

Transcript

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

March 22, 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
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, good morning, everyone, and thank you for joining the Interoperability Standards Workgroup. I am Mike Berry with ONC, and we are always excited that you could be with us today. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting, or can be made verbally during the public comment period that is scheduled at about 11:55 Eastern Time this morning. I am going to begin roll call of our workgroup members, so when I call your name, please indicate that you are here. And, I will start with our cochairs. Steven Lane?

Steven Lane

Good morning.

Michael Berry

Arien Malec?

Arien Malec

Good morning.

Michael Berry

Hi, Arien. Kelly Aldrich? Medell Briggs-Malonson? Hans Buitendijk?

Hans Buitendijk

Good morning.

Michael Berry

Thomas Cantilina? Christina Caraballo?

Christina Caraballo

Good morning.

Michael Berry

Good morning. Grace Cordovano?

Grace Cordovano

Good morning.

Michael Berry

Steve Eichner?

Steven Eichner

Good morning.

Michael Berry

Sanjeev Tandon?





Sanjeev Tandon

Good morning.

Michael Berry

Raj Godavarthi?

Rajesh Godavarthi

Good morning.

Michael Berry

Jim Jirjis?

Jim Jirjis

Good morning.

Michael Berry

Ken Kawamoto? Leslie Lenert? Hung Luu?

Hung S. Luu

Good morning.

Michael Berry

David McCallie?

David McCallie

Hello.

Michael Berry

Clem McDonald? Mark Savage?

Mark Savage

Good morning.

Michael Berry

Michelle Schreiber? Abby Sears? 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 (00:01:59)

Steven Lane





Well, thank you, as always, for all of you, on whatever time zone you are in, for joining us today. We really appreciate it. We are in the home stretch of our Task 1 work, and looking forward to making as much progress today as we possibly can. So, we are going to jump right in. We are going to focus in on recommendations that have been coming through, many of which we have already discussed, but we are also hoping to give Hans and Clem a bit of time. They have put a lot of thought into a number of recommendations that have not gotten a lot of airtime, and we want to give them a chance to focus on items of high priority to them. We are hoping to finalize some recommendations around health status and the laboratory. Hung Luu has put a lot of effort into his recommendations that we have talked about briefly, and then we will just continue to get as far as we can.

Given the time available, we want to be as efficient as possible and drive towards recommendations that we can feel comfortable with and not go down too many rabbit holes because we just do not have time for that. Arien, do you want to add to that intro?

Arien Malec

I just want to note that we have taken a lot of the workgroup deliberations and memorialized them as a set of recommendations, so if you have not looked at the spreadsheet, you could look at that, review the recommendations, make sure you are in alignment with how we formalized some of this, because that is going to form the basis for some of the formal recommendations letter.

Steven Lane

And, I want to give particular thanks to Arien and Mark, as well as others, but I know there was a lot of time spent over the weekend trying to formalize those recommendations, and we are going to hope to review as many of those as possible here today. All right, good. So, let's go on, then, to the next slide. Just a reminder of our charges, we are focused here on Charge 1. We are not going to belabor the point. Let's go on to the next slide. Clem, are you here? Hans, are you prepared to guide us through some of your high-priority recommendations and see if we can work through those?

Hans Buitendijk

Sure.

Steven Lane

We will let AI pull up the spreadsheet, and we can edit in the background, and just point us to the rows you want to discuss.

IS WG Draft USCDI v3 Member Recommendations (00:04:57)

Hans Buitendijk

Okay, let's see. I will have the spreadsheet up as well. Sorry, I was thinking I was going to be after Clem and I could organize my desktop a little bit better. First of all, the overall comments that I have, which need to be taken in the context of USCDI from our perspective as we are moving through, and I am wearing a little bit more of an EHRA hat, is that we really need to cover much more than what is currently stated to set out, a core set. We believe that we actually need to go to the EHI, if not beyond that level, so for those who have not heard that statement before, we want to make sure you are aware that that is the context. So, from our perspective, no data element being proposed in itself is inappropriate. It is good. The main challenge is timing on do we have the standards in play that if we get to certification, that we can move





forward with that in SVAP or otherwise, so that is, for us, a key element of is it ready or not, not whether it is good or not. They all need to be addressed.

In that context, there are a couple things that I want to run by. I will go in roughly the order. The first one is around discharge summary, so it is actually a couple of rows higher there. The challenge there, the clarity, is that the suggestion indicates specific data to include, yet the discharge summary as it is currently being defined, as part of clinical notes, is narrative, so the challenge is are we going to start to shift into now creating effectively a discharge summary document, not a note per se, that is fully structured, that is already part of C-CDA document type? So, this becomes a bit of a challenge. Are we trying to replicate that given its narrative note in play?

Another part is that as we get deeper, which gets too far afoot today, some data or discharge summaries if you are in that HIT system/EHR that is specialized on ambulatory, they would not have the notion of a discharge summary. So, here, the suggestion is that really does not fit that well because we are not trying to create discrete data within narrative, but that might be a clarification question that we have, but it is critical for us.

Steven Lane

Arien?

Arien Malec

Yeah, thank you, and I think sometimes in USCDI, we cross over into interoperability use cases and interoperability specifications. Hans, the way I would think about what you are saying is that the discharge summary is a note, and there is also a discharge summary that might be an implementation guide either attached to consolidated CDA or to a FHIR implementation spec that specifies the format of a structured discharge summary that would include the narrative, as well as accompanying data. Would that be a useful way to frame the point that you are making, Hans?

Hans Buitendijk

And, perhaps that might be, then, in USCDI to indicate there is a discharge summary note construct and there is a discharge summary "structured document," or whatever the right term is there, so that we distinguish that so we are not trying to say we are trying to accomplish everything with one because there is value to the note and there is value to a set of structured data.

Arien Malec

That seems pretty clear to me. So, we should specify that the discharge summary in this USCDI context is the narrative note.

Steven Lane

Any objection to that?

Hans Buitendijk

And, the note that David is making, "Please do not lose the narrative," absolutely.

Steven Eichner





Really fast, I think that also applies to the disability descriptions as well, that there is a distinction between structured and unstructured data, and we are interested in those.

Steven Lane

But specifically to this particular data element that is in USCDI, our comment is simply to be as clear as possible on the part of ONC that this is, in fact, an unstructured note, not a particular structured document type. Is that correct, as we are saying?

Steven Eichner

I believe so.

Steven Lane

Okay. AI? Sorry, Mark, you are up first.

Mark Savage

Yeah, just a quick question. I see that there is a separate discharge medications data element. I do not know if it is structured, unstructured, or anything. I was just poking around as you were talking, Hans, but I wondered if there was anything to say about the intersection there or not. I do not know of an intersection.

Arien Malec

Mark, if you are talking about the discharge med list, that was the item that we discussed a couple of workgroups ago that CMS had brought where I think the conclusion is we want USCDI to have the notion of lists, but a discharge med list would be different from a discharge narrative note, and both of those would be included in a discharge summary that would be a set of structured information. AI has a question or comment.

AI Taylor

Yes, it is a comment, thank you. I wanted to point out that the specific pieces that are specified in the definition of “discharge summary” are elements that are required of the discharge summary. That is part of the transition of care and/or the view, download, and transmit certification requirements. So, this is adding those data elements to this. Sorry, I should not use the term “data elements.” The required components of a discharge summary align with what is already required for the discharge summary as part of the transitions of care criteria, so this is not adding anything new that is required of EHRs, only restates that the content must include...

Arien Malec

So, AI, I get confused, then. Is USCDI supposed to be an interoperability specification or the set of data elements from which interoperability specifications draw? Because the way I would conceptualize USCDI is that USCDI needs to include all of the data elements against which we would define an interoperability specification, and there is an interoperability specification for a discharge summary, the consolidated CDA document that would draw from USCDI with all the required data elements.

Steven Lane

Yeah, and I think following that, if the statement is that the discharge summary should include the data elements that are now currently spelled out, as well as narrative note, that might help if it bifurcates in the





standards side, whatever happens there, but we wanted to avoid the impression that it currently gives that we are somehow trying to make sure that inside the narrative note, there are those data elements present. That is the part that would get confusing once you start to get down the road. Ike?

Clem McDonald

One slight complication is the narrative could contain all that stuff.

Steven Eichner

True.

Clem McDonald

[Inaudible – crosstalk] [00:12:38] to prove it.

Hans Buitendijk

Right, but if we say it must or it should be able to contain that, it is not going to say much because it is free text. If we put it next to it and say there is structured data that addresses those things, that sends a different message downstream as we define the standards for it. That is what we are trying to avoid confusion around.

Al Taylor

Hans, ONC is not saying that the free text component must contain all of these things. Narrative is certainly one piece that we want to preserve at ONC, which is why we introduced clinical notes in the first place.

Hans Buitendijk

Correct.

Al Taylor

The content of that clinical note could potentially be structured, but not necessarily required to be structured, but overall, the content should include at least those components.

Steven Lane

Ike?

Steven Eichner

I guess the other piece in there is threading a needle off of things like medications that are not otherwise codified. How do we make those things findable in a record in a patient note? Because there are other things that are out there that we do not have a structure for today, but are really relevant and really high-priority pieces of information for patient care. In my personal, please do not hit me with intramuscular injections. It is effectively an allergy, but there is no way of codifying it as an allergy. If there were three or four things that you really needed to know about my care up front, my jaw does not move. There are three or four little pieces of information that are absolutely key. How do we highlight those from a standards perspective so there is a way of prioritizing them downline on display, that they are findable pieces of information?

Steven Lane





So, I have tried to capture this in a recommendation here, which is not showing up on Al's screen yet. There we go. "Recommend ONC clarification that this data element is specific to the unstructured narrative portion of a discharge summary and does not include any specification or requirement of discrete data elements." Does that capture what we have been saying, Hans? Is that what you were looking for for EHRA?

Hans Buitendijk

Not quite because the challenge that I have is that if we say certain data must be part of the narratives note, which is typically and mostly narrative, free text, there is no way that we can validate that admission or those structured data that are in there. If you say in addition to narrative note, there is this other data, that is a different part, but specifying what should be part, effectively, of a free text note is hard to do in USCDI.

Arien Malec

So, the way I would say this, then, is that we should specify that this is the narrative note of a discharge summary, period.

Steven Eichner

To follow up on my earlier question, there are some pieces of data that we have no current way of codifying or putting in a structured document, So, for those elements that we have no current way of putting in a structure, what do we do with it?

Hans Buitendijk

Put it in a narrative note, but it is not that we can validate that you actually did that or not because we have no codification or structure to it.

Steven Eichner

Right, so I guess what I was looking for is a "may include" kind of thing, a recommendation to include ABOC as critical pieces, but obviously not necessarily requiring it in the absolute sense. Does that make sense?

Steven Lane

Yeah, I think it goes to a level of detail that is probably beyond USCDI. It sounds like, Hans, EHRA just wanted this fairly straightforward clarification, that this is simply the unstructured narrative portion of a discharge summary, and that is why it is under clinical notes.

Clem McDonald

Can I just clarify this? I think your first position was better, Steve. It is just a narrative summary. It is not necessarily a part of anything else, either, and it is probably instead of, in some cases.

Arien Malec

I do not think we should say whether it is instead of or not instead of. Is it narrative note, period, end of story.

Clem McDonald

Yeah. I thought Steve's first position was the simplest and best when he first described it.

Steven Lane





Well, look at the language I have and see if that is good enough because we are just going to try to move this over to our document to the HITAC. Does that capture it, or do we need something more? Hans, good?

Hans Buitendijk

Yup.

Steven Lane

Okay, no hands. In the interests of time, where do you want to go next, Hans?

Hans Buitendijk

Health insurance information. The next one is the coverage status. I believe the coverage type was covered with the prior discussion that Mark Savage had some comments around.

Steven Lane

And, somebody sorted this, so we have a funny set of things showing here. Al, would you mind unsorting so we can see all the rows? Because I think this may have been incorporated into a recommendation.

Al Taylor

It is sorted by Hans. It is all of his comments.

Mark Savage

Steven, I did include Hans's comments here as a part of the broader recommendation on health insurance information.

Hans Buitendijk

And, I may have a tweak suggestion, but that is not for today. That can just be a tweak later. The coverage status I think I am going to skip because that was a medium priority. Then, go to reason for referral. That one is next on my list. This is creating a couple different challenges because the language being used in the submission, the placement under procedure, and the terminology used, there is something that has the opportunity for confusion. The thing is that typically, when the term "referral" is used, it is frequently more about a visit, an appointment, an encounter that is being set up, during which there might be procedures that are going to be done. And, in the submission, there is talk about it being a request for something, and one of the examples is for transport.

So, I think we have a little bit of a challenge with where it fits under procedure or not, but the key seems to be that it is the reason for a request, and a request can be for a service, a test, a procedure that is being done, a request can be for transport, a request can be for an encounter, so, some of those terminologies we split up in different data classes, and other ones we combined, and there are different ways that it happens in the standards as well. I think here, we need one to make sure if this is the reason for the request of something to happen or is this the reason why it was done, which are not necessarily two of the same things. That is what we would like to get clarity. We think what is meant is the reason for a request to be made to get something done.

Steven Lane





You are saying as opposed to the diagnosis, clinical condition, or clinical question, really more about what is the service? Is that what you are saying?

Hans Buitendijk

Correct. So, the example that was used in the submission of reason for transport is because the patient has a heavy oxygen tank that needs to be moved, so we would like to get a taxi, or it might be I want to have a lab test done for some particular reason that is not necessarily rising to the level of a diagnosis. So, that is the clarity that we are looking for because it might need to end up in one kind of area, or it might need to end up somewhere else with more “The procedure is now done; why did you do it?”, and then you are typically a little bit more into the other clinical reasoning of diagnosis, conditions, etc.

Steven Lane

Arien, your hand is up. Go ahead.

Arien Malec

Thank you, yes. So, the way I would think about what Hans is saying is in an e-prescribing context, the notion of an indication for a medication is pretty common. We either would conceptualize this as the indication under which a procedure was performed. I think the right way to think about the prospective reason for referral would be attached to an order or service request/referral request where there is a clinical indication for a service, procedure, or referral that wants to happen, and again, it is the same kind of notion of the prospective indication to rule in/rule out, etc. That is what is occurring to me, but I think if we are talking about a procedure, which is something that actually happened, we really want to talk about the indication or the reason for the procedure as something that happened in the past, as opposed to something like a referral that wants to happen prospectively.

Hans Buitendijk

Right, and a submission, the text, when you read through that, seems to be more on the side of the requests being made and why you are making the requests than it is on the procedure having been done and why it was actually performed. That is why it is confusing as to which direction we are trying to go. Both are valid.

Steven Lane

AI?

AI Taylor

What Hans is suggesting and what is written in the workgroup discussion field is really the intent of reason for referral. You use the terms “consultation,” “transport,” or “referral.” The reason that that referral was made, whether it was a referral not for a surgical procedure, it is listed in the procedure as data class because the consultation or referral is a type of procedure, so it refers to the procedures that are requested services, so it is not after the fact on a billing form, an indication for a surgical procedure, but the reason a consult is made, and again, as I said with the previous discussion, the reason that this is added is because that is a specific requirement in transition-to-care certification requirement, and that transition of care is the process that this referral comes into play with. So, the transitions of care like a transition to a consultant or a transition to a service provider, like a transportation service provider.

Steven Lane





So, Al, is there a set of data that you anticipate being put into this? Is there a value set?

Al Taylor

We did not identify a clear value set, but we could certainly give some examples like the examples that we have just been talking about. So, why did the patient need transportation? Why did the patient need to see an orthopedic surgeon? So, some referrals are for services that require prior auth and things like that, so it could potentially be used for that as well as the justification for sending a consultation or a referral.

Arien Malec

Yeah, this is also a procedure, so we need to make sure that the terminology that we use is consistent with reason for CABG, reason for etc. That is why I was formalizing as “indication” with a more general set of terminology.

Al Taylor

We certainly can look at appropriate examples that prove that [inaudible] [00:25:10], maybe using some of the same examples as we just discussed and Hans suggested. Hans, what you are asking for is really the intent. You had the right idea when you were asking about are these examples that we are talking about, and they are.

Hans Buitendijk

So, there are two things that jump out. One is would it be better to have a more general data element name, like reason for request, of which a referral is an example, or there are a couple of other examples. So, the request spans a few more areas. That also indicates if procedures if really the right place. Is this left specifically for procedures, or is it for other ones as well, where a request is made? So, that is the clarity, I think, that we are looking for to proceed, and depending on what the scope actually ends up being, there are more places to be touched or fewer places to be touched.

Clem McDonald

Could I just make a comment? I worry, sort of like David did, that we may be just putting a huge burden on the people who are asking for this stuff. So, if you go to the airport and you want a wheelchair, just ask for it. You do not have to give them a reason. A whole lot of this stuff is the same way. It will be obvious, and I do not know who needs that reason all the time. I think it would be nice to have a place to put it, but I really worry about the excessive amount of work to express things when you want to write an order or write a referral.

Hans Buitendijk

Well, I do not think we are necessarily saying that this is going to be required to be collected all the time, but there are places where it is relevant to be collected.

Clem McDonald

Well then, maybe you should make it explicit that this is optional.

Hans Buitendijk

But, aren't most of them optional?





Steven Lane

Again, this is a motif that we keep coming back to. Just because we have specified it in USCDI does not force anyone to collect it.

Clem McDonald

No, I know, but if people pick this up, it mutates, they forget where they came from, and I think we should say that these things... Prescriptions hardly ever have a diagnosis on them, for example. I think they would be nice, but they do not. So, I think we should make it a little bit explicit this is not intended that we keep adding work to the primary care docs, who are fleeing the field as fast as they can get out of it because of all this crap.

Hans Buitendijk

On a general note, from what Clem has indicated, we have been talking about and indicating that there needs to be more clarity on what in USCDI is really meant to be used by certain HIT because not all HIT supports this, needs to support it, either as maintenance, viewing, or otherwise. So, I left that conversation on the side for a moment, but it does go to the point, and I think I have a way to address that, but I am not sure whether you want to get into that today, Steven and Arien, or for a separate discussion to clarify how we can really make sure that while on the one hand, there is no intent that what is in USCDI is used by everybody, it needs to be applicable in your space. In the transition to where it is HIT that is certified, there are some gotchas in that approach that we need to iron out.

Steven Eichner

This is Steve. Really fast, Clem, to your point, the question about how there does not have to be a rationalization as to why I need the wheelchair at the airport or a diagnosis attached to a particular prescription, it may not make a difference on the clinical side, but it makes a huge difference on the payment side. I cannot get reimbursed for it by my health insurer if it is not determined to be medically necessary, so without that language that says the wheelchair is required to deal with this diagnosis, who is paying for it? It is the same thing looking at something like a prescription, especially looking at off-label use or things that were misaligned there in terms of looking at how physicians can certainly prescribe medications for things that are off label. It does not mean that the health insurance companies care to pay for it. So, that is another context, not just that is prescribed, but why it is there may not make a difference. That may not be ubiquitous, but it is a factor out there, really reflecting on how the information is being used and by whom, not just that the information exists.

Steven Lane

Okay. I think we have a recommendation text here. Is anybody uncomfortable with how we have captured this? Hans, does this address your concern?

Hans Buitendijk

Correct.

Steven Lane

Great, all right. Hans, we are a third of the way through our meeting today, so I would like to invite Clem, if that is all right with you, to highlight your top couple of priority items, Clem, amongst the many thoughtful recommendations that you have made.





Clem McDonald

Well, I thought I already sent you the highlighted one, did I not?

Steven Lane

You did, but it is not about me, it is about the workgroup.

Clem McDonald

How can I find what I highlighted?

Steven Lane

If you want to work on that, Clem, we can come back to you. That is fine. I did not mean to jump the spot.

Clem McDonald

If you could just constrain it to mine...

Steven Lane

Okay, I will just sort it to yours.

Clem McDonald

Some of these I do not think are important, so let's drop down.

Steven Lane

I do want to acknowledge how much work you have put into this, and hence, give you a chance.

Arien Malec

And, we should just note anything that is marked has already been addressed.

Clem McDonald

The purples have been addressed?

Arien Malec

Yes.

Clem McDonald

Oh. Well, I just wanted to clarify about the SDOH on two levels. I think it is really two different places.

Steven Lane

Which row are you in, Clem?

Clem McDonald

It just moved.

Steven Lane

Sixty-six, perhaps.





Clem McDonald

Give me a minute.

Steven Lane

That is fine. We can come back. Again, no pressure. Okay, back to our agenda. We wanted to complete review of health status, Entries 26 through 36 and 70. Do you want to take us there?

Al Taylor

Is that right, Steven?

Steven Lane

That is what we have on the agenda.

Al Taylor

Sorry, just clarifying.

Steven Lane

Mark or Arien, you guys put a lot of thought into this. Do you want to walk us through any of the drafted recommendations, or do we want to leave that to people to review them and provide input?

Arien Malec

Maybe we should give an overview for the drafted recommendations, and then let people go and read all the details.

Steven Lane

Sounds good.

Arien Malec

Mark has his hand up.

Mark Savage

I think the same thing. We already discussed them individually. The final recommendations try to capture what we discussed, so I think there is nothing really to revisit, but just to make sure that the language captures what we thought it should capture.

Arien Malec

Why don't we go to Row 26? Entries 4, 5, and 26 are the big ones.

Steven Lane

So, we are on 26. Let's go there.

Arien Malec

On Row 26, we support the inclusion of disability, functional, and cognitive mental status. We recommend that the data element that was labeled "mental function" be labeled "cognitive mental status." So, we





recommend that they be included as “health status/assessment.” In the health status and assessment recommendations, which I believe are Item 4 or 5, we also recommend that health status assessment be inclusive of patient self-assessment, so, no implication that these are clinical assessments, but inclusive of patient-generated health data.

And then, there are a bunch of detailed recommendations related to the value sets that could be included as a core value set, inclusive of the ACS Washington group survey that was recommended by the disability rights panel that we had, as well as a set of the functional status, cognitive mental status, and disability status recommendations recommended by Holly and Terry. So, really intended to be a superset recommendation related to all of our deliberation on disability status, functional status, and cognitive mental status. If we go up to Entry 5, or it could be Entry 4, if my memory is off by one...there we go.

Al Taylor

For assessment?

Arien Malec

Assessment, yup. So, this is the overall recommendation relative to assessments. So, our general recommendation is that we think about health status as health status/assessments, with LOINC as the applicable code set. Whoops, back and forth.

Al Taylor

Sorry.

Arien Malec

That is all right. We recommend that we fold the SDOH assessment into the health status assessment class, just conceptually, it belongs there. And again, as I noted, we contemplate that assessments are inclusive of self assessments and patient-generated health data, and again, just putting in a set of recommended SDOH assessments from the work that Holly and Terry provided. So, those are the high-level recommendations that we are making relative to health status assessments and how to handle the specific status types that we contemplated for cognitive mental status, disability status, and functional status. Any questions there? Hans has his hand up.

Hans Buitendijk

Yeah, one quick question. Overall, I support the recommendation with some of the renaming and the alignments. The question is mostly on the tools and the assessment tools that are being suggested. A question there is since there are so many different assessment tools out there, some tools not used by many, do we feel comfortable that this is a reasonable core set that is useful to most providers to have that sharing opportunity?

Arien Malec

So, Hans, just structurally, 1). You will see in the first recommendation that when we say that LOINC is the applicable code set, we clarify the intent is not for every EHR to be able to produce every possible assessment, and 2). In these areas where we are listing these assessment types and associated LOINC codes, we are very clear that ONC may consider the following sets, not that we recommend that this be the core value set because Holly and Terry did a ton of work. I think it is worthwhile to think about that as the





starter set for a core set, but this would be clearly something where you would want a multi-collaborative group to create the core starter set. So, I think we are very careful to acknowledge the work that Holly and Terry did, but also not to make recommendations that this be the one and only set.

Hans Buitendijk

And, on the latter point, that is totally appropriate. I am curious about the first part, that you indicate that we encourage ONC to work with the community to establish a core set that is more widely used. That might be some part of the recommendation as well.

Arien Malec

Yeah, we recommend that ONC work with stakeholders to identify and specify core LOINC subsets for each of the assessment categories.

Clem McDonald

Hans, could I just add, though, that that may never happen? I think it is really, really useful to say, "Here are some starters" because a lot of times, people do not care, but they can find it and get it done, and it would be nice if there were not 10,000 different things for the same thing if we really ever are going to collect data across the country for any use. So, I really think it is a good idea to encourage a starter set of some kind. And then, there will have to be more, and of course, they can go to lots of other LOINC panels, too, if they like.

Steven Lane

I think we have clarified that, Clem, and AI, your hand is up. I know some of these were also included in the taskforce recommendations last year, and I think you have mentioned to us that you did include that detail in some of your documentation, correct?

AI Taylor

Yeah, but I wanted to specifically address the question about developing code sets. Those are done. Those have been developed, and all of these SDOH assessment instruments have associated LOINC codes, the panels have LOINC codes, and the subset domains have LOINC codes as well, and that was after about six or 12 months of work by the Gravity Project to develop these code sets, and they are establishing value sets within the VSAC to be able to represent them, and a list like this or a list like the value set that Gravity is actually the value set author and steward for is the set that we are very likely to point to as the example set or the minimum set, depending on what we end up calling it, but that is already done. I just want everybody to be clear that that is already being done, and it is our intent to point to a reasonable set of examples already. So, you can include the recommendation, but that recommendation from last year has already been acted on, and I do not want to say it is complete, but that work has been done.

Arien Malec

Good, and I think that is consistent with the recommendations anyway, so that is excellent.

Steven Lane

All right. Anything else on this one, then, Mark or Arien?

Mark Savage





Not from me, thank you.

Clem McDonald

There is something that comes to mind. There is a little confusion in how it is now written for SDOH because it will say we have got concerns, and that could be LOINC or SNOMED. It cannot be LOINC. It has to be SNOMED. And, on the other side, they talk about questionnaires, and they talk about LOINC or SNOMED. Well, it really should be LOINC in that case. I will get to that, but I do not know if that shows up in this part. But, one of them is for an assertion of a finding or a diagnosis, and the other one is for gathering questions with variables on the ends.

Arien Malec

Thank you. So, I think, Clem, your point is that a health status should be a SNOMED code and an assessment should be LOINC-coded.

Clem McDonald

Steve, Liz should be sending you the list of issues, kind of thinned down.

Steven Lane

All right. Was there another one you wanted to touch on this morning, Clem?

Clem McDonald

Yeah. Well, I have a number of them I wanted to touch on. If you look in your email, I think she just sent it to you with the reference numbers.

Steven Lane

Okay, I am not seeing that in my personal email.

Clem McDonald

Let me just see what is happening.

Steven Lane

Maybe we should jump out and come back, then. Clem, we will look for that. Sorry, I do not mean to be disjointed here. With regard to health status items, Mark and Arien, did we cover the highlights as you guys put them together?

Mark Savage

Steven, there were some others that got categorized as health status, but I think the suggestion that people just review to make sure that we captured them as the best use of time. So, for example, pregnancy status was an example. I think you just read it first.

Steven Lane

Yeah. Can you jump to pregnancy real quick, AI? There we go. Yes, this captures the language we put in last time. Okay, so this is basically giving support to ONC's inclusion of pregnancy status in draft V.3, correct?





Mark Savage

Correct, with the one suggestion of at least capturing intent to become pregnant because of the implications for things like fertility and medications, but not listing out, as it was under the member recommendation, but just identifying the other things for ONC's consideration.

Steven Lane

Very good. And of course, ONC will know how to consider that.

Clem McDonald

Could I clarify? Is there a specific list of answers? Do we have a particular term?

Steven Lane

I think there was a yes/no/don't know.

Mark Savage

Whether they make a use case.

AI Taylor

Data/element/definition are those three examples. That does not include [inaudible] [00:44:51] or contraceptive status, as Arien was asking about.

Steven Lane

So, the recommendation here that would come from our workgroup would be to add to the three established values in the value set the additional value of intent to become pregnant because of its importance. Does anybody object to that?

Clem McDonald

No, I just would like to know how to get it implemented as a physical variable.

AI Taylor

Other than adding it as an example or part of a value set? I think that would be sufficient, but Clem, I will just put it out there.

Clem McDonald

But, if we just present it as text like that, it will not be able to be sent around very well.

Arien Malec

No, so I think the recommendation should be inclusive of creating a value set, presumably in SNOMED. That is the list of proposed responses. And then, AI, just to be clear, this is not inclusive of contraceptive status, which means that we are not able to address REMS or other teratogenicity issues.

Clem McDonald

What is the variable here, then? Is it called pregnancy status?

Steven Lane





Pregnancy status. That is the data element.

Arien Malec

Pregnancy status, and it would be a value set, presumably encoded in SNOMED, that would be precise in terms of the meaning of each response.

Steven Lane

Any objections? No hands up? We are going to let it go. All right. Mark, anything else from the health status section?

Mark Savage

Let me just take a quick peek at a separate list, and I will get back to you in a second.

Steven Lane

No problem.

Clem McDonald

So, I have the list of the numbers.

Steven Lane

Okay. Do you want to pick another one or two to go through, Clem?

Clem McDonald

Yeah. And, Liz said she sent it to you and Arien, so I do not know. Twenty-eight.

Steven Lane

Twenty-eight. Al is going to get us there.

Clem McDonald

That is pregnancy status.

Steven Lane

Yeah, that was.

Clem McDonald

Okay, then the next one is 29.

Steven Lane

That was smoking status.

Clem McDonald

Yeah. Maybe we have already covered this. The ones we now have in USCDI are in a spec. It really does not do half of the way we usually ask it, like pack years and how you soon you wake up in the morning and take a cigarette. There are five, six, or seven very sensitive measures about the addiction and all, and they





are in LOINC and they are in PROMISE, which is that federally supported, automatic, computer-based questionnaire. So, I would like to see about extending it some.

Steven Lane

When you say “extending,” do you mean specifying a value set?

Clem McDonald

Well, specifying additional LOINC terms with answers. One of the very sensitive detectors of how addicted you are to tobacco is how early in the morning do you have to take your first smoke, and then there is pack years, which is an ancient and universal element that people have been collecting for years, and there are a handful of other ones. We could propose a specific list, but I think what we have now is just too short, and there is not a variable. It is an observation, and there is not a variable collect or package them.

Steven Lane

So, you are talking about adding, as we have discussed before, examples that could be used to populate this data element, example value sets, but not requiring specific ones?

Clem McDonald

Yes. Well, I am really talking about a package of a question and a set of answers. That is how we have done all the surveys. That is how all of the assessments are done. And then, you have a handle on the whole package, and the answers can be SNOMED or whatever.

Steven Lane

So, again, we have covered a lot of assessments, we have discussed many of them, and the idea of being able to specify example assessments that include questions and answers. So, you point out in your justification the PROMISE and the FINEX, but then you say these should not be excluded, so do you mean to say that you would like to include those as examples of instruments that could be used to capture smoking status?

Clem McDonald

Instruments or variables. I mean, you must have asked pack years in your practice.

Steven Lane

Of course. Al, do you want to comment?

Al Taylor

I did. I think somebody wrote the comment that I just entered in the workgroup discussion field. As a reminder, ONC currently requires that certified health IT capture smoking status using SNOMED, but does not specify particular codes that must be used, as they had in 2015. So, just as a matter of reference, the current requirement is to capture smoking status using SNOMED codes.

Clem McDonald

I think that is fine. I would only suggest we add to it.

Steven Lane





But AI, I think what you are saying is it was more specific, and we have made it less specific. Is that accurate?

AI Taylor

Yes, that is accurate. There was pushback on the eight that we selected because, as Clem pointed out, depending on your perspective, if you are a heart doctor, you really are more concerned about the last 30 days of smoking, if you are a cancer doctor, you worry more about the last 30 years, and because there was not an agreement about how to best use the set of codes, we actually removed the specified codes from the requirement in the CURES edition, and in USCDI.

Steven Lane

Okay. So, why don't you get out of the field, AI, so we can see which of our changes have stuck? Okay, yours stuck, mine did not.

AI Taylor

No, mine did not. I am looking at mine, and I do not see it.

Steven Lane

Okay. I guess neither one of ours did, because we were both in there at the same time. All right, is there a recommendation to come out of this, Clem? So, what you have heard is there was more specification, but there was pushback.

Clem McDonald

No, I disagree. There is a list of six SNOMED codes, and they are okay, but it is not what anyone has ever used in terms of routine practice. I would not change them. I am only suggesting we should add an assessment type of questions to capture more variants that are currently being used, which I think is what Dave is just saying.

Steven Lane

So, AI, how do you feel about that? Is that going to go anywhere?

AI Taylor

It is a change in direction, and as we have done in the past with other data elements, we had been less specific or less stringent in the requirements because there are multiple different approaches to smoking status. Again, depending on what you want to do with the information about smoking status, you could use a different kind of assessment. If you smoke at all, you are going to get smoking cessation counseling. If you have a heavy pack year history, you might get cancer screening. It depends. So, we have been less specific about how exactly to do it, meaning we do not say EHRs must be able to use specific assessments or specific code sets. So, if the workgroup wants to recommend adding back or adding more specificity, that is fine.

Clem McDonald

AI, I would suggest adding more options, some of which are more specific.

AI Taylor





Clem, all options are available if none are specified.

Clem McDonald

Give examples so people can find their way.

David McCallie

David here. It seems like we have made some progress on this general notion of assessments, and we have used that list of potentially appropriate assessments in a number of our categories, and that seems quite powerful, and it seems to me this is just another case where selecting the appropriate assessment based on clinical context makes as much sense as it does in SDOH, disability, or any of the other places where we now have a standard way to capture potentially complex information if the context requires it, or very simple information if the context does not require it. I would word it the same way as all of our other assessments.

Steven Lane

Okay. So, I just put in a recommendation, if we can slide a little to the right, on 29. “ONC to clarify that this data element could use a number of assessment instruments, and include a set of examples.” Does that sound good, AI?

Clem McDonald

What about smoking? Have you included the words “smoking history”?

Steven Lane

No, this is under smoking status.

Clem McDonald

All right. I have another one, then.

Steven Lane

Okay, one more.

Clem McDonald

Forty-one. I am going to get to a bingo here.

Steven Lane

Okay, this is laboratory specimen type, and your comment was “Should be optional.”

Clem McDonald

Yeah. I heard the arguments, but it is not true in chemistry that it is important. In microbiology, sometimes it is, but even there, there are names like “stool culture.” It is all connected, and it would be a huge burden to the laboratories and users to have to be specific all the time. I think there are many good cases to have additional specificity in a specimen because there is some particular peculiar reality, but the average test is serum, or it is blood, or it is urine. They are all concatenated in one name in all the lab manuals and all the lab offerings, so I just do not think we should make it required.





Steven Lane

And here again, AI, would you consider the fact that there is a data element called “specimen type” within the laboratory class? Does that imply that this is required for every single laboratory test, or simply that this is where it would be captured and would be sent if available?

AI Taylor

Two things. The reason that we added it is because it is a critical piece of certain sets of labs, and it is an available piece for many, if not all, kinds of labs, and in particular, this was brought up in response to the COVID pandemic, where specimen type is critical to the validation of the lab test itself. If it is an inappropriate specimen, it is not a valid result. And so, this is specifically introduced to address some of the requirements around pandemic labs. If it were to be part of USCDI as a data element and it was made available for voluntary update by EHRs, an EHR voluntarily updated to a future USCDI version, then it would be required that that updated EHR be able to capture specimen type.

Hans Buitendijk

Is it that it captures it or that it is able to report on it, which are two different things?

AI Taylor

Able to capture and exchange in the appropriate exchange transaction.

Hans Buitendijk

I think at some point, we need to define terms like “capture,” “maintenance,” and “support” further.

Clem McDonald

Well, there is structure in all the messages in V.2 and FHIR for a specimen, and it is like six, seven, or eight elements. It is not a simple element. Clearly, it needs to be available, but there is still the implication. If you look at lab testing, 98% of it has the name of the specimen in the test, and it does not cause any problems. So, I do not know if it would be a big burden to make that have to change.

Steven Lane

Arien?

Arien Malec

I have got my hand up. Just from a perspective of following process, part of the conceptual issue that we have here, and I have been framing mentally some recommendations and written some to a number of people, is that we have two classes, medications and labs, that are, in fact, highly formally specified in interoperability requirements that are in certification, so for medications, the controlling data classes and data elements are controlled by the implied content model in NCPDP script standard as well as the implied content model in consolidated CDA and FHIR, and for lab, a little less specified because we do not require LRI and LOI, but in practice, every EHR and many certified health information technology systems can interoperate lab data via HL7 V.2, and certainly are required to interoperate via consolidated CDA and FHIR, that each have a content model that is inclusive of multiple elements.

And, the landing place for me that would be the best here would be to repoint USCDI to the implied content model for interoperability that is already specified in those implementation guides rather than adding on-





twosie “Well, we need to do this because it is required by COVID.” Well, what about the other thing that is already required that is not already specified? It would be better to do fell-swoop content modeling.

And then, with respect to this notion of “required to capture,” when you look at interoperability specifications, in some cases, interoperability specifications require certain elements because that data class does not mean anything without the inclusion of the required data element, but in many cases, we intentionally do “required if known” or other kinds of content specifiers to underscore that in real-world interoperability, there are many things that should be included if they are available, but are not always available. As Clem notes, specimen type, test kit, etc. may be implied in the order or the orderable and implicit in the orderable. They may be well-known specimen types. It may be pleonastic to include them, but there are cases where it is important to include them and they should be included when relevant, and again, pointing at the implied content models that are already in place for interoperability would, I think, address this area better than adding onsie-twosie element types based on Use Case X and Use Case Y when, in fact, all of this information is already specified in the controlling interoperability requirements.

Steven Lane

Hung Luu?

Hung S. Luu

I guess I would like clarification on Arien’s strategy, then. Are we then to just leave the lab section blank and just say “refer to LRR,” or are we saying that we should, in fact, be inclusive of all the elements that have been specified and will be specified in interoperability strategies and make the lab list more robust? Because currently, the two lab elements currently contained in Version 1 and Version 2 are inadequate for interoperability, and my concern is a lot of interoperability is happening now. If the effort to make this list more inclusive takes five to 10 years because some of the elements are not even comment section, then that is going to hold back a lot of progress.

Arien Malec

Hans wants to get in.

Hans Buitendijk

Yes. I generally agree with Arien that we have a bolus of standards where a lot of this data is actually already defined. Some of those already are, in different ways, part of certification programs, other ones are not, but it is out there, and I support his suggestion, as it also indicates that USCDI really should start to encompass full EHI. At the same point in time, does that need to be done immediately, or are we looking more for attributes for which standards do not fully exist yet or have not been adopted? I think it is a roadmap discussion at some point in time to be had because clearly, it is going to be a multiyear process to get to them all. But yes, all these things are defined in standards, but they are not necessarily defined in C-CDA or FHIR US CORE.

So, while it is in ELR, ECR, or some places that support workflows, it is not in the general access capabilities that FHIR US CORE have. So, we also need to start to harmonize that because that is going to get increasingly challenging. I am wondering whether that should be a discussion on how do we want to progress USCDI after we wrap up the immediate USCDI Version 3 recommendations, and then focus on how should it really grow, what should it focus on, and can we take advantage of those boluses of work.





Arien Malec

That is right. So, Hans, just to be precise, the way that I would recommend doing this, and I agree that we probably should take this on after we finish our ISA portion, but the way that I would formalize doing this would be to point USCDI at the implied content model that is already required by implementation guides that are in certification, and then assess the adds to that content model for items that are not already required in implementation guidance, carefully coordinated with the implementation guidance that would then require or add those additional data elements. To memorialize that, if we do not have LRI and LOI guides in certification, which we do not, then the controlling content model is the US CORE FHIR model, as well as the consolidated CDA model. We would formalize what that is, and then we would propose adding to USCDI in conjunction with adding to the US CORE standards.

Hans Buitendijk

Arien, I generally agree with that. I just want to note that to date, the USCDI has been focusing on vocabulary standards only that are being referenced. It is not referencing any other standards. Those standards are more the opposite direction, “What do I need for certification?”, that support the USCDI, and that is where the other one is coming. So, we have to work through that, so, having that conversation after USCDI V.3 would be great if we can put it on the calendar.

Steven Lane

Okay. So, again, the recommendation I am trying to capture is not really for our report to HITAC, but for subsequent work. Is that fair?

Arien Malec

Yeah, and I think in our report to HITAC, we would acknowledge that this issue exists and list it as a priority for immediate future work.

Steven Lane

Great. All right. Clem, last word.

Clem McDonald

I think I am fine without that resolved. I have got three more, but really, the one I would like to get in relates to something Arien brought up. It is really two things. I do not know whether it is 60 or 61, but basically, I think we have to include what we used to call the normal flag. It is in the interpretation. Everybody uses that. You read the report, and you look for those little Hs or stars or whatever, and it just pains me that they are not in there. Apropos of what Arien brought up, we ought to have normal ranges in there too because that is one way to validate across different sources and all the rest, and I do not know why that has been forgotten, but those two things, the normal ranges, though I think “reference range” is the official name, and the interpretation, which is really an abnormal flag, which it used to be called, just a signal, not a text interpretation, are so useful in reporting and all that I just do not understand how we forgot them.

Steven Lane

Al, can you clarify? Are those at Level 2?

Clem McDonald





I do not think so.

AI Taylor

Specifically reference ranges?

Steven Lane

Reference range and the normal/abnormal, perhaps critical flag.

AI Taylor

I would have to check to see if those are in USCDI at all.

Clem McDonald

I do not think they are, AI, and it is as much my fault as anyone's because I have been on this for the whole time.

Steven Lane

Thank you, Clem, for raising that, and we are going to move on. Thank you so much, Hans, Clem, Mark, etc.

Clem McDonald

Are you going to take a position on that?

Steven Lane

We cannot. It is not in our scope. Unless it is at Level 2, we cannot discuss it.

Clem McDonald

Well, Level 3, I thought we could propose new ones.

Steven Lane

Yeah, but we can only choose from Level 2 to bring them into Version 3. We cannot bring them out of thin air at this point. That is a different process. AI is shaking his head in agreement. So, I want to move to Hung Luu, who put a lot of effort and made a presentation to us last time, and I wanted to come back to those recommendations and see if we can finalize anything out of those before we go to public comment. Hung?

Hung S. Luu

Thank you, Steven. And so, the additions I would like is the test kit identifier and specimen source site, and also to specify, for values and results, the ontology to be SNOMED so that it is standardized across reporting. So, the reason is partly COVID because of the fact that some of this information is required by the government agencies to be reported by the lab, but currently, there are not uniform opportunities for labs to capture and transmit the information. The laboratories are still meeting the laboratory requirements. Oftentimes, it is a lot of workaround, and so, I am asking that this be included in Version 3 so that it can be accommodated by the electronic infrastructure so that it is not manual entry by laboratories trying to meet the regulatory requirements for this. And also, in the future, for a future use of laboratory data, in order to have robust interoperability, we cannot subsist on the few lab elements that are currently in there. There is the recommendation that there has to be a more robust coding system, and I think this would contribute to





that. Especially as the FDA moves toward real-world data use for regulatory decision making, a lot of these elements are essential and are not currently captured in our current coding and transmission strategies.

Steven Lane

So, those are pretty straightforward recommendations. In Column H, “Recommend inclusion of test kit unique identifier in V.3, and include SNOMED CT under applicable standards for values, results, as well as specimen type,” which we were discussing earlier. Does anyone want to support or refute those recommendations?

Clem McDonald

Isn't this just the same problem we had with normal range?

Arien Malec

Yeah, it is the same issue. There is a bunch of stuff that is obvious and already specified in US CORE that is not currently in USCDI. I think of all of this, the “add SNOMED as applicable” standard is the cleanest, just given the existing structure of USCDI, but I think for the rest of it, we would want to go down the route that we just discussed.

Hans Buitendijk

And, maybe to add, actually, as we get to this level of detail, a lot of this is in other standards than FHIR US CORE or C-CDA, and it is a question of how do we pull those in, because that knowledge, those exchanges, lab reporting for public health, otherwise are already happening, even if that happens at some points in time in a very localized way.

Arien Malec

Yup, and people have mentioned CLIA as well, CLIA CAP, but particularly CLIA because HHS already has regulatory requirements for data elements.

Steven Lane

So, with regard to the test kit unique identifier and its inclusion in V.3, I know, Arien, you had some thoughts about that last week.

Arien Malec

Again, for that one in particular, my general stance is we should structure the obvious and already included by default because they are included in FHIR, or included in consolidated CDA, or included in CORE before we add the non-obvious ones, or the ones that require changes to implementation guidance. As I said, of all of these, the cleanest one to add would be adding SNOMED as an applicable vocabulary standard because it is already de facto required for interpreting values, as opposed to findings, as opposed to numeric values.

Clem McDonald

It is already in the lab specifications.

Arien Malec

It is already in the lab specifications, yup.





Hans Buitendijk

Yeah, and to note is that test kit unique identifier is not necessarily clarified in FHIR US CORE. It is a work in progress in ELR, or has already been specified **[inaudible] [01:13:59]**.

Steven Lane

Yeah, that is definitely another specification that actually is de facto required, which is the ELR spec, but alas, the LRI and LOI specs have never been required in certification.

Hans Buitendijk

LRI has been.

Steven Lane

All right, so, what is the discrete recommendation we would like to propose? Actually, AI, why don't you make your comment first?

AI Taylor

I just had a question, and pardon my ignorance on this. Who manages the list of test kit unique identifiers?

Clem McDonald

The FDA, I think. I am not sure.

AI Taylor

Is that right, Hung?

Hung S. Luu

Yes, the FDA.

Hans Buitendijk

At least from an approval perspective, yes.

AI Taylor

Well, presumably, it would be approved test kits and machines that are running these tests.

Hans Buitendijk

Yeah, they are effectively unique identifiers.

AI Taylor

I did have another follow-up question on that. Is there a direct link between a test kit? Because I think that when they are approved, the test kits get a LOINC code or have a LOINC code associated with it, which I want to say that maybe the test kit LOINC code might be unique. If that is not true, let me know.

Hung S. Luu

No, that is not true. The LOINC codes are many to one, and so, many test kits are coded to a single LOINC code, which posts to **[inaudible – crosstalk] [01:15:33]**.





Hans Buitendijk

The LOINC code represents the test. The test kit is the device, and that can be identified by manufacturers in a variety of different ways. So, test kits are approved, but not necessarily identifiable.

Clem McDonald

Could I add to that? It is a complex space, so there could be separate test kits or codes from the FDA for the reagents, for the machine that does it, they can have different sorts of reagents in different cases so it is often a hierarchy or a cluster of things, so just be aware of that complexity that might occur. And, the LOINC codes can be many to many because the test kits will not often distinguish between specimens.

Steven Lane

All right, I would like to formulate some recommendations, and I am going to turn to my illustrious cochair Arien to help us with this. Let's look at Hung's recommendations regarding SNOMED for both specimen type and values/results. Show should we phrase this?

Arien Malec

This would be one that we recommend that in USCDI V.3, SNOMED CT be included as a value set or a vocabulary standard applicable to qualitative findings.

Steven Lane

These in particular for values, results, and specimen type.

Arien Malec

Yeah. Right now, lab results include LOINC as a vocabulary standard. We would propose including SNOMED as a vocabulary standard, so LOINC is the test, UCUM typically is the... So, it is either a numeric value with a UCUM code or a SNOMED code if it is a quantitative finding.

Clem McDonald

So, that was exactly what was specified in the previous version of USCDI. They split them out, saying if the answer is quantitative, it has to have UCUM, if it is not quantitative or if it is ordinal/nominal, it has to have a SNOMED code, and the test itself is LOINC. That is an old spec.

Arien Malec

Yeah. This has been a consistent set of recommendations.

Steven Lane

All right. So, here, let me get out of my field so you can see what I wrote. So, "Recommend that USCDI V.3 note SNOMED CT is an applicable vocabulary standard for values and results, LOINC still used to specify tests, UCUM for units." Sorry, you will have to scroll a little bit there, Al, or I will just shrink something so we can see it better. Okay, Al, can you refresh a little bit so we can all see that? There we go.

Arien Malec

Yup, and I would just use "qualitative" for qualitative lab results.





AI Taylor

Yeah, we got it.

Clem McDonald

I think the word “value” would be safer. “Result” is a very ambiguous term that often includes both the test identifier and the content of what comes out of it. I think if you distinguish between value as the thing we are talking about or the answer, it would be clearer.

Steven Lane

AI, you are in the field. Do you want to make a change there to make it clearer, or do you want to recommend a change?

AI Taylor

For value/results?

Clem McDonald

I think that is good now.

AI Taylor

We know that SNOMED results are qualitative and UCUM are quantitative. We get that. There are a set of LOINC answers as well. Some of them are mapped to SNOMED. I just throw that out because we were, at a time, considering LOINC, SNOMED, and UCUM as reasonable options for applicable standards, but because there were “so many” different potential applicable standards, we went to none, basically.

Steven Lane

And, for specimen type?

AI Taylor

Well, specimen type is interesting because although SNOMED is recommended, my understanding is that the LOINC codes are the ones that are used to associate specimen type in the LIVD set, but I might be wrong on that. Somebody can quickly correct me if I am wrong.

Hung S. Luu

Actually, the LIVD set specifies SNOMED for the specimen type.

AI Taylor

Thank you for correcting me. So, that recommendation aligns with the LIVD set, which is really the model for this becoming a new data element.

Clem McDonald

Could I just bring up one more issue of the answers? So, we should clarify. SNOMEDs are concept code answers, and at least in some spaces, and I think it has been as true of the recent assessments, that survey instrument creators do not like to play with the words in their surveys. They want exactly that same string. And so, when those strings are replaced with a concept, it often does not come out to be the same validated





survey instrument. So, just be aware of that. In some cases, it would almost be ideal to have both of them. The SNOMED code is a string code, literally what that string was, just for the record.

AI Taylor

Yeah, the LIVD cross test works through that, Clem, and that is how they came with a set of defined codes that define the universe of specimen types.

Steven Lane

And, with regard to the test kit unique identifier, are we going to leave that for another day?

Clem McDonald

I think we need to dig a little deeper. It would be good. I support it if we can make it happen. I am not even sure if the FDA is getting everything codes yet. Does anyone know?

Steven Lane

Hung, do you want to comment?

Hung S. Luu

It is a requirement, and so, this is a requirement that has to be met by the laboratories to provide the test kit information for the COVID testing that they are supplying to the public health laboratories.

Clem McDonald

I understand, but there are laboratory-developed tests that do not get those, and I thought the FDA was a bit behind on getting everything coded. I am not sure.

Hung S. Luu

And, that is also in the newest version of the LIVD file, is that there is information for the test kit and the instrument. And so, this would make it decrease the burden on the laboratories to have to manually supply it when we could accommodate it through the electronic infrastructure.

Steven Lane

Okay. Somebody popped a recommendation into Column K, which is oddly formatted, but that is okay.

AI Taylor

It was me, sorry.

Steven Lane

There, I will get it out of there. You need to wrap your text.

AI Taylor

I do not know how to do it.

Steven Lane





Get out of there, I will do it. "Format, wrapping, wrap." There we go. All right. So, Al, you suggested "Recommended inclusion in V.3 of FDA test kit unique identifier as applicable standard or value set." Again, that is not a requirement, it is if you have it, you should exchange it using this. Arien, can you live with that?

Arien Malec

As I said, my conceptual issue is not including this, my conceptual issue is all the other stuff that is super obvious that is actually much more impactful for interoperability that we are not including, as Clem notes, reference ranges, without which it is really hard to interpret a test result. If I had to get something, I would get a reference range and a normality indicator over getting the test kit.

Clem McDonald

I would like to understand why we can add the test kit, which I think is a good idea, but we cannot add reference range.

Arien Malec

Clem, my interpretation here is that in the early days of USCDI, we as a nation made a decision that lab and medication are really complex objects that are already formally specified in implementation guides, and it would be really complicated to put together a reference model, so we are just going to call it medications and labs because everyone knows what they are, and then, now, we are looking at that and thinking we need to add something, but we do not know now what forms the core set that we are adding to or that we are proposing against. That would be my interpretation of how we got to this place, is some day, back in the past for USCDI V.1, we all thought we knew what we were talking about because we had the core specifications, both for consolidated CDA and FHIR, we had the applicable implementation specifications, we thought we knew what all these things meant, and now we are trying to add to these things, but we are not quite clear what we are adding to.

Steven Lane

Okay, let's hold that thought and go to public comment.

Public Comment (01:26:19)

Michael Berry

Great, thank you. We are going to open up our meeting today for public comment, so 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 on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your lines. Let's look to see if we have any public comments. And, I am not seeing any public comments. Oh, we had one that popped her hand up. Laura King, you have three minutes.

Laura King

Hi, thank you so much. So, my name is Laura King. I am the Director of Public Health at the American Heart Association, and my background and training is being a registered nurse, and I have worked in public health for over 25 years. First, I want to thank the Interoperability Standards Workgroup and the ONC for their efforts to advance and expand the United States Core Data for Interoperability. High blood pressure impacts more than 120 million people in the U.S., and it is the leading modifiable risk factor for preventing death from cardiovascular disease.





The accurate measurement and interpretation of blood pressure is vital for diagnosing high blood pressure and assessing effectiveness of treatment. Access to a common set of health data classes and elements will help physicians, healthcare practitioners, and public health professionals diagnose, treat, and care for patients with high blood pressure and ensure these individuals are engaged and empowered with data and much needed information and support across the healthcare community.

The clinical evidence and guidelines outline the importance of proper estimation of individual's blood pressure requires multiple blood pressure measurement readings, meaning that the blood pressure should be diagnosed after two or more blood pressure readings and have obtained at separate intervals and then averaged. This is the case regardless of where their blood pressure is taken, such as in an office setting, or if a patient is measuring their own blood pressure at home. Thus, consistent communication of average blood pressure is critical for addressing hypertension nationwide. Including the average blood pressure in the USCDI Plus would make it easier for physicians and other healthcare providers to diagnose and treat blood pressure and access blood pressure control more accurately.

Practitioners need health IT systems that can store and exchange average BP separate and apart from individual readings. This would assist with improved documentation, enabling physicians to utilize more accurate and appropriate information in their clinical decision making and help solve one of many interoperability issues that have challenged the systemic uptake of SMBP, which is outlined in the PHI report. The Centers for Disease Control and Prevention, the American Medical Association, and the National Association of Community Health Centers agree with the American Heart Association and support a standardized average blood pressure data element. The AHA asks the Interoperability Standards Workgroup to include the Level 2 average blood pressure data element and its recommendations for inclusion in the USCDI Version 3. Thank you.

Steven Lane

Thank you so much, Laura. We really appreciate that. Is there another public comment?

Michael Berry

I am not seeing any other public comments, Steven.

Steven Lane

Wonderful. Laura, of note, one of your colleagues also made that same recommendation last week, I think, and we have not had a chance to take it up as a workgroup, but certainly, your recommendations have been recorded in the public record, and ONC is well aware of them, so thank you. That does bring us to time, painfully. We, your cochairs and leads, will continue to try to capture and massage the recommendations. Real quick, Al and Mike, my recollection is we do not have a second meeting this week. We are meeting again next week, and I think that is the last time we have to go through any recommendations before we craft the draft document to then review with this group on the 5th. Do I have that right?

Michael Berry

Yeah, the 5th is the last opportunity that we have to review finalized recommendations before we finish constructing the letter.





Steven Lane

Okay, so the 29th will be another chance to go through recommendations that have been submitted, and we will go through the list again and prioritize those to bring forward to this group, and we will let you know with the homework. Once again, if any of you, including Clem, have particularly high-priority items that you would really like us to address next week, please let us know and we will try to put that on the agenda.

Clem McDonald

I do, Steve. I have three more, I think.

Steven Lane

Good. Resend us the three, and we will see if we can fit them in next week, okay, Clem?

Clem McDonald

Okay, thank you.

Steven Lane

Same to you, Hans. If you have a couple more, hopefully we will have time for them.

Hans Buitendijk

Sounds good.

Steven Lane

Thank you all. Have a great day.

Arien Malec

Thanks, all.

Mark Savage

Thank you.

Adjourn (01:31:42)

