had a number of conversations about the importance of identifying the source of data, and if we can get our provenance author recommendation right, we should not need to then have it as an add-on to this or any other data elements in the USCDI. Al, can you comment on that?

Al Taylor
There is certainly the potential to have provenance data elements applied. New provenance data elements or existing provenance data elements would apply all that information about the collection method. It is sort of a proxy for collection method, and if the workgroup wants to recommend a particular collection method, which would actually be the first time, except for labs, that a collection method is specified or identified, but if the workgroup wanted to make that recommendation, they would certainly be welcome to.

Steven Lane
Any other questions on this?

Steven Eichner
This is Steve Eichner. Real quickly on a couple points, I think perhaps looking at the word "evaluation" rather than "status" might split that term in terms of being more reflective. To me, it does not make sense for it to be included in the demographics class in the USCDI as we look toward the potential future of the USCDI. Maybe there are other elements related to disability condition, and it makes sense to me to have them align all the related elements in the same class so I am not jumping between classes trying to find all the reasonably related data points.

If you drill down a little bit further to a real-world example, my health condition is not my disability. My health condition is a particular diagnosis code that happens to be a particular disease. The disease actually can impact my disability status, but it is not my disability status. The particular condition I have is progressive, and it progresses differently in different people, and the way the coding schemes are designed right now, they do not reflect the progression of the disease in anybody, let alone in a consistent fashion across the patient population.

So, yes, I have the condition, and whether my left arm is locked, my right arm is locked, frozen, immobilized with HO, that differs in every person, and that does not describe what my functional limitations may be in

terms of saying there has been HO on my left shoulder. That does not convey whether I have lost 20% of movement or 99% of movement. Those different levels have different values, reasons, and utility in the healthcare environment. Understanding all of that at different points may be terribly relevant or terribly useful so that if I am looking at the combination I need to get into the office, the receptionist does not necessarily need to know that I have 20 degrees of motion left or two degrees left for certain purposes.

But again, how do we create this longer-scale framework and organize our data up front so that we have the capacity to grow in a logical manner? I do not think we need to get it all in one fell swoop, and having it end up as a structured approach makes sense. Again, I would love to come back and see both structured and unstructured data supported in this iteration so that we have the capacity to include whether it is a patient-produced or physician/care team-produced evaluation or assessment of my ability or disability status in my record for coordination of care across my healthcare providers and care team so that I am not describing what my needs are for an accessible van in the same language for the 12th time. That is a real-world example, and we are bouncing it around between four different systems, and nobody has a way as storing it as an attachment to my file, so it has been lost four times, resent five times, and it is just a pain, to be honest about it.

Steven Lane

So, I want to get us clear so that we can move on, if possible. I think we decided last time, and anyone can correct me if I am wrong, that we were going to refer to mental and cognitive status as opposed to mental function. Was that everyone's recollection? Yes? Okay.

Mark Savage

Steven, that may be. I am just pointing out there was a preference in my discussion with our presenters for cognitive status rather than mental status. That is the pleasure of the workgroup.

Steven Lane

Yeah, and I think what the workgroup suggested was to add it as opposed to replace it, so if we can tolerate that, we will go with mental and cognitive status, and maybe we will use the slash because "and" implies perhaps something different. And then, the other key component in our recommendation is… And again, I do not personally think it is worth us specifying which data class this goes into. I think we can acknowledge the discussion, and the various views about that, and the potential implications, and leave that up to ONC. Does anyone feel differently that it is really worthwhile throwing our weight behind which class this data element goes into?

Mark Savage

I am fine with that. There is a lot on our plate.

Steven Lane

Okay. So, we will discuss the issues. And then, the other part of this is the issue of being able to capture the method and source of collection, so I think that is critical, and it sounds like we can do that in a generic way as opposed to having to do that for each individual data element, so I think we can call that out here. Are there any other key components that we want to be sure we capture in our recommendation around these data elements and this data class? Okay, again, I am hoping that between now and next week, the cochair and workgroup leads can work on the actual wording for this and come back with something

meaningful. I am looking forward to a busy weekend. All right, then let's go on. Did you want to go to health insurance next, Mark?

Mark Savage

I can, or pregnancy status, whichever you prefer.

Steven Lane

Oh, I did not know we needed to go back to pregnancy status. Your choice.

Mark Savage

Why don't we go to pregnancy status, which I believe is Entry 27? So, again, the USCDI Taskforce last year recommended this is the priority, and I strongly recommend that we, in turn, recommend its inclusion in USCDI V.3. I did point out two levels of possible augmentation, one at the very least to capture the intent to become pregnant because that has significant implications for clinical care. This is not my area of domain expertise. I have talked to some people, and the timing and where one is around pregnancy… There is much more than just the intent to become pregnant that is really important here. So, for example, in the postpartum session, that is when you have the greatest maternal mortality, and so, capturing timing for purposes of better care at particular stages is really important. I have captured that in the recommendation, that I think that is important, but I do not know where we are in the stage of having established value sets that we can use. At the very least, I think augmenting to include the intent to become pregnant. Right now, it is just yes, no, and unknown, as far as I can tell.

Steven Lane

And, just to be clear, within pregnancy information, pregnancy status itself is listed as Level 2, and there are quite a number of additional data elements that have been submitted and are at the comment level, which does not include, as far as I can tell, intent or the data set that you just described. So, Al?

Al Taylor

I just wanted to remind everybody that the original intent of pregnancy status was to capture the risk pregnancy may have on other conditions or what other conditions may have on pregnancy, and the specific use case for pregnancy status that led to this was the screening that needs to occur during the evaluation for Zika, so that was a particularly acute issue back during the Zika epidemic, and so, the simplicity of this data element at the time and since, and why it is elevated to draft V.3, is to capture that relationship of the possibility of being pregnant, which could drive care, depending on what the possibility is.

I can see how not just during pregnancy, but at a particular stage of pregnancy, there might be an increased risk or decreased risk depending on what it is that is under consideration, but I am just saying that some of this recommendation is significantly altering the original scope of that pregnancy status data element, not to say that the recommendation should not be made, I am just pointing out that it is a fairly significant shift from the original intent of this. There could be other data elements that would be closer to the original intent of this recommendation. So, I am not saying not to make it, I am just saying this is the background behind the original data element.

Steven Lane

I think that is really helpful, Al, and we always have to remember that perfect is the enemy of good, and that this is an iterative process, and it would be hard to argue against the value of adding this to V.3, as has been suggested in the draft V.3, whether it makes sense to try to ask for more or to provide some additional guidance. This is a simple enough value set, but we have no information about whether it is currently collected, exchanged, or anything else, so I think it may be a value set that needs to make its way through the process, through a submission specifically, or through public comment, and when I look at pregnancy status on the site, there are some public comments, but it does not look like it includes that in particular.

Al Taylor
I also wanted to mention, Steven, that the reason we did not define a value set or a set of example codes is because if you look at value sets around pregnancy status, there is a very wide range of options and number of options. Some value sets state every conceivable complication related to pregnancy, and there are at least dozens, if not hundreds, of terms that could represent where one might be at in a pregnancy, and then there are ones that are very simple, like pregnant/not pregnant, so there are different value sets depending on what the use case is that that value set serves, and so, that is one of the reasons. What Mark is presenting is another set of terms that could be useful. It is sort of an in-between set of not super specific, but also not very generic. So, the recommendation could specifically recommend a particular value set, this one or something else.

Steven Lane
So, does anyone feel strongly that we should wade into the waters of value sets in our recommendation, or could we simply say yes, this is great, let's move it forward, and wait for more commentary to come in from the community? Arien?

Arien Malec
I am basically having the same conceptual confusion that I am having for medications and for lab results. Are we saying that for pregnancy status, there is an implied ontology that may be relatively sophisticated for capturing pregnancy status, including intent, including use of contraception, etc., that are applicable for multiple conditions, or are we saying that we should confine ourselves solely to the Zika case and confine ourselves to pregnancy status for Zika screening, or are we basically being silent on ontology, making the recommendation that pregnancy status go forward, and leave it to the community to work out the implied ontology?

Steven Lane
I will respond. I do not think there is anything about this recommendation or this data element that is specific to Zika, even though that was the experience that led to its submission. Clearly, this is relevant. I think the key question is simply do we include in our recommendation a suggested value set, or do we leave it up to the industry to work on that and maybe bring one forward through their commentary?

Arien Malec
Got it. So, I think what we are saying is despite that it came from CDC specifically for Zika, we are not limiting ourselves to the Zika use case. We are also not going to point to a specific value set or ontology because we do not know what that is. We are suggesting that pregnancy status be added, and in the period of time between V.3 finalization and inclusion via the standards development process that industry coalesce on a recommended ontology and set of value sets. Is that right?

Steven Lane

I like it. I am trying to capture it.

Mark Savage

I like it.

Steven Lane

So, does anyone feel uncomfortable with simply recommending this move forward, and perhaps with a suggestion to ONC that they work with the community to bring in value set recommendations in the future? All right, we are going to move this forward.

Mark Savage

Steven, I am happy to help if it is useful to ONC. I have been consulting with some people about this too.

Steven Lane

Anybody who wants to help on the wording of these recommendations between now and next Tuesday, and I literally mean next Tuesday, not in the figurative way that that is sometimes used, please do so. All right, that was pregnancy, and then I think you wanted to go to health insurance, No. 19, which we have touched on in the past.

Mark Savage

Correct.

Al Taylor

We are almost at public comment. It is 11:54.

Steven Lane

We are. I think the summary on Item 19 was that we recommended it in prior years, and somebody sorted, so all of these…

Mark Savage

And continue to do so.

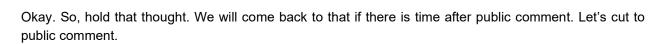**Al Taylor**

I got it, hang on.

Steven Lane

Yeah, you did the sort deal, the filter deal.

Mark Savage

Steven, you are right. That is the basic summary. It was a priority last year. We think it is a priority this year. Please include it.

Steven Lane

Okay. So, hold that thought. We will come back to that if there is time after public comment. Let's cut to public comment.

Public Comment (01:23:39)

Michael Berry
All right, thank you, Steven. We are going to now open up our calls to the public for any comments. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be just on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's take a look to see if we have any public comments. I am not seeing public comments, so I will turn it back to our cochairs.

Steven Lane
Excellent, and again, I really appreciate the tremendous engagement the public has given us in the chat. I personally have not been able to monitor every piece of it as we have gone along, so I look forward to reading it once we get it out.

Michael Berry
Steven, I am told there is a public comment.

Steven Lane
Oh, good. Did we get one? Mike, is there public comment?

Michael Berry
Sorry, I was just trying to take myself off mute. We have Ulrike Merrick. Go ahead for three minutes.

Ulrike Merrick
Hey, this is Riki Merrick with the Association of Public Health Laboratories. I just wanted to thank you for considering adding those lab data elements. I have been trying to get those in for a while because they are essential to making lab data interoperable, so I just wanted to say that out loud. I left plenty of comments in the chat.

Steven Lane
Thanks so much, Riki. That is very helpful. Anything else come up?

Michael Berry
No, that is it.

Steven Lane
All right. So, we were just talking about health insurance. Can we pull that back up, Al, Entry No. 19, just so we can get clarity on that? This says health insurance information is the data class, and coverage status, type, relationship to subscriber member. Al, looks like somebody renamed Column E, which needs to be changed back to data class.

Al Taylor
No, that is just how I can sort it, Steven, but E is data class.

Steven Lane

Got it, okay. Anyway, again, the recommendation is to include this in USCDI V.3. It was recommended previously. It was at Level 2. Does anybody disagree with that as part of our workgroup output? All right, we will include that. And then, I do not think it makes sense for us to dive into anything new at this juncture, but what we have left is there was a recommendation, which is Entry 33, regarding health status and whether it should be brought over, as ONC had suggested, or left back where it was.

Arien Malec

Sorry, I just noted Hans's comment on coverage type, and it occurs to me that in the same way that we just decided for pregnancy status relative to coverage type, we might want to include coverage type as part of our coverage recommendations and make recommendations to ONC that they work with NCPDP, WEDI, X-12, and HL7 to reconcile the vocabulary for coverage type.

Steven Lane

That is No. 20, correct?

Arien Malec

That is No. 20, yup.

Steven Lane

All right. Anyone disagree with us trying to include that as well?

Arien Malec

It is actually included in the one above that we already endorsed, so I just wanted to note the seeming disagreement between those two and just suggest that we add to 19 the recommendation that ONC work with industry to reconcile the vocabulary set.

Steven Lane

Perfect. So, we invite people to continue to interact with the spreadsheet. We will come back to No. 33 around health status, we will come back to No. 70, which captures the recommendation that we heard a couple weeks ago to include the ICF as a harmonized standard, and then, we are going to invite both Clem and Hans to take the mic for a little while to work us through some of the recommendations that they felt were worth capturing. What is our timing now to finish up our recommendations? Can you remind us, Mike or Al?

Al Taylor

We had set the new recommendation cutoff for next Friday, and then, the following week, two Tuesdays from now, would be the last chance the workgroup would have to massage the recommendations.

Steven Lane

Okay. So, our time is short, but I think we are in a groove. Hung, we will also come back and revisit your recommendations next week and see if we can figure out whether we are going to try to swallow the hairball or just pick a few nose hairs and make progress in that way. So, thank you all. We are at time. I have to go see patients. Have a great day.

Mark Savage
Thank you. Bye.

Adjourn (01:29:06)