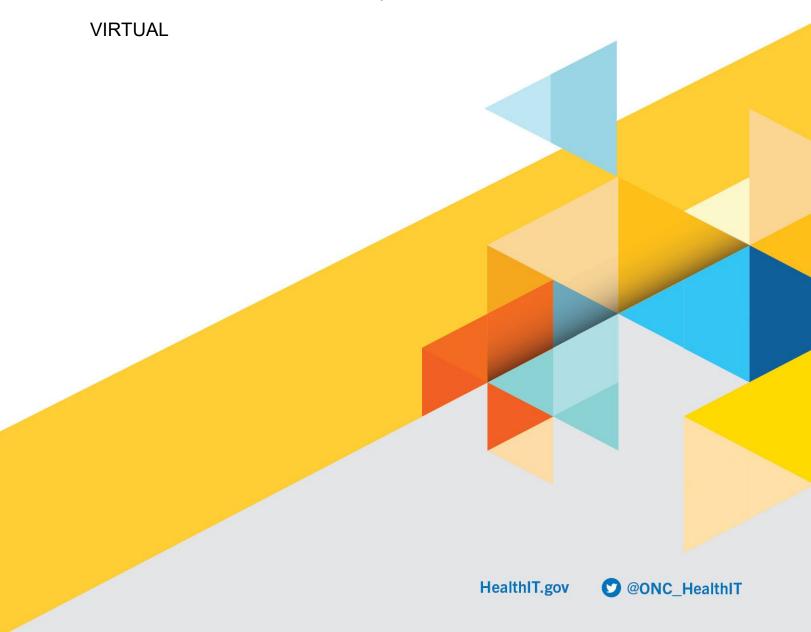
## **Transcript**

# HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) U.S. CORE DATA FOR INTEROPERABILITY TASK FORCE 2021 MEETING

June 29, 2021, 10:30 a.m. - 12:00 p.m. ET



## **Speakers**

Name	Organization	Role
Leslie Kelly Hall	Engaging Patient Strategy	Co-Chair
Steven Lane	Sutter Health	Co-Chair
Ricky Bloomfield	Apple	Member
Hans Buitendijk	Cerner	Member
Grace Cordovano	Enlightening Results	Member
Jim Jirjis	HCA Healthcare	Member
Ken Kawamoto	University of Utah Health	Member
John Kilbourne	Department of Veterans Health Affairs	Member
Leslie Lenert	Medical University of South Carolina	Member
Clement McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Mark Savage	Savage Consulting	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Daniel Vreeman	RTI International	Member
Denise Webb	Indiana Hemophilia and Thrombosis Center	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	Staff Lead



#### Operator

All lines are now bridged.

#### Michael Berry

Great. Thank you very much and good morning, everyone. I'm Mike Berry with ONC. And I'd like to welcome you all back to the USCDI task force. We really appreciate you being with us today. I'm going to open up today's meeting with roll call. And I'll start with our co-chairs. Steven Lane.

#### Steven Lane

Good morning.

#### Michael Berry

Leslie Kelly Hall.

#### **Leslie Kelly Hall**

Hello.

#### **Michael Berry**

Ricky Bloomfield.

#### **Ricky Bloomfield**

Good morning. I'm here.

#### Michael Berry

Hans Buitendijk. Grace Cordovano. Jim Jirjis. Ken Kawamoto. John Kilbourne.

## John Kilbourne

Good morning.

#### Michael Berry

Leslie Lenert. Clem McDonald. Aaron Miri. Brett Oliver. Mark Savage.

## Mark Savage

Good morning.

#### Michael Berry

Michelle Schreiber. Abby Sears. Sasha TerMaat.

#### Sasha TerMaat

Good morning.

#### Michael Berry

Andrew Truscott. Sheryl Turney.



#### Sheryl Turney

Good morning.

#### Michael Berry

Daniel Vreeman.

#### **Daniel Vreeman**

Good morning.

#### Michael Berry

And Denise Webb.

#### **Denise Webb**

Hello. Good morning.

#### **Michael Berry**

Good morning, everyone. I see a number of other task force members joining us and we'll take note of their attendance as we go. And now, I'd like to turn it over to our co-chairs, Steven and Leslie.

#### Past Meeting Notes (00:01:38)

#### **Steven Lane**

Thank you so much, Mike. And sorry my camera is not working. I just downloaded the new Adobe and it looks different but it's not giving me that option. So, you'll have to believe that I'm standing here in foggy California and it's all good. Thank you all as usual for joining us. I see we've got great participation this morning and really appreciate people's time and attention. We continue to endeavor to post our past meeting notes to the web. I, actually, have the last two weeks waiting for me to review them. I'm going to hope they get to that today and we'll get those up shortly. We continue to focus in on our Phase 3, Task 3 recommendations today. And we will, of course, have public comment five minutes before the end of our meeting as always. We really do invite any members of the public who are joining us this morning to feel free to chime in and offer us verbal commentary. I, actually, don't see any public members this morning. Usually, they're here with us but maybe they'll join.

Did anyone have anything else that they wanted to be sure that we touched on today that's not on the agenda?

#### **Leslie Kelly Hall**

I think we're good.

#### Task 3 Recommendations (00:03:05)

#### **Steven Lane**

Great. Okay. I think on the next slide, we have a reminder of our Task 3. And here it is. A reminder that we've been through our Phases 1 and 2, have made our recommendations to the HITAC and they have been transmitted to the national coordinator. And now, we're working on developing recommended priorities for the Version 3 submission cycle. I think we're all looking forward to July 8 in just a couple of weeks when



HITAC

Al has told us that USCDI Version 2 is going to be published as well as the guidance for the Version 3 submission cycle, which, of course, is already in process but has not had a lot of traction. Al, is there anything you want to tell us about the July 8 plans? Anything we should be aware of?

#### Al Taylor

Only that that date is not an official date and it's subject to change.

#### **Steven Lane**

All right. Very good. And we do have planned our next meeting after today will be July 20 when we are going to be reviewing the Version 2 publication as well as the guidance for the Version 3 cycle. Actually, it's interesting. I'm sure Al, the team is hard at work putting together all of those materials and preparing for their publication and communication. And our task force, we hope, has had a chance to inform that process. It would be great to see how you've put that all together and what we're going to be up for the next cycle. So, today what we wanted to do was go back to the documents that we have been rather slowly and painstakingly constructing with our recommendations for Version 3. And I don't know, Al, if you want to be ready to pull up our two Google Docs. I think that would be great. But we started initially developing a spreadsheet the described specific data elements that we thought were worth discussing. And we used that when we made especially our Version 1 recommendations.

Since then, we did identify a number of those data elements that we were going to defer for our Task 3. And we have that list in the spreadsheet that is mostly things that we talked about early on. There are a couple that have been added since based on discussions both with the ISP task force and the public health folks. Mark has put a lot of effort into adding a couple of items in that spreadsheet. But I think the real key question in my mind and one that I hope we can address is whether it's necessary for us as a task force in our Task 3 submissions to be focused on individual data elements. There is, as we well know and as we have provided commentary, there is an established process through the ONDEC for stakeholders to submit data elements to provide commentary and support for data elements. And there is a clear path for data elements to be elevated from comment Level 1 to Level 2, into a draft and, subsequently, into a final version of USCDI.

And we've added a lot of commentary as to how we think that ought to go and we'll see what ONC has done with our ideas. But at the level of individual data elements, I don't really know that having the task force throw their weight behind them at this point in the process really makes sense. I think when we start the next process and we're invited to provide input on a draft Version 3 then, it really makes sense to get into the individual data elements. But at this point, the data element is either going to be submitted or it won't. It's going to be leveled according to specific criteria. And I'm just not personally sure what good it does for us to spend a lot of time focused on individual data elements at this point in the cycle. So, interested to hear what other people think about that perspective before we dive into individual data elements and discussing them.

#### Leslie Kelly Hall

So, Steven, I also agree with you because I think what has come up through this process has really been items that could be reflected as guiding principles or clarification requests at a very high level. And so, I think that's where we've ended up with most of our emphasis on the V3 comments. So, I agree with that approach. We have a lot of agreement coming through the chat.





Okay. Hans, Sheryl, Denise.

#### Leslie Kelly Hall

Mark's hand is raised. Mark?

#### Mark Savage

Sure. So, I think the one thing I'd add is I think it is okay for us to have thoughts now about gaps. We've had that conversation and recommending how ONC sets priorities. So, yes, we've laid out those principles. But in the interest of making most efficient use of time in a linear process, I do think any thoughts from the task force on gaps could be useful without getting into the minutia of individual data elements.

#### **Steven Lane**

I think that's fair. Thank you. And thank you for the task force members who are joining late. Welcome, welcome. So, again, I think what I had hoped to do was kind of quickly run down the list of submitted data elements. I don't want to spend too much time on it if we can avoid it but just see if there is something there that really does warrant a flag or a commentary recommendation from us as part of our Task 3 knowing that we'll be spending much of August pulling those detailed recommendations together. So, I'm just going to run us down. And I think, Al, what we're looking for is the spreadsheet, not the Word document. So, we got the Word document. See if you can get your way to the spreadsheet. That's where we're going to start. That's perfect. Okay. But I'm just going to speak to it and, hopefully, all of you have access to it. I see that Hans is in it presently and Dan is there. So, most of you know where you're going.

So, I, actually, spoke to Terry O'Malley this morning about the first item that he had presented about provenance and the time and the individual who did the last data review. I also had a chance to interact with Hans and Ricky about that. And I think Terry's feeling is that there is a desire here to know who and when the most recent review was performed of a given data element. This has not been submitted to ONDEC. This is not in the hopper. There are lots of provenance data elements that are in the hopper making their way through the process. And Terry's feeling that he may arrange to have this submitted to ONDEC. But at this point, he felt that we didn't need to focus too much on this. So, I just wanted to acknowledge that we had closed the loop on that. And, again, Al is showing the Word doc and we're speaking to the spreadsheet at the moment.

#### Clem McDonald

Hey, Steve, could you make it a little bigger?

#### **Steven Lane**

Again, we're looking at the wrong document. There you go. This is the one we want. So, hopefully, you can see that one, Clem. And I'd really invite you to pull it up yourself if you can on another screen so you can navigate as needed.

#### **Clem McDonald**

Yeah. That's fine.



#### **Steven Lane**

The next one had to do with operative notes. Again, we've discussed this. It's a note type that was not included in USCDI Version 1. It has not even been suggested for Version 2. No one has weighed in on this in ONDEC. We discussed this and encouraged people to do this. But I don't think, again, that there is really a need for our task force to weigh in on this, at this point, except really, I think, just to generally encourage people to engage with ONDEC, to add comments and make their voices heard. But I don't think there would be a need to weigh in. Yes, sir.

#### Clem McDonald

I thought the operative note was not expressively stated but is part of the clinical notes.

#### Steven Lane

It's not explicitly stated and the LOINC code for procedure notes was explicitly included but the procedure notes, when you look in LOINC, are the non-operative procedures. So, whoever put together V1, specifically, includes procedure notes and didn't include operative notes. But you're right. You could, certainly, send them. Our organization is making them available and everyone is going to need to make them available as part of the transition to all EHI under information blocking in October of 2022. But whether or not somebody wants to add this as a request in ONDEC for us to be considered for Version 3, obviously, it would be a very small list. It's just another LOINC code. It would be easy to include that in Version 3 but is that going to really make a difference given the transition to all EHI just next year? So, again, someone can do that if they think it's worth it but it's not our place to comment is my thought.

#### Leslie Kelly Hall

Steven, I do think it's worth a comment only because it's so key to many patient stakeholders who don't have that access now. And it is a common area of suppression when speaking in other committees where folks say operative notes not appropriate. And it is. So, we just want to make sure that that doesn't get put under the rug.

#### Unknown

There's also a common use case for cancer patients, post op, second opinion, which I know has been a hot topic as well. So, the benefit to risk ratio is high.

#### Steven Lane

Yes. Having said that, I don't think it does any good for our task force to weigh in on this in the absence of somebody going to the trouble make a request in ONDEC.

#### Al Taylor

Steven, this is Al. The Social Security Administration made a group submission for addition of about, I don't know exactly the number, but it was quite a number of data elements. And I believe that was one of the data elements that were submitted. Well, it was a combined list of clinical notes that Social Security Administration had requested. So, technically, I think it was just added as a group.

#### Steven Lane

Got it. Okay. Well, I'm capturing this in the spreadsheets. Again, does anybody feel that this is worthy of a task force recommendation to HITAC given that it's already captured? So, it's a yes.



#### **Leslie Kelly Hall**

Yes.

#### **Steven Lane**

Okay. So, make formal recommendation. All right. I've captured that. Is there anything else on that? Unfortunately, I don't think we wanted Hans to put the link to the document in the public chat. I did that in a prior task force and got my hand slapped for it. We try to keep those to ourselves and not anybody in the public.

#### Hans Buitendijk

I didn't realize this was for the public. I thought it was the member chat.

#### **Steven Lane**

Yeah. We don't have any public on the phone at the moment so I think you may be good. I think we can just invite the ONC to leave that out of our posted minutes. That would probably be best.

#### Hans Buitendijk

[Inaudible] [00:16:25]. Yes. I'm sorry.

#### **Steven Lane**

Okay. The next one was reason for visit.

## **Clem McDonald**

Just a clarification. There is a code called surgical operative notes. It's [inaudible] [00:16:42] just for the record.

#### **Steven Lane**

Yes, indeed. All right. Reason for visit, here, again, we felt that this was something that was worth capturing as a data element. Again, we could include that as a task force recommendation but there is an established process for that being submitted and advanced through the ONDEC system. So, I don't know whether anyone feels that that warrants task force recommendations, specifically. All right. I'll just let people speak up. Grace, you were the original one who submitted that. I think we all agree that it's a great data element and it should, eventually, make its way and that it will be included in all EHI though it's unclear how that's going to all manifest next year.

#### **Grace Cordovano**

Steven, it's Grace. I'm sorry. I just want to be sure I'm 100% clear here. Anything that anyone added into this Google Doc early on in our process and throughout these task force meetings also needs to be formally submitted in ONDEC to be consistent and comprehensive, right?

#### **Steven Lane**

The only way anything gets into USCDI, as far as we know, is it gets submitted in ONDEC. And then, it goes through the process of leveling prioritization and selection. So, us independently weighing in, as far



as I know, doesn't provide a path to USCDI inclusion. We can weigh in on things that are in ONDEC. But I don't recall, and maybe Al does, whether this one, actually, is already in ONDEC.

#### Al Taylor

I was reading the provision. I think it is.

#### **Steven Lane**

Okay.

#### **Grace Cordovano**

Can I make a suggestion for process moving forward? Is it possible that we encourage, for future task force suggestions, instead of going into a Google Doc first encouraging ONDEC and pulling down new things that are submitted into a Google Doc for discussion so that we know that they're already formally submitted? Would that help?

## **Steven Lane**

Yeah. We did discuss that early on sort of having an extract of what was in ONDEC to inform our discussions. And I think the feeling was that that was going to be a lot of work and that everyone had access to ONDEC and they could look at it. I think there are a lot of things in ONDEC. There are hundreds of submissions so it can be a little challenging to find everything and know what's there and perhaps having it in a spreadsheet format would make that more valuable. And Al, we did talk about that early on and I don't think we did anything with that. Can you comment?

#### Al Taylor

Well, as far as a capability to extract that doesn't exist right now. But Grace, all of the published data elements, which are the ones that were accepted and given a level are available on the three different tabs in ONDEC. So, Level 2, which are the ones primarily considered for addition to USCDI in future versions along with Level 1 and comment, which are the ones that might need some additional work. So, that's readily available, public, and always updated. So, I would caution a little bit about relying on an extracted spreadsheet, which is a point in time snapshot. But the purpose of those level tabs is to provide the most updated information. So, I would recommend relying on that. We are working on an enhanced search function to allow both submitters and reviewers to just go looking for something that they're thinking of. I think that would help. So, if we're thinking of reason, you can type in "reason" in the search field and you should be able to come up with the data element that represents that reason for visit if it's there.

So, I would lean towards not creating an extract function and just relying on updated information that's on the live website.

#### **Steven Lane**

Thanks, Al. And, again, I do think it makes sense for us when we start the V3 cycle next year to look carefully at what's in Level 2 and have comments on those items that are high priority to advance to the next version. But, again, I think spending a lot of time with the task force weighing in at the comment level or Level 1 really doesn't do us a lot of good if things are misleveled in our personal perception. We should go in and make those comments in ONDEC as a task force.



#### **Leslie Kelly Hall**

I would encourage, once it's in ONDEC though that we do have that ability. So, now if we have some gaps like this then, I think we need to make sure that it's noted and that we can offer the support. So, this would be offering support of this contingent upon ONDEC entry.

#### **Steven Lane**

Perfect. Okay. Again, I don't mean to be rude but I also want to make sure we make progress here. The next one was date of immunization. What was the point here? We recommended including it in Version 2 and then, it's already covered in the CDA and US Core. And I guess we dropped it and left it for this discussion. I don't distinctly recall that discussion. But, again, I don't think there is anything in terms of our overall Version 3 priorities where we need to weigh in on this so much as waiting for next year's cycle. The next one was an autopsy report, again, a very specific report type. I think we did have some discussion about how valuable this is and the fact that it is. I don't recall whether there is a specific LOINC code for this particular report. I don't know if anybody on the call knows that. Again, I don't think it was every submitted in ONDEC. So, if it's important to a population, it should be submitted and advanced through the process.

#### Clem McDonald

So, Steve, I just want to clarify. There is a general category that's been approved and is going to come forth about clinical notes. I thought it included all of those things. Now, if we start to pick them one at a time, we're going to lose some. People may not think they have to do the other ones.

#### Leslie Kelly Hall

It's often times op notes are explicitly not provided, for instance, in open notes. It's explicitly not available easy because it meets the most resistance inside a health system for releasing that information.

#### Clem McDonald

Well, there are at least 20 operative notes in LOINC from various specialties currently, surgical operative notes. I'll put them in the web. I think CDA had a very specific set of, not just the note but specific subparts like blood loss, etc. And Hans may know something about that. I'm not saying we don't want it. I think we want it. But I think we just highlight that there is already machinery and I think it's required in CDA. I don't now for sure.

#### **Hans Buitendijk**

No, it's not. Operative note is one of the CCA document types but it's not required. And in certification, actually, there are only three document types that are spelled out. So, I think we need to look at that and say which ones are there, which ones are not there, which ones require more work, if they require specific guidance on how to do it or is it just a general purpose one.

#### **Clem McDonald**

Don't get me wrong. I'm absolutely for the operative note. It's just that we don't want to distract them from some of the stuff we've already said.

#### **Steven Lane**



Yeah. And as Al pointed out, there is a submission from Karen P. at the SSA with a long list of specific note LOINC codes. And that suggestion is sitting down at the comment level, which is kind of interesting to me. I'm not sure why it's a comment and why it's not further along given that these are all pretty well established codes. But that's for ONC to grapple with. We can, certainly, provide a recommendation that ONC revisit the comment leveling of that list of note types.

#### **Clem McDonald**

Well, whether we ought to also emphasize because it's already been asserted that all clinical notes should be included, let's pound on that somewhat more.

#### Steven Lane

Well, to be clear, Clem, it's not all clinical notes. Version 1 included a list of eight specific clinical notes. And in draft Version 2 that, actually, shrunk to five because we moved some of the ones that were in Version 1 out of there. So, the question will be whether Version 3 ends up including a longer list. But it's not all clinical notes. It's a very specific list.

#### Clem McDonald

Well, it should include all clinical notes. It's easy enough.

#### **Steven Lane**

And that's, certainly, something that we could include in our recommendations that all available clinical notes should be included in Version 3. There is nothing wrong with us suggesting that.

#### Leslie Kelly Hall

I agree with that.

#### Clem McDonald

Yeah. I misunderstood or I would have been suggesting it all along.

#### **Steven Lane**

Okay. And I will capture that. Wonderful. Good discussion and we've got that now. There was another one similarly on the results. So, one specific test result is blood type. And Leslie and Grace both said, "This is really important. This came up in COVID." And lots and lots of patients came and said, "I don't know my blood type. Will you please order that? I want that to be available." But, again, it's just a lab result. I don't think USCDI has any role to play in saying this is a particularly important lab result. Lab results are already included in US Core and CDA. So, I'm not sure that we need to do anything about this.

#### Clem McDonald

Well, it's worse than that because there are subtypes of blood type and all. So, I think you're right, Steve. You just should include all of them.

#### **Steven Lane**

And we already do, right, because we include labs.

#### Clem McDonald



Right.

#### **Steven Lane**

Okay, good.

#### **Leslie Kelly Hall**

So, let me ask a question. So, blood type is often a lab result indicated within an actual visit themselves and not been taken over two constants that shows up. It's a result within that particular visit. Is there a way to inform or elevate so that blood type is part of the consistent information known about a patient rather than by visit and by individual lab results?

#### **Clem McDonald**

It's a problem because it doesn't always stay the same. That's why nobody gets a transfusion without getting it typed again.

#### Al Taylor

There are also situations where blood type is more important for the particular care setting. The one that comes to mind is right up my old alley, which is pregnancy management. So, especially a woman who is RH negative. There needs to be an almost constant reminder of that fact throughout the course of the pregnancy, especially mid-pregnancy and at delivery. So, the solution to that is there is different kinds of dashboarding where you can present the most relevant information in a particular setting. And ONC hasn't weighed in on particular requirements for dashboarding or screen lay out because there are so many variations to it.

#### **Steven Lane**

So, I guess the question is is there something for us to do to suggest something about USCDI related to test results, be it blood type, RH, genetic results, you name it that are constant and could be tested once in a lifetime and that that data should travel with the patient. But, again, they are already test results so they are already required to travel with the patient. But there is something special about certain results that you only need to test once.

#### **Clem McDonald**

Well, Steve, I think it's really a reporting function we're asking to highlight in a dashboard. And there is an international standard for key data that should travel with the patient. I don't remember where the URL is. That would be what I'd focus on probably. These are the things you should always include when you're traveling or whatever. And it would probably include blood type.

## Steven Lane

You would think. So, again, my question is do we need to weigh in on this given that these are lab results?

#### Leslie Kelly Hall

I think if we said some patient information including lab results like blood type have a constant value. We encourage ONC and standards organizations to investigate and promote how this type of data can be carried with the patient longitudinally.



#### Clem McDonald

Well, I think it's called minimum data set, actually, the one that is international.

#### Hans Buitendijk

Are you talking about the International Patient Summary, International Patient Access topic?

#### Clem McDonald

Yes.

#### Hans Buitendijk

I'm just checking whether they include a blood type, specifically, or not.

#### **Clem McDonald**

Do you have the URL? You could put it up.

#### Hans Buitendijk

I think that one is public so I can put it up in the chat as soon I get that.

#### **Steven Lane**

Also, Hans, we were reassured by the team that there was no harm done by posting that link.

#### **Hans Buitendijk**

Thank you. Plus, it's visible on the screen right now in the address line.

#### **Steven Lane**

Good point. Great point, Hans. All right. So, is there more work to be done on that? That doesn't sound like we've really gotten the recommendation nailed. And Al, I wonder if you could slide a few columns to the right so that you're showing Columns G through L. That would be ideal. Or maybe just hide Columns D, E, F. I'm just trying to capture more showing what we're doing. It sounds to me like we may need to think more about that and get more information about this International Patient Summary. What did you say it was called, Hans or Clem?

#### Hans Buitendijk

There are two. There is International Patient Data Summary and the International Patient Access. I'm about to put in the IPS link in the chat and I'm then onto access.

#### **Steven Lane**

Okay. Well, let's not belabor that point. I think we need to come back to that and give it a little bit more thought if nobody disagrees there. The next one was advanced directives. We've had a lot of discussion about advanced directives and the fact that they are in there, that they've been leveled, that we think they're really important, and that we hope that the community provides information that allows ONC to bring them up to Level 2. Again, I'm not sure what, if any, value we can add at this point as we recommend priorities for Version 3. Are there any thoughts on a specific recommendation that we would make around advanced directives? Mark?



#### Mark Savage

This may be a place where it's worth ONC inviting, not just being silent and ONC, usually, isn't just silent, but explicitly inviting people to move a little more quickly on this one.

#### Clem McDonald

I also agree. It's very important. But it's a tough problem. I don't think we can whitewash that. You've got to have your most recent one. There is no common place for storing them where you can go and find what they are. Patients are often not able to talk when they come in with the state. They look in their hospital record. That would count. And there are deep problems. And I think we need a central place for them to make this work.

## Leslie Kelly Hall

There has been significant work done that Lisa Nelson has shepherded through HL7 around advanced directives to help resolve that problem. But throwing up our hands and saying it's tough, I think, is not a reason not to try to promote it. And especially post [inaudible] [00:36:25] and advanced directives. [Inaudible] [00:36:27] there is definitely a construct for that. Advanced directives, there is a requirement. If someone says, "Yes, I have one," then, we're obligated to go find it and put it in a record. So, I think there is work being done. And the only way it will continue to be done is with pressure. So, I would advocate that we want to place emphasis and promotion of advanced direction [inaudible] [00:36:52]. Especially during COVID, we had patients with no family members at end of life. We had a dearth of data around this and it was so highlighted in COVID that I think we need to emphasize it.

#### Clem McDonald

I don't disagree with any of that. I just worry about specifying something to be done without having the machinery to do it and if we should push the -

#### Leslie Kelly Hall

We did put this in the consolidated CDA patient generated data, specifically, around advanced directives so there are some standards there. But there is more that's been done since then. So, I would suggest that we get some more information about this and add it. But work has progressed dramatically.

#### **Clem McDonald**

Good. Okay.

#### Hans Buitendijk

And there is definitely a project in flight, Corey Spears and Lisa Nelson are working on that.

#### **Steven Lane**

All right. Thank you, Hans, for finding those HL7 documents. It doesn't sound like either one of those has a specific reference regarding the blood type or other once in a lifetime tests.

#### **Hans Buitendijk**

They could hold it. It's just that is not explicitly stated.

#### Steven Lane



Sure, right.

#### Clem McDonald

And even the genetic tests that we do because of some new methods and some new databases and all of that so it's a tough space.

#### **Steven Lane**

Okay. I think we will also come back and look at how we might craft a recommendation around greater ONC focus on advanced directives. Again, it's not immediately clear how we would phrase that but I think that might be a job for August so we've got that captured. The next one had to do with location of work and the recommendation to include this as part of work information or social determinants of health employment information, which one was leveled as Level 1, the other leveled as a comment. Mark previously made a comment that Gravity Project employment status domain is in process. So, again, we've talked about this. It's going through the process. It's been captured by a couple of different folks at a couple of different levels. It's not clear to me what value we can add other than encouraging people to weigh in and work the process. Does anyone feel that this requires specific focus from us? All right.

Seeing no hands and hearing no voices, we'll keep going. The next one was unique device identifier. Devices used or applied. CMS has weighed in and suggested that this be included in Version 3. Again, we had said we recommend discrete codes for devices used by a patient. We gave some examples. It can be represented by the FHIR resource device use statement. This is not profiled in US Core beyond implantable devices and it's not supported in CDA beyond implantable devices. So, the focus really has been implanted devices as opposed to applied or otherwise utilized devices. I think there clearly is an opportunity here for the industry to make suggestions to include this. CMS, I believe, has already submitted this. Michelle, are you on? I don't see you. So, is there anything else about this?

#### Clem McDonald

Well, two thoughts. The implanted devices I still don't think is working well. That stuff is carried in the surgery systems. And they haven't made the hard link with it that they could just deliver the stuff automatically because when you're checking out the physician discharging a patient, it's a chore to figure out what the heck these device numbers are. But the surgery systems that put it in the body knows. The second thing is about devices the patient carries, I think that's an excessively burdensome thing. If they have a home blood pressure cuff, what does it matter if they own one if they're not using it. And how are you going to get the code for that if you're a primary care doc and you've got 10 minutes to see the patient? I think that's overkill.

#### **Leslie Kelly Hall**

So, let me address first the implantable devices. I think there has been dramatic work done. It's been important in supply chain and as a patient with two of them. It's important to know when recalls happen. And that was some of the emphasis, not just for CMS. And so, it's in meaningful use. It's in BDT. So, an implantable device would need to be continued. For the actual devices themselves for wearable, we could provide some sort of direction statement that says whether it's wearable or used devices in a health system. For instance, the issues around COVID were devices that public health had a dramatic interest in them. I think we heard that in our session last week. And so, perhaps we need to work on this a bit. I do agree with you, Clem. There is a plethora of wearable devices that may or may not be relevant or even captured. But there is also the need to continue the work we're doing on implantable devices and devices that are



wearable but incorporated into the medical record by design like cardiac devices that are sent home with the patient that are, actually, prescribed to the patient for use.

And so, perhaps we can share about that.

#### Clem McDonald

I just worry about how you capture all of this stuff when it's mixed use and they may not have it anymore. It's in a drawer somewhere. How do you even figure it out?

#### Leslie Kelly Hall

Yeah. I think the emphasis is on prescribed devices that are wearable in the home.

#### Clem McDonald

Yeah.

#### Hans Buitendijk

That would be helpful clarification to know because the interpretation otherwise might be a variety of devices that have been used in clinical care and we've seen during COVID with electronic lab reporting in particular that getting the information on the devices that were, actually, used in performing the tests is very hard to do because the systems have just not accommodated at the level of detail you need to make that useful beyond a free text whatever people enter. And it's a similar kind of issue as Clem described. The surgery suite is where the implantable device really becomes known other than if it's a historical recollection by either a provider or a patient. So, that has been a challenge to get good, accurate information from the source rather than down the line. And that's similarly the case with lab instruments is that it's really the lab and the devices that should know it but they just are not capturing it at that level of detail. And that's a lot of effort to get it into the chain.

So, narrowing the scope that it's what goes home with the patient would be very helpful to make that more manageable. And FDA is already trying to progress the other ones as well.

#### Leslie Kelly Hall

Yeah. I think the key is it's a prescribed device.

#### **Grace Cordovano**

Could I make a comment?

#### **Steven Lane**

Who is that? Michelle?

#### **Grace Cordovano**

It was Grace.

#### Steven Lane

Oh, sorry. Yeah.



#### **Grace Cordovano**

Just from the patient perspective, any of the devices that are implanted, if a patient or their care partner has any challenges and they need to call the manufacturer, the first thing that they ask for is the device ID. the model number. And they won't even field your call without it. So, while I can appreciate it challenging, patients and their families are expected to keep track of these if there is any sort of troubleshooting or questions that require a call to the manufacturer.

#### Clem McDonald

Well, I think that one is sort of easy if they just made the linkage from the surgical suite to the medical record. And it's not been pushed or focused on yet.

#### **Steven Lane**

So, let me just clarify for everyone. It's also in USCDI Version 1. The unique device identifier is already there. Down at Level 2, there are a number of additional items that have been suggested. The expiration date, the identification code, the lot number, the manufacturing date, the serial number. So, people have thought deeply already and made submissions about additional specific data elements that would be preferred here. But, again, this has all been on implantable devices. I think what was raised by Michelle and CMS had to do with applied devices. So, that's the change. Leslie has suggested that we focus only on those that have been prescribed for you as opposed to just whatever the patient happens to be using. And I guess I just want to see if we feel that this warrants a recommendation from our task force knowing that Michelle and CMS have already got this.

#### **Clem McDonald**

Those are really good suggestions because the deliverer of the prescription would know or could know that ID and pass it on.

#### **Steven Lane**

Probably not though. I prescribe these all of the time. I say, "Go get a blood pressure cuff and use it. Go get a FreeStyle Libre and use it. Use your Apple watch." I don't know anything about what they end up buying or using.

#### **Clem McDonald**

Okay.

#### Mark Savage

Steven I have one comment at the appropriate time.

## Steven Lane

Yeah. Go ahead, Mark.

#### Mark Savage

I think the idea of prescribed may make sense to me as a management tool at this point in time. But USCDI and ecosystem go beyond just what's in an EHR. So, we're having a conversation about patient devices and SDOH. You're going to have things going back and forth between patients and community referral providers. I know from my work at UCSF, the kinds of things that happen with diabetes and insulin pumps



and continuous glucose monitors and how those things can sometimes be patched. So, I would say if we're going to say prescribed, I would say it's sort of a management tool for this point in time. But it's a broader ecosystem and it's not just what the doctor prescribes. The patient has a role in this, too.

#### **Steven Lane**

That's a really good point. So, again, does our task force have a need to say anything about this as we suggest priorities for Version 3?

## Leslie Kelly Hall

I think it's an overarching principle that we identify that devices will continue to be prescribed, used by patients. And that data will become more material to care as more care is pushed into the home and with telehealth and others. And we encourage ONC to launch and support a broader review of device interoperability.

#### Clem McDonald

Could I add a little to that? I think if you use the new ID that makes it harder for these broader applications. But maybe we need a vocabulary of devices that people can just look up and say without having to find the device to find what the number is and all of that stuff.

#### Hans Buitendijk

That, actually, has been one of the challenges between did FDA do it and what the manufacturers provide in their documentation, what's on transactions just to get the correct device identifier that you can use or whether there is free text because of how it's done or when it's scanned, it's the actual documentation and collection mechanism is the challenge, not can you have it in the system for implantable devices even. So, that's what we could just be aware of that.

#### Clem McDonald

Yeah. That's it.

#### **Steven Lane**

Okay. I continue to try to capture thoughts in the documents that we're all viewing together. Do people feel that this should be a formal Task 3 recommendation? Again, it's not, specifically, about Version 3. It's more sort of overarching. But we can do what we want.

#### Mark Savage

This is Mark. I do.

#### **Steven Lane**

Okay. So, those are getting the yellow highlights. The ones getting the green highlight are more we need to think about this some more. We're, actually, doing great so thank you all for the great discussion. The next one, actually, came out of our discussion with the ISP task force, which had to do with ventilator pump, dialysis, and other device settings. Again, it's not about unique device identifiers. It's about device settings. One thought would be to expand the title of the UDI data class. But I think there is probably there already. This would probably be a new data class having to do with device settings. Again, this is one of those things where it's like really, if you're in a community help center using an ambulatory HR, do you really need to



know what the pump settings were on the patient's dialysis or ventilator when they were in the ICU? So, the question of is this really the role of the USCDI defining the core data of interoperability? But this was raised by the ISP group. So, we probably would bring it here for further discussion.

#### Clem McDonald

So, Steve, those are observations in many worlds and they're generated by ICU systems. And there are LOINC codes for lots of them. So, there's a big ICU system at Beth Israel that's part of this mimic. And they have many of those kinds of dimensions in them. So, does IEEE under anesthesia systems. So, it's a variable that's out there electronically and could be captured and standardized if there was interest. It's not a matter of people having them. They don't have to read it. You don't read the whole ICU.

#### Steven Lane

And, again, by definition, this is going to be included in all EHI next year and will be required for access, exchange, and use. So, my personal feeling is that this doesn't belong in USCDI. We're not going to, eventually, want every small office, practice, EMR to be able to capture this from the ICU system. I think it's important data and I'm glad it's going to be in all EHI. But I, personally, don't think it belongs in USCDI. John Kilbourne, you have your hand up.

#### John Kilbourne

That was a mistake. I was cleaning the screen with my finger. Sorry.

#### **Steven Lane**

Okay.

#### John Kilbourne

While you've got me though, I would agree that this seems that it would be unwieldly to require this. There seem to be higher priority items that are going to require items to be exchanged than ventilator settings. Ventilator settings that you had last month, I don't know how applicable they are in the future, for instance. So, I'm agreeing with the idea that this may not be a high priority.

#### Leslie Kelly Hall

I think the discussion came from public health on ventilator status and settings for COVID analysis and research. And it was a one time thing. I think that the dialysis settings also were brought up in the context of have we looked at devices by disease type? So, do we need to be more specific about that? I don't think we have enough here to make a recommendation. Overall, there does need to be support of especially a disease based function, whether it's renal issues or cancer issues where the devices themselves contribute to the overall ongoing status of the patient care record. But that's just too hard to do to describe. So, the two use cases for disease specific and/or research for use in ventilators and others post COVID.

#### **Clem McDonald**

Well, one more input and I don't disagree with anything that's been said about that's been said about the importance of the urgency. But Medicare requires the collection of detailed dialysis stuff on a monthly basis already. And there are standard codes for it, too, just for the record.

#### Steven Lane



Hans, your hand is up.

#### Hans Buitendijk

Yeah. A question and a note. The question is on the last comment in the cell, it seems not to fit. Is there or is there not agreement of whether the settings are part of the EHI designated record set definition or not? That's probably one of those that's starting to become a gray area. So, it's an open question that might become more but I'm not sure what it is. And that might drive, as well, whether it should or should not be considered. The second part is just a note for the settings in the FHIR side are currently being modeled and more likely to be in R5 than in R4 because that's already closed. And they are not following the observation model that has been done in the past in Version 2. So, just as a heads up. They're modeled differently but they are being addressed workers in progress to really understand them better and see where they fit and how to get them in.

#### **Steven Lane**

All right. So, that's all helpful. I've captured that in the comment. Thank you. I guess just a guicky for Al or maybe not so quicky. My intuitive sense of all electronic health information would include electronic health information maintained in surgical and anesthesia systems and the information blocking would require that data to be acceptable and accessible in a machine readable format. I think that's how most people see this. Al, can you comment one way or the other since Hans raised the question as to whether that would be included in all EHI?

#### Al Taylor

I don't know. I'd have to look into it. I'll take the question and come up with an answer. I don't have it right

#### **Steven Lane**

Okay. Thanks.

#### Mark Savage

Steven, I think another answer to that is it would be in the designated record set.

#### **Steven Lane**

I would think, yeah.

#### Mark Savage

So, I think since it's electronic, it's probably EHI, too, but I understand Al's point about wanting to check.

#### **Steven Lane**

Yeah.

#### Hans Buitendijk

And if that's the case then, I think while maybe it's not a high priority, assuming that it's considered part of EHI because it's part of the DRS and as it becomes electronic, therefore, it's EHI. While it might not be the highest priority perhaps, I will go back to the argument that then, it should become a target for USCDI.



#### Clem McDonald

Well, it's going to be sitting electronically somewhere. So, it would be relatively free to get it in terms of manual labor.

#### Hans Buitendijk

The question is what drives the standards to get on the same page. And right now that is USCDI more so than just EHI.

#### **Steven Lane**

Well, my question, Hans, is whether core data for interoperability and, again, I keep thinking about the little, rural doctor's office or the community health center whether they need to have a system that can capture and store these device settings and pass them on to somebody else when these were really very specific to either the transfusion or the ICU or the OR. That's really the guestion that I have. I think having it as part of the DRS and all the EHI makes perfect sense but I'm not sure it makes sense to be in USCDI. And that's until we say USCDI is meant to expand to all EHI, which is a different discussion.

#### Hans Buitendijk

Right. And I think that the two discussions of is the goal for USCDI to at least encompass EHI and within USCDI, actually, to that. The point that you're making I completely agree with. There are settings and there are systems where some of this data is not relevant or that you would not need to worry about. And that goes back to the comments around stratification. So, those two things go hand in hand to make sure that the right settings are or are not encumbered by data requirements or systems that are not relevant in their context. But they are part of designated record sets. So, we do want to make sure that they are exchangeable in the standards format. So, it's a little bit of an interplay between those that we need to have clarity to. It's not just one or the other.

#### Clem McDonald

I think you're making a good point. And I want to emphasize the ICU data, even if it's lab tests, can be overwhelming to a practice. So, there are two questions. I think that the systems have to be able to handle it. These would just be different codes on the same kind of data structure most of the time I think. So, I don't know that it's a big deal. But then, the question is does the physician's office have to receive everything that the hospital delivers. That's a big question. Even inpatient could kill the inpatient office system.

#### **Steven Lane**

Okay. I don't think we're going to resolve this right now. And I don't think we have to. But it's a great discussion. So, we've had a couple of late submissions. Mark was kind enough to put together a lot of good thinking about patient generated health data as well as priorities. And then, Grace has recently added a comment about tumor board notes. Mark, do you want to tackle this here and now? Or do you want to wait until we get to the Word doc? What's your preference?

#### Mark Savage

I'm at your pleasure. Whichever you prefer.

#### **Steven Lane**



All right. And Grace, I think yours is kind of quick. So, why don't we do that? Again, you've identified an interesting mate type. Tumor board notes, I'm not sure they would be considered progress notes. I don't think we determined that they would be in our organization though I imagine some people might. They're, obviously, very important documentation and potentially of great interest to patients and caregivers. I totally get that. I think they also would be helpful to exchange between organizations if a patient is receiving care at multiple organizations or transitions their care. Again, a specific subtype of a clinical note. Does anybody know offhand, Al or Dan or anybody, whether there is a request in ONDEC for tumor board notes to be added?

#### Mark Savage

I'm not aware.

#### Clem McDonald

So, I go back to the idea of we take all clinical notes because some places might classify those as multidisciplinary notes or whatever. And we're going to lose stuff if we're too specific.

#### **Steven Lane**

Yeah. We've already captured that. Thanks again for that reminder, Clem. And when, again, I look at the SSA recommendation, they have this long list of specific note types. They're not in alphabetical order. So, just glancing through it, I don't see tumor boards jumping out at me. But, again, I think this is one of those things that somebody should probably submit in ONDEC and get it leveled. See if there is a LOINC code for that. I don't know. Dan, do you remember is there a LOINC code for tumor board notes?

#### **Daniel Vreeman**

Of course.

#### **Steven Lane**

There you go.

#### **Leslie Kelly Hall**

This is Leslie. And I think the emphasis here was that it's often not included in view, download, and transmit right now. And so, having it called out in USCDI can help for patient access. So, it's one of those notes like op notes that are often left out of open note strategies. And we want to make sure that, especially with our cancer patients that it is more visible.

#### **Steven Lane**

Yeah. I don't think it's our role as a task for to advocate for individual data elements that have not yet been submitted. Our role is really to -

#### **Leslie Kelly Hall**

Right.

#### Steven Lane

So, there is a LOINC code. I just found it. Thanks, Dan. That was an easy search and someone should ask for that to be made part of USCDI. I totally agree.





#### Clem McDonald

But shouldn't it be there anyway whether they ask for it or not? That's what I keep coming back to.

#### **Steven Lane**

Yeah. But we got that. We got that already. We got that all notes should be included. But if somebody wants to make a particular ask around this one, they need to do that. That's all we're saying.

## **Clem McDonald**

Can I bring up something I talked about before and I don't know where it stands? It's the ophthalmology/tonometry. NIH submitted. I brought it up at a couple of meetings. And it just kind of fell off. It's used electronically.

#### **Steven Lane**

No, Clem. It didn't fall off at all. We, actually, discussed it at HITAC. We, specifically, discussed it in our Phase 1 recommendations.

#### **Clem McDonald**

Did they say it's going to be in 3?

#### **Steven Lane**

Well, we don't know if it's going to be in 2. We don't know until next week or next month whether it's going to be in 2. And then, we can take on whether it's going to be in 3 next year.

#### Clem McDonald

Okay. Thank you. I'm sorry. I forgot that twist.

#### **Steven Lane**

Okay. Can I hand it off to you, Mark? Where are we at? We're at 8:37. We've got good time. I think, Mark, you can tackle this.

#### Mark Savage

Okay. Which one are we on if you can just point me in the right direction?

#### **Steven Lane**

Sorry. I brought it up in the list. It's now on Row 48. And it is add a patient generated health data class.

#### Mark Savage

Okay. So, this is just a more tailored recognition of the broader discussion, which you highlighted last time, Steven, about right access. And I was thinking about that and thought that focusing on patient generated health data, which was a part of the meaningful use approach but then was dropped was perhaps a good way to structure a task force conversation about it. As I was thinking about it, I was thinking that a lot of elements that might be collected together in such a data class have already been discussed. They're already present in other places and I gave some examples there. Family health history, patient demographics, pregnancy status, social determinants of health. The patients might submit those. There



HITAC

may be some that are new. So, this is a recommendation to start the discussion and get ONC thinking and inviting how to bring this together.

#### **Steven Lane**

One thing I'll add, Mark, and Al had a chance to clarify this, I think, yet again for me on another call, is that ONC is not interested, at this point, in supporting the replication of data elements in multiple data classes. So, as you say, a lot of these data elements are already captured. There is no specification related to who captured the data or in what type of system it was captured. USCDI is about the data. And these are already part of USCDI. We've been discussing device data, which, of course, is patient generated in many situations, which might go into another class. I think that, in my mind, the purpose of having a new class in USCDI would be to hold new data elements. So, I guess the question is are there new data elements that would fit in a patient generated health data class that wouldn't fit anywhere else because, if not, I'm not sure we need the class so much as a discussion that there is a use case related to patient generated health. Am I making sense?

#### Leslie Kelly Hall

Yeah. I think what we've got is like the consolidated CDA covers patient observation, result, finding in the same way. It just has a new stakeholder or author indicated as the patient or the patient's team member. So, much of this is when we did this construct and were trying to think about it as observation results in the same construct as a provider. So, how do we indicate when the USCDI should add new authors of existing standards? There is nothing in ONDEC that would indicate that kind of distinction. What are your thoughts, AI?

#### Al Taylor

Well, what Steven said accurately represents the position that we've taken in the past about that the data itself is separate than the author of the data. And my personal opinion is there is a lot of stuff in healthcare that's patient generated, including a symptom, a questionnaire response. Anything that asks a question of a patient is patient generated data, even though it comes across as like an audit C score or a hunger vital sign score. Those are patient generated data. It's just who was, actually, writing it down or typing it in. So, we do have author organization and author time stamp for provenance, which can apply to any of the data. And you don't know if author organization has a capability of accommodating patient or self but something like that construct of pairing two things, a data element and a provenance, I think that is designed to be modular. USCDI with those data elements are designed to be modular.

And so, I'm personally struggling with getting examples of what is uniquely patient generated data that's not otherwise an observation or a finding.

#### **Leslie Kelly Hall**

Or a questionnaire. And it's a catch 22 because when the group started working on patient generated health data, this was under the standards committee, we looked at how do we make this as compatible with existing structure. How do we make it as compatible with current movement of data? And so, that's why the work was done under the consolidated CDA with a new header that indicated this new author type. So, now here we are where yes, it's not unique data class and it's probably not unique data elements. It's just a new author. How do we promote the inclusion of this new author type into exchange? And where do we take that? How do we promote a new author type with exchange?

#### **Hans Buitendijk**

This is Hans. Perhaps we can suggest and it's being thought of as a data element, not a data class but a data element, and that you look at either of the data classes, allergies, health concerns, procedures, etc. In FHIR, they pretty much all can have an author. And they may be the patient, at times, or a person. It could be somebody else. We can use the USCDI that the data element is author and the vocabulary behind it is the set that we believe, at that point in time, is the right ones to extend it to. And that would include a patient or person on behalf, a caregiver. And we could get explicit about it. And I'd use the data element.

#### **Steven Lane**

It's interesting. As a clinician I'll add that this comes up when we talk about vital signs. And it's come up, specifically, this past year with virtual visits. And when we're "rooming" a patient for a virtual visit and we ask them to report their blood pressure, their pulse, their weight, etc., whether that data should be filed in the exact same data element as if it were being collected by a healthcare professional in a clinical setting or whether it should be a different data element for patient reported blood pressure, pulse, temperature, O2 sat, what have you and then, leave it up to the system to determine whether patient generated vital signs get graphed in the same place with clinically generated vital signs or whether they're kept separate or whether you could have either/or. Again, I don't think we make a big point about differentiating whether a blood pressure was collected by a physician, a nurse, or an ER tech. But we're saying if it's collected by the patient then, that's a totally different thing.

It's an open question. And I'd love to hear from maybe Sasha or Hans about how the certified health IT systems manage this and whether there would be value in USCDI wading into this area or whether this should just be left to industry to just sort out.

#### Hans Buitendijk

I'll let Sasha go first and then, I'll go back to the other comment that I just made.

#### Sasha TerMaat

Yeah. I was thinking about quality reporting as an example since I know there has been some headache to your example, Steven, of patient captured vitals in the quality reporting context because CMS does attempt to draw a distinction. But some of our standards don't make that distinction very well. The quality reporting standards with CQL, for example, don't have a good way to express the distinction between who captures the vitals, even if that's a concept that CMS seems interested in for quality reporting. All of that though is kind of musing in my head. I don't know that I have a great sense of the best way to tackle this in USCDI. I agree it doesn't seem necessarily a different data class. And it may not be the only example of this either. Patient generation is not the only provenance or provenance related status that would be of interest. There are other things that folks are interested in distinguishing within their systems such as whether the author was part of your organization or another organization or, to some extent or another, how trusted the other source was.

Whether it's another clinic that you would place a high degree of trust in or whether it's data that is sourced from maybe a long chain of claims or something and you don't have as high of a sense of its clinical validity. And there is maybe a wider conversation there to think about how we want to handle those in USCDI.



## Hans Buitendijk

Adding to that is the modeling approach that FHIR is using is they allow for different and multiple author types so distinguishing the data that way. However a system internally manages that is up to them. But from a communication perspective, interoperability perspective, it's the same kind of data, perhaps maybe more less structured or textual because of the nature of the source. But the author is then the one that indicates what it belongs to in that regard as the source. So, that's a very natural way to do it. I completely agree that have we done full support of that? Is that problematic in some areas in the way that measures or otherwise are being expressed and how you can include it or exclude it? But if we're talking about it from an interoperability perspective, it's the most natural place to do that as an author because it's otherwise effectively the same data.

So, that's, I think, where we need to consider that and manage it in USCDI as a data element of the classes where we care about that and where we want to be more explicit to ensure is it only the clinician. Is it the patient? Is it perhaps another source? And when I say patient or their caregiver. So, that seems the most natural place to, actually, manage that. And yes, we have a bit to go through to make sure that data is then properly stratified and segregated depending on whether it's to be included in a measure or not and how systems manage it internally for other reasons. But that's not interoperability. That's their individual capabilities to handle that.

#### **Clem McDonald**

Could I make a comment? This is Clem.

#### Steven Lane

Sure. And then, Dan has his hand up after you.

#### **Clem McDonald**

The key thing is the data is the type of author that we want to distinguish. And what you show on a display, that's all reporting function. It shouldn't be part of the standards of what you send. But lurking under all of this is something Mark brought up about right access. And that's a huge challenge. Most systems don't model much right access to anything. And it's a challenge because the coding may not line up. It's a challenge because people could shut your system down by overloading it. There are all kinds of challenges. And there's a challenge because the physician has to be responsible for every data element that comes in at any time of the day or night. They're going to get pretty stressed out. They're not going to be able to do it unless there is a two-way agreement about what comes in. So, just something to think about. If we're talking about open right access, it's a tough challenge.

#### Leslie Kelly Hall

This is Leslie. I don't think we're talking about the open right access. But when we did start describing this in use cases, it was a patient response to a physician request. That was kind of the easiest first place to do patient generated data. It was a questionnaire response. It was advanced directive. It was a finding, observation, result. And that was one that we felt had the most likelihood for early adoption. But once we move, I think, to a FHIR based approach, the natural conclusion or evolution of any request for data is a response. And so, we will evolve to have more of a dialogue than a single query. There will be more in the future. But right now, we want to make sure that any requested information of the patient can be included and interoperable with the patient as an author in response.



That's perfect. Yeah.

#### Mark Savage

Just a quick comment harkening back to the ONC discussion in 2013 to 2015 that the HIPAA right to submit a correction or amendment to the record is also an example of patient generated health data. And it's, actually, been around for 20 years. So, there are some new examples but there are also some longstanding examples of how this is helpful. Thanks.

#### **Leslie Kelly Hall**

Advanced directives as well.

#### Mark Savage

Yeah. Birth plans.

#### **Steven Lane**

Okay. So, I'm going to wrap this back to you, Mark. Oh, I'm sorry, Dan. You're up. My bad.

#### **Daniel Vreeman**

I'll be brief and say I want to strongly support Hans's comments. From the perspective of USCDI, we absolutely should be sure that we can designate the performer or the author or the creator of the kinds of data that we want as a separate attribute that drives all of these things. And we absolutely do not want to create different measurements, observations, questionnaires based on who submitted it. And so, that I think is sort of a key principle notwithstanding what Mark was just talking about, which is that if there are classes of data elements that are almost always generated in the context of patient initiation, we still want to include those. But for the most part, whether it's a heart rate, blood pressure, questionnaire, etc., we definitely don't want separate patient specific variables for those.

#### **Steven Lane**

And let me just add before we go to public comment and you can pull up the comment slide if you like that Version 1 of USCDI already includes author organization and time stamp. We, specifically, left out author because we felt that that was challenging. But that is already at Level 2. And then, at Level 1, there is source submitted by DaVinci having to do with what sort of data system sent you this data. And then, at the comment level, there are already a whole host of additional provenance items, including author credentials and author roles, which we have discussed and we captured this data. So, there is no lack of submissions to cover this. And I think it brings us back to the question, which we'll take up after public comment as to whether we need to do anything about this notion of a new data class. So, let's go to public comment.

#### **Public Comment (01:23:02)**

#### **Michael Berry**

All right. Thank you, Steven. Operator, can we please open the line for public comments?

#### Operator



Yes. If you would like to make a comment, please press Star 1 on your telephone keypad. A confirmation tone will indicate the line is in the cue. You may press Star 2 if you would like to remove your line from the cue. And for participants using speaker equipment, it may be necessary to pick up the handset before pressing the star keys. We will pause for a brief moment to poll for comments.

#### **Michael Berry**

And while we're waiting, I'll just note that the task force is taking a few weeks of well deserved time off. And we will be reconvening on Tuesday, July 20 at our usual time of 10:30 a.m. Eastern Time. Operator, do we have any public comments?

#### Operator

There are no comments at this time.

#### Michael Berry

Thank you.

#### Steven Lane

Thank you. Hans your hand is up.

#### Hans Buitendijk

Yes. Based on your comment, Steven, just before the public comment break, I think we need to be considering that provenance as a data class effectively applies to all other classes in that it is providing the provenance of each one of those and what do we need to keep track of. If just in there we add to the provenance author patient and caregiver, as an example, unless we don't mean that it would imply that it is applicable to all other data classes as USCDI is growing and maybe not all data classes are going to be relevant that the patient is the source for that perhaps. But we need to consider that so that we can still then only on the individual classes where it would not apply or where we want to explicitly make sure, we still have to go through that to make sure that provenance suddenly does not, with an author perspective, imply that across the board that everything must be patient generated if that's not what we mean.

#### Leslie Kelly Hall

Well, Hans, every author has relevance or it's material to certain types of data and certain types it's not relevant. So, you're not going to have the anesthesiology record be performed by the radiologist. So, there is a sense of material or relevance that has to apply for any author.

#### Hans Buitendijk

And that's the reason why I would suggest that we have to be careful looking at provenance as the sole place for declaring author that we have to do it on each of the respective data classes to make sure there is no confusion around that.

#### Steven Lane

And I'll give credit to Gary Dickenson who submitted author role as an item that has been leveled as a comment. And he does, specifically, reference FHIR and HL7 tools for supporting them. So, Mark, I don't see anymore hands. I can try to get through this. Is there a need, Mark, for a separate data class for patient generated health data at this point?



#### HITAC

#### Mark Savage

The comment that we shouldn't have data elements in multiple classes that continues to make sense. We've talked about that before. I think where this comes from, for me, and I'm looking at Recommendation 2 from the ISP task force about thinking about a roadmap, a broader structure. There they mentioned administrative and research but I'm thinking about patient generated health data. And I think that's, actually, the conversation we've just been having. How do we integrate the patient source of data the same way we've been paying attention to the clinical source of data? I think that conversation is worth continuing. To your specific question about whether we're ready for a patient generated health data class, I'm not so clear about that. I am clear about the broader conversation though, the need for a broader roadmap. I'll close with saying there are a few examples that I hadn't highlighted before. The over the counter medications, I think there are some things that we acknowledge are important clinically but they would come from patients.

So, I think there is still some room for additions. But maybe that's a little more on the margins of your question, Steven. Thank you.

#### Steven Lane

Thank you. So, we're at time. Mark, we did not get to your other suggestion around priorities, which I think is going to be a great place for us to take up our discussion when we meet again in three weeks. We will encourage folks to continue to review our Word document. Mark's items did get captured in that document as well along with some other items that came out of our discussions with the ISP task force and public health. So, looking forward to seeing everybody, hopefully, to discuss the USCDI Version 2 and the V3 submission process on July 20 followed by our deep dive on social determinants of health on the 27<sup>th</sup>. And then, we will determine what we're going to be doing in August to pull all of this together. But I think we can probably plan now to have a meeting on August 3 to pick up this discussion. The 10<sup>th</sup> is during HIMSS. So, I would invite the ONC team to calendar us for August 3 to continue our discussion here. And with that, thank you all very much. Have a wonderful day.

Adjourn (01:29:19)