U.S. Core Data for Interoperability Task Force

Transcript
March 14, 2018
Virtual Meeting

Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good afternoon, everyone, and welcome to the U.S. Core Data for Interoperability task force. We will call the meeting to order starting with a roll call. We have Christina Caraballo.

Christina Caraballo – Get Real Health – Co-Chair
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Terry O'Malley.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Steven Lane.

Steven Lane – Sutter Health – HITAC Committee Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Clem McDonald.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Brett Oliver. Is Brett on the line? Ken Kawamoto?

Ken Kawamoto – University of Utah Health – HITAC Committee Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Valerie Grey? Is Valerie on? Laura Heermann Langford? No Laura yet? Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Public Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Nancy Beavin?

Nancy Beavin – Humana – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Kim Nolen?

Kim Nolen – Pfizer – Public Member
Hi, I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Rich Elmore?

Rich Elmore – Allscripts – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Eric Heflin? Do we have Eric on? Dan Vreeman?

Dan Vreeman – Regenstrief Institute, Inc. – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Mike Perretta?

Mike Perretta – Docket – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
And, Rob Havasy.

Rob Havasy – HIMSS – Public Member
Here.

Eric Heflin – Sequioa Project – Public Member
This is Eric Heflin joining late as well.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Brett Oliver sends his regrets.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer

Okay, thank you. Christina, it's all yours.

Christina Caraballo – Get Real Health – Co-Chair
Great, thanks. Good afternoon, everyone. A review of the agenda today. We are going to go over our meeting goals, review our homework, and get a consensus from the group on our proposed data categories. One thing to note that Harry mentioned is that we are changing – or, pointed out that we will change to data categories as opposed to stages to align more with ONC at the USCDI. On this slide, the charge – you guys all know this one, but today, we want to continue the preparation for our preliminary recommendations, which are due on March 21st.

I have a couple housekeeping things. Next week, on the 21st, we will be presenting to the high-tech committee on all of our updates, so this is our last week to get our first round of draft recommendations together. If you look in the right-hand corner, you'll see that Adam is live editing for us to see what is going on a little bit better. Is that now in the main screen? Okay, now it's in the main screen. We did get confirmation that if we want to form subcommittees going forward, we are allowed to under the task force. There was one more thing. We are now at an hour and a half instead of one hour, so you guys are with us for an hour and a half.

Moving on to the next slide, we wanted to just give an overview of the homework. Thank you all who submitted your homework assignments. I know it was tough during this week, so it was really appreciated. We have consolidated what some of the takeaways were and wanted to present them to the group. There was general consensus on the proposal of the process to advance the data class from proposed to implementation in the USCDI.

Some additional questions that arose from the process that required additional discussion were as follows: Widespread deployment and testing. What does this encompass? Is it all stakeholders? Incorporate better information on what the concept of the degree of interoperability means. Clarify stakeholder groups between Category 1, one stakeholder, and Category 2, multiple stakeholders. Clarify what it means to have a primary sponsor to shepherd the data class through the process. Criteria for semantics standards. Who will coordinate and monitor this work. And, we shouldn't limit

evaluation only to HL7 and FHIR adoption. I want to pause there and see if there is anything else that anybody would like to add for consideration or offer more clarity.

Rich Elmore – Allscripts – Public Member
Christine, are you planning to go through each of the steps? I'm not quite sure where to ask questions.

Christina Caraballo – Get Real Health – Co-Chair
Yes. What we have coming up is a look at each of the categories – the three categories that ONC had and the two additional proposed ones. And then, we will go into actually discussing each criterion under them in more detail. We can always come back to this if we need to. If people would just like to move on to the next…

Nancy Beavin – Humana – Public Member
I think it would be easier to talk about each of them in context with the stage slide that we are referring to.

Christina Caraballo – Get Real Health – Co-Chair
Sounds good.

Eric Heflin – Sequioa Project – Public Member
This is Eric Heflin. Could I ask a question?

Christina Caraballo – Get Real Health – Co-Chair
Yes, go ahead.

Eric Heflin – Sequioa Project – Public Member
For those commenting about the last item, that we should not limit evaluation to HL7 and FHIR, did they actually comment indicating what should be included?

Christina Caraballo – Get Real Health – Co-Chair
Adam or Stacy, do you remember who made that comment or if there was additional information on that?

Rob Havasy – HIMSS – Public Member
I think I was part of it.

Christina Caraballo – Get Real Health – Co-Chair
Okay, Rob.

Rob Havasy – HIMSS – Public Member
I gave an example in my response, but I didn't present the list of alternative organizations that we should include.

Eric Heflin – Sequioa Project – Public Member
Okay. I was wondering if it would make sense to take the positive side of that discussion, rather than just say we should not include those two, and include the following additional sources.

Rob Havasy – HIMSS – Public Member

I would support that.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Right, but what would they be?

Rob Havasy – HIMSS – Public Member
The first things that come to my mind are IHE International, IHE USA, ANSI, and ISO.

Mike Perretta – Docket – Public Member
Mike Perretta here. Were you calling on me?

Christina Caraballo – Get Real Health – Co-Chair
I was.

Mike Perretta – Docket – Public Member
I am confused by this. Isn't Fire part of HL7? When you Google FHIR, the first thing that shows up is HL7.org or FHIR. So, saying HL7 and FHIR is confusing to me.

Eric Heflin – Sequioa Project – Public Member
I agree. HL7 is the organization. Under that are things like HL7 Version 2, Version 3, FHIR, and CDA and reference information model. If you want to have organizations listed, it would just be HL7, if that makes sense.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
I just wanted to ask you guys a question. Is there way just to do a blanket statement about either a maturation model…?

Eric Heflin – Sequioa Project – Public Member
That was a good idea. We talked about that exact issue last year for the ISA. We talked about what the candidate sources would be for standards for inclusion with an ISA. Perhaps that could guide us here. I will try to look that up in the background as we are talking.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
We will always leave something out, and there are always new ones coming down the pike.

Christina Caraballo – Get Real Health – Co-Chair
Rich, do you have a comment?

Rich Elmore – Allscripts – Public Member
Yes. I have a question for Christina and Terry. I had the impression from an early conversation that part of the brief wasn't to talk about transport standards, it was to just focus on data classes. I don't want to oversimplify what it means to talk about FHIR, HL7, and all the other ones we just mentioned, but it sounded like that was out of scope. So, I am just asking a question. Is that part of what we should be including?

Christina Caraballo – Get Real Health – Co-Chair
That is an excellent point. Let's go on to the next slide and we can always come back to comments on this one after we go through what we are doing for our recommendations for next week. Here are the

draft categories, moving from proposed to USCDI. I'll remind you that we have two new ones: Category 1, "proposed," and Category 2, "preparation." Under "preparation," we have identified that this should be, "The value of data class demonstrated and work to technically specify data classifications." Under Category 3, which is "emerging," we have identified that to be, "Areas where technical specification of the data class is complete, there has been technical development of the data class, and the data class is tested informally."

Category 4, which is "candidate," is, "Testing of the data class in production setting is conducted." And then, finally, Category 5, "USCDA, CDI," "Data class is ready to be implemented." We have had a general consensus on this in the homework and support, so we just wanted to formally ask the task force if everyone is in agreement that these are our recommendations. Before taking a vote, are there any comments? Steven, I see your hand up first.

Steven Lane – Sutter Health – HITAC Committee Member
When we started this with the draft, there was a process of putting things in queue and what was a higher priority than something else. That is not incorporated here at all. I believe that is by intention. We are talking about the process here as opposed to the prioritization. Is that correct?

Christina Caraballo – Get Real Health – Co-Chair
That's correct. On this, we are simply talking about the categories or buckets to move through the process. We are not actually talking about each of the criteria under those categories, but we will break them down later in this conversation.

Steven Lane – Sutter Health – HITAC Committee Member
In the original draft, there was a merging – I don't have the document in front of me but there were things that were coming up, and then there were all these years. So, it seems that it is in the candidate the various years of prioritization really is going to happen inside of Category 4. Is that fair?

Christina Caraballo – Get Real Health – Co-Chair
Yes.

Steven Lane – Sutter Health – HITAC Committee Member
Great, thanks.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
It is a great question. I think there is probably going to have to be a prioritization step somewhere, but I think we have sort of assumed – or, it's implicit in this series of categories – that the prioritization happens almost at every step. It is largely based on the size, force, or impact of the stakeholder groups that are pushing it forward. I think ONC is going to – there is will have to be some prioritization step, especially if the work involved overwhelms ONC's bandwidth to shepherd it and move it forward.

Steven Lane – Sutter Health – HITAC Committee Member
I don't mean to distract us, but there is also the bandwidth of the industry to actually bring these things to market.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Yes. That may be the rate-limiting step.

Christina Caraballo – Get Real Health – Co-Chair
Rich?

Rich Elmore – Allscripts – Public Member
Yes. There are a couple of things I thought we talked about that did not necessarily make these headlines, so I wanted to ask about them. One is the notion that the data exists electronically. Maybe this is in Stage II preparation. I'm not sure but I would think we would want to call that out. I think it is an important consideration. The data class is linked to a use case rather than just being a data class in the abstract.

Christina Caraballo – Get Real Health – Co-Chair
For the second one in the breakdown, we did have a Category 2 to define the specific use cases. I am jumping ahead and looking to see if we actually put that the data exists electronically. We can take note and make sure that is captured.

Rich Elmore – Allscripts – Public Member
I just had one other comment. I don't want to disrupt what you were going to say.

Christina Caraballo – Get Real Health – Co-Chair
Adam can live edit when we get to that slide. I'll just put a note that we should make sure that we have that, that data exists electronically.

Rich Elmore – Allscripts – Public Member
Okay. The last comment was just a general comment about Stage 4 and Stage 5. Maybe we will cover this when we get into detail, but I worry about testing of data classes in a production setting that represents readiness for USCDI. One of the failures of interoperability exchange has been that we have had connect-a-thons, we've had lots of work in the abstract on what the definitions are of data for exchange. I don't think that we have done enough as an industry to prove that interoperability with enough experience across a variety of applicable systems. I would just ask if we can maybe set a higher bar as a standard for moving out of Stage 4 and into Stage 5.

Christina Caraballo – Get Real Health – Co-Chair
Okay. That is a great comment. I'll table that discussion for when we have that Category 4 slide. Moving on to Ken, your next comment?

Ken Kawamoto – University of Utah Health – HITAC Committee Member
Thank you. First is a minor comment. The value of data class has been demonstrated. It probably has not been demonstrated or a cogent case has not been made for the value of data class. I see it already demonstrated further down the line. Probably, the bigger issue – I think it has been already touched on, but it may be the kind of thing that we want to put into an asterisk or something that says in all of these steps, these criteria will be evaluated. That is that the benefits relative to the costs are favorable and conducive to things moving forward. For example, I don't see much specifically talking about the costs associated, whether it is providers having to enter, data or technically challenging, or whatnot. So, I think that probably should be in each step. Is it worth it?

Going from candidate to USCDI – just because people have demonstrated that it can be shared, you don't want to force everyone to do that. So, I think that benefit-to-cost notion would be useful to have that all around. I also think it would be useful in all these steps to think in terms of stakeholders, to say

that we want at least for each step to be at least cost-versus-benefit neutral for patients and providers. There is a notion of an overall cost-versus-benefit analysis, but you can imagine an extreme case something may not be particularly useful or even negative for a patient or provider but is useful for some for-profit industry. I assume we should say that may not be the right case. So, having this notion not only of cost-benefit balance for society as a whole but specifically for patients and providers not being negative would be a useful thing to try to make sure.

Christina Caraballo – Get Real Health – Co-Chair
An excellent point. Maybe we can even do an introduction slide for our recommendations that says in each category, we would like to consider these with the cost-benefit and the other things that you mentioned. Moving along, you are next to comment, Laura, you are next to comment.

Laura Heermann Langford – Indiana University – Public Member
I appreciate the comments Ken just made, but I also want to get back a little bit on the priority piece. It is important that between Category 1 and 2, we do have sub-bullets so there is the known expectation that not everything proposed would go directly into preparation. I'm wondering if the first bullet point under Category 2, where you talk about the value, the benefit-cost would be part of that prioritization from proposed into preparation. That is the end of my comment.

Christina Caraballo – Get Real Health – Co-Chair
As a reminder, we have broken these down more. This was just what this means at a high level for each of the categories, but the movement and advancement from one category to the next are on the following slide. This slide is mainly to say, "Are we on agreement in agreement with these five categories?" Leslie, do you have a comment?

Leslie Kelly Hall – Healthwise – Public Member
Yes, thank you. I would like to offer as a category the interest of the public health or emergence issue on thinking of Zika or other public health issues that, through either regulatory arm or danger to society, there is a data category that will jump from 1 to 5. That would be another category rather than a value under consideration or preparation. It's like a sixth category: "Emergent national health."

I'd also like to make sure we have consistent understanding of what costs and benefits are and whose cost and whose benefit because the stakeholders we are representing are broader than payers, patients, and providers, but also public health researchers and others. As such, the data stakeholders may be participating in providing data to the ecosystem as well as retrieving information from the electronic health records, so we need to be broader in our understanding of both the creator and distributor content as we review this. Thank you.

Christina Caraballo – Get Real Health – Co-Chair
Leslie, we have discussed having the red flag to pull out more immediate issues – for example, ONC has mentioned the opioids. Would you suggest actually putting another category that is outside of the progression or a bucket?

Leslie Kelly Hall – Healthwise – Public Member
I would. You may have to go through the same steps, but it is not something that will be necessarily proposed, valid, and tested. It might be something that says, "Look, we have a public health emergency. We need the following fields to be not only gathered here but made available to public health and to the patients. We have 30 days because we have an epidemic." So, this is another

category in my mind, and it is something that is not triggered very often, but when it is, it is something that we have knowledge of a way to respond to that.

Christina Caraballo – Get Real Health – Co-Chair
Okay, so the framework exists to support it. That is a good point.

Steven Lane – Sutter Health – HITAC Committee Member
Christina, a question for Leslie. Do you think that requires a different category, or is it a fast track through these categories?

Leslie Kelly Hall – Healthwise – Public Member
I guess it depends on whether we believe that category would have to be initiated through industry consensus or not. I think it is one that says we have a framework that has been agreed upon by the industry, but we have a lever that we are pulling now to make this go. I think it could be either/or, but my feeling is the framework should be able to apply whether this is any one of these emergent categories or the 1 through 5.

Christina Caraballo – Get Real Health – Co-Chair
Eric, go ahead with your comment.

Eric Heflin – Sequoia Project – Public Member
I like Leslie's idea. I was involved with the California PULSE activation for the wildfire disaster. There, people literally moved mountains in order to accommodate deploying a system quickly for care of displaced victims of the wildfire disaster. Literally, within hours or days, entire organizations like the VHA, CVS, Walgreens, Serner, Epic, and others changed their entire approach to allow things like that to occur. I do not think this can be done by progressing through all these stages. For example, going from emerging to candidate probably entails **[inaudible] [00:25:34]** and others, as well.

I am excited about Leslie's idea of having a fast track, but I don't think it is realistic for them to go through all five of these steps. We need a parallel process for an emergency category for an adoption. For example, it could use FHIR, which has the ability for the vocabulary to be extensible. Instead of going through all these steps of convening and reaching consensus, we could establish it through an expedited process – "Here is the vocabulary we will use in response to this public health disaster," which I am envisioning would occur within a few days, not weeks, months, or years.

I have two other brief comments I read ahead. I think this slide is confusing. We should take out all the sub-bullets because I think a lot of our comments were actually related to how the sub-bullets on Slide imperfectly convey what's in the more detailed slides later in the deck, so I suggest we just make this slide have Categories 1, 2, 3, and 4 with no sub-bullets to avoid future confusion for others that read this.

A final comment is that some of this sounds very much like you could build on the work that we did with the ISA – Interoperability Standards Advisory. They actually have a specific discussion about maturity and have identified which data standard could go through and be assessed against which maturity level. There is a nice table. I put a link in the chat that points to it. They do talk about a couple of things that we are just briefly touching on. I think we'll touch on them later, but it includes

standards process maturity, implementation maturity, adoption level – whether it is federally required – cost, and test tool availability

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I have comments on a couple. I am actually supportive of all of Eric's comments except the first one, and this relates to a previous discussion. I don't think it's realistic to say that in a month's time, you could get anything into a standard throughout the country. It typically takes years. But, I think Eric's point about the emergency thing - what you really want to do is get the major categories working now so that when emergencies come up, you can switch them around. That is what happened when they turned on these systems. These are systems that had data and standards in them.

The other part is that I think you have to take these super emergency things and do a different pathway. People can't install new systems in that kind of timeframe under any circumstances. I think it needs a different pathway to talk about emergency stuff. The more we get things to work all the time, the better off we will be when an emergency happens. So, the faster we get through some important big categories, the better off we will be.

Christina Caraballo – Get Real Health – Co-Chair
Okay. Harry, did you have anything to add on this? I think this is a really good discussion. It sounds like the group would also like to see the second category for fast tracking. I see your hand just came up, Michael.

Mike Perretta – Docket – Public Member
Yes. This is to add to Eric's point. If we do end up with a mechanism to expedite certain data classes, do we have another mechanism to terminate them, so it is no longer an emergency and they can go back into the queue? I'm not sure how that would work. That was just my thought.

Christina Caraballo – Get Real Health – Co-Chair
In the interest of time, let's table it, and we can at least identify that the task force has said that there needs to be another category. Let's get through the general process now, if that is okay with everyone. I think we were going to take a quick vote on the actual categories, or we can skip that ONC and leave that to you on what we should do. Adam or Stacy?

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Unless there are very strong exceptions to these categories that would apply to the normal, general process, I would suggest that we move on, or perhaps we could postpone that until we go through the individual slides for the categories.

Christina Caraballo – Get Real Health – Co-Chair
Perfect. Thanks, Adam. Let's move on to the next slide. The next slide is Category 1, which is "proposed." In this, any data class ONC receives via the feedback process that lacks the demonstrated value or technical progress to be placed at a more advanced will be placed here. This would be an HL7 standard level that does not apply to advance to Stage 2 or Category 2, which is "preparation."

The data class must do the following: Demonstrate wide-scale value to at least one of the following: First, a large number of patients; second, a large number of caregivers; or third, multiple nonpatient caregiver/stakeholder groups. Then, you get bonus points for having relevance to the government policy priorities. The thought process here is that this is essentially a catch-all for proposed data classes that have not yet begun any technical development or demonstrated sufficient value to be considered. In other words, we received your feedback, but you did not give us enough to take any action. Specific definitions of value would be determined. I see hands up. So, in the first step, we have Rich.

Rich Elmore – Allscripts – Public Member
Yes. I have a question about whether or not we want to make this a catch-all bucket or if we want to ensure the proposed has some serious chance of making its way through the steps. I worry about this becoming a collection point. The funnel can exist outside of the process to the extent that people make suggestions. To get into "proposed," it should be able to have a serious chance of making its way through the process. We talked earlier about these HL7 standards bullets.

I think to the point that Eric made earlier, to use the model of ISA where they talked about maturity, it is not the same kind of maturity, but nevertheless, I think that might be a better way to frame this than to frame it in terms of a transport standard which may, in fact, be out of scope for what we are doing. Then, in terms of the advance to State 2, "preparation," it feels like we need to be more specific. We need to set a more concrete bar. I am afraid that most data classes that we could think of could find a way to pass these tests. It seems like we ought to be providing more directive guidance on what will make it pass from "proposed" to Stage 2.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
That is a great comment. What would you propose? What is a reasonable bar or one of the many bars?

Rich Elmore – Allscripts – Public Member
Let me think about that, and I will come back and raise my hand again.

Christina Caraballo – Get Real Health – Co-Chair
So, we also took a step back because we had the more in-depth criteria. It was all getting lost, so I think it is a good point, Rich, and I think that might be our next step. But, let's define an outline here so that we can build upon it. With getting through "proposed" and not just being a bucket that does not exist, you mentioned ISA. Do you think that would be a dotted line to the ISA so that it continues to generate momentum or be looked at?

Rich Elmore – Allscripts – Public Member
First of all – we shouldn't be confused. What I said was that it is a collection of standards - almost like a catalog of standards. All I was trying to do was reinforce the point that Eric had made earlier, which was that we can take a page from that playbook, which was to say there is some form of expressing maturity for these data classes. They are not standards in the same way that are expressed in the ISA, so I don't think a direct link to ISA would serve us well in this case. It was the way in which we express maturity that would be useful.

Christina Caraballo – Get Real Health – Co-Chair
Okay. Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member

First, I want to verify that Class 1 is low, and as it goes up, it gets stronger, right? Class 1 is not the best class to be in. Is that correct? And then, I have a couple comments. Category 1 is the least successful candidate, right?

Mike Perretta – Docket – Public Member
It is the beginning of the journey.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. I wanted to clarify that. When you're higher, you're better off. I have a couple issues here. We ought to say something about how you have to be able to define the class. This is class data – I don't think we're talking about message standards or things like that. You have to be able to define it. I think it implies that it is a class. You're not just asking for the diastolic blood pressure. I would like to know other people's thoughts on this. If you have to define the class, that already is a bar. You have to say what it is so that people will know it when they see one. That's what I would add to the class. I agree with Eric's position. I also agree that it would be nice if this were tighter. But, one of the things is that if we don't say what it is in a way that others can understand and discuss, there will be problems.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
That made me think of two things. The data class – will we know it when we see it? There are two pieces to that. For, Category 1 - Clem, to your point, you have to have enough of a constellation of data elements to be a recognizable class. This gets back to the use case issue of tying them to use cases. Do you have enough data to actually move a use case or series of use cases?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I support what you are saying. You have to be able to have a pile of stuff that looks like it is something. You have to be able identify examples as well to make it easy to digest.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
The other stuff would be precisely defining that as the work of the preparation stage. You have to have something that looks like a data class to get out of "proposed." Is that what you are saying?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I almost think you should say something looks like a data class before you propose it. Otherwise, you would just be circling. No one will know what people are talking about. It should be a fundamental. "What do I mean? I don't know what I mean." Well, forget it. Go back and think about it some more." You should be able to give examples of what it is. It's the PHQ9, or it's the this, or it's this set of things like this. I don't know if we'll get anywhere if we just say, "I want good stuff." It's not decidable.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Does it have to be a data class tied to a use case? Do they have to be considered together?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I am not as intense about use cases. I just want to know what people are talking about when they ask for something or when they grade it up. At least, I think you have to have some examples to describe and exemplify what you are talking about. Without that, it is hopeless. I don't think use case is enough. You could say, "I have a use case that I want to be able to take care of any kind of problem that is an emergency." What is that? What does that include?

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Yeah, we might want a better use case. But in my understanding, for Category 1, "proposed," do people agree that this needs to be clearer than a wide-open door where you can put anything in you want? Do you want to have some criteria to get into "proposed"? Do you have something that starts to look like a data class? And then, we have to define what we mean by "data class."

Clem McDonald – National Library of Medicine – HITAC Committee Member
That's what I'd say.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
This is Terry. The countervailing argument to that is that we wanted the first step to be barrier-free to encourage people who have an interoperability need that they have not brought forward for whatever reason – to just give them an unimpeded path to get that interoperability need out so other people can see it?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Just to clarify, are we talking about data classes, data content, or the whole vision of interoperability, which is a much bigger spectrum? We're just talking about classes of data.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
We're starting with the data classes.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Interoperability will get into bigger things and important things, but it's not the same.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
That's where we ought to go, right?

Christina Caraballo – Get Real Health – Co-Chair
There are a lot of hands up. I want to make sure we get to everyone's comments. Ken?

Ken Kawamoto – University of Utah Health – HITAC Committee Member
Great, thanks.1 A few comments. In terms of identifying the notion of value, this is going to be the key thing. This is where we make the cost-benefit analysis. I would recommend we tighten this a little bit. I would not necessarily say it is for a large number of patients. I think it's just total value. If there is something that affects 1,000 of us, but it could make the difference between life and death, that should be considered more highly than something that is a tiny thing for million patients. I have one suggestion for the notion of what a benefit is. We might want to consider something like quality-adjusted life years saved so we are clear.

One thing we need to do is prioritize. That means we need a common metrics that we weigh different potential things we could work on against each other. That is one approach that has interesting side effects. It definitely promotes a focus on children and things like that, which I think is a good idea, but it is just a side effect of that. The other thing is that I would be careful about what we consider to be other stakeholder groups. We may want to be more explicit. The way to do that may be to say, "Other stakeholder groups' needs – pharma or for-profit businesses who see an opportunity in healthcare - that is great, but we need to make sure that…" We were very careful when - maybe just saying patients and their caregivers come first. Hopefully, that would be a win for everyone. There are a lot of those

opportunities. I think we need to be careful if we just make it so this kind of information is shared. We need to prioritize cases that are best for us in our role as patients.

Christina Caraballo – Get Real Health – Co-Chair
Thank you for that comment. Eric?

Eric Heflin – Sequioa Project – Public Member
I'll try to be very brief. I think we were commingling a couple of concepts in the discussion we had on Slide 6. I think it might be useful to separate those. One concept is how things get into this category, the second concept is what is in the category, and the third is how to get out of this category. It might be useful to clearly discern those. I am in favor of the original concept, which is that this category should be the initial input into the process. It has no barriers for entry, other than someone reaching out and perhaps submitting a proposed idea in a standard templatized format so there is some administrative burden reduction. Then, things are assessed, and they do not exit this category until they meet a lot of the criteria that we have been talking about. That is it for my comments.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Eric. Steven?

Steven Lane – Sutter Health – HITAC Committee Member
Yes. I have one comment in response to Ken. We talked before about this notion of quality-adjusted life years and the challenge that patients and others are going to want data for all sorts of reasons that we can't predict. I think we agreed that it was difficult for us as a group or for ONC to say what the value is. Life, death, life years – that may be a value for moth of us, but there are other values as well. I just caution us about thinking that we can actually define that. The other thing is a stylistic thing. Where we have the large N of patients, large N of caregivers, we can use the word "number" instead of N. That is more understandable to laypeople.
Christina Caraballo – Get Real Health – Co-Chair
Okay. Leslie?

Leslie Kelly Hall – Healthwise – Public Member
Yes. I struggle a little bit between whether we accommodate that data is set for all stakeholders or whether we have to identify separate stakeholders for the different point of entry. For instance, if a patient generates data, they probably won't have a sponsor who will see that through a defined process. There is no natural sponsor for the patient. However, if you look at critical data like this is a finding, observation, a result, that information could also be generated by a patient. The structure should be able to accommodate data classes irrespective of the stakeholder if we identify the stakeholders as equal. If we choose not to identify the patient as an equal stakeholder, then we have to think about another process because that point of entry will not be able to be met in many cases because there is no natural sponsor.

I do lean toward making sure the stakeholder and patient are somehow identified so that when we go through this and say, "If I was a patient generating this data, would it make it through this process?" The answer should be yes. That's just one way to decide how the data gets through. Also, I think that these steps are process steps. When we talk about "proposed," I think what we are saying is it's an applicant process versus saying it's someone who is applying to have this considered. Thank you.

Christina Caraballo – Get Real Health – Co-Chair

We originally had “identified” as opposed to “proposed.” I don't know if we want to go back to that. Terry mentioned the that idea was to at least capture everything so that we could start seeing if multiple people or stakeholders were asking for the same thing. Let me make sure I get everyone's comments in. Nancy, I see your hand is up.

Nancy Beavin – Humana – Public Member
Thank you. I am a little bit confused by the wording of the third – “at least one of.” So, large number of patients, a large number of caregivers, multiple nonpatient caregiver stakeholders - does that mean…? I don't know if that means they have to be a caregiver group and a payer, so that would be multiples, or is it multiple caregivers stakeholder groups? I'm not sure if there is a better way to word that, but that particular text is a little confusing for me. Can you help me understand that intent?

Christina Caraballo – Get Real Health – Co-Chair
Yes. I can let Terry talk as well, but my thoughts are that with the USCDI, we are trying to hit that core set of data that is going to impact the greatest number of people on a national level. I think after we’ve got that large number, we can revisit that. Terry, do you want to add to that on our thinking process?

Nancy Beavin – Humana – Public Member
My question is for “multiple,” would that be three payers be three stakeholder groups, or does that mean it has to be a payer and a caregiver? It isn’t clear to me what “multiple” is. Is that multiple payers and caregivers?

Terry O’Malley – Massachusetts General Hospital - Co-Chair
It was an attempt to somehow quantify value. Nothing beyond that. I would not put any precision on “more than one” or “three.”

Nancy Beavin – Humana – Public Member
I wasn't sure if it meant “more than one” or if it meant “more than one combination.”

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
May I interject? This is actually aligned a little bit with something that I think Ken mentioned. I do agree it could be clarified, Nancy. The intent was to get beyond - for anything that is not a large number of patients or a large number of caregivers, it was just the large stakeholder groups. Three pairs would not really apply here. It would have to be a payer and another public health group. So, they are neither directly patient or directly caregiver and it would take more than one of those groups.

Christina Caraballo – Get Real Health – Co-Chair
So, we have four more stages to get through. I'm going to move on to the next slide. I do see that Clem has a comment. After Clem’s comment, we will move on to the next slide.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I wanted to support and clarify the idea that data class should be supported regardless of where comes from. I want to make sure that the form it comes in will be important to the success of the transmission. For example, if the patient had a lab result that they could send or had a home glucose from a machine that they could send, that will work fine. But, if they send a note as text, it won't work as well because no one will be able to know what it is. I want to be sure that those distinctions are live.

Christina Caraballo – Get Real Health – Co-Chair
Okay. Thank you. Adam, can we move on to the next slide? The next category to discuss is the preparation. This is what we've identified so far. "The data class has demonstrated value as defined in Category 1. The HL7 standard level is in development." And then to, advance to Category 3, which is "emerging," "The data class must clearly define the scope of the data class including the following: First, names, definitions, and data formats, vocabulary of proposed data elements. If the choice of a data format is between computable and non-computable, there must be justification for the selection of non-computable. Second, it would be to define specific use cases for multiple stakeholders, including any that would use or benefit from implementation of the data class. Third, designate a primary sponsor to shepherd the data class through the process."

Our thought process here is that this is the time when the real technical work and assessment begins. Data class proposers must show in detail what data elements make up the data class, what data is being collected, and in what forms or vocabularies. They must also provide detailed use cases for anyone who will use that data. I see Eric has his hand up. Go ahead.

Eric Heflin – Sequioa Project – Public Member
I like this in principle. The only thing I would add is to avoid real-world interoperability issues that we have all been victim to over the years, the onus should be on the proposer to demonstrate how an existing data class does not already solve this issue. The intent would be to avoid duplicate and overlapping data classes, which obviously exist heavily in the industry now and cause problems. For example, the **ehealth** exchange has a data class for the purpose of use. HL7 created their own virtually parallel data class that is incompatible even though it has the same conceptual. It would be good to avoid similar situations as that.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Rob?

Rob Havasy – HIMSS – Public Member
Thank you. So, one general comment, and then I kind of agree with Eric except for one point. When I started looking at these slides – and, I'm looking now as we're going from Stage 1 to Stage 2 to Stage 3 – based on a comment someone said earlier, I think we could increase clarity if we drew this not as bullets under stages, but as a diagram where in the transition between stages, we have the input and output criteria, which is what is required to get in and out of Stage 2.

As I started thinking about that, that really started to make this much easier for me to follow. I am going to try to redraw this for my own use that way, and maybe it will help others. Based on what Eric just said, I like the idea of reducing duplication, but I am not sure our role is to prevent innovation and prevent new standards coming where they may replace old ones. So, I would amend a word or two in something Eric said. "Demonstrate that is not a duplicate or, if it is, how is it better or how is it advancing what they are proposing?" Thank you.

Eric Heflin – Sequioa Project – Public Member
I'll take that as a friendly amendment. Sorry, Christina.

Christina Caraballo – Get Real Health – Co-Chair
I did have a question of clarity around that. For this, you would still need – this is for inclusion in the USCDI. Even if a data class existed and if you want it included in the USCDI, wouldn't you still have to

put it through this process? It might go through pretty quickly, but I don't know that it would be separate. Are you saying we should identify that it exists or does not exist as a reference to move through the USCDI? I want to make sure I understand that properly.

Eric Heflin – Sequoia Project – Public Member
Building on Rob's idea, I think that is a good way to capture it. That is part of the proposal or the process to go from Stage 2 to 3. It should be determined if the data class being proposed is unique or duplicative or overlapping. If it is duplicative and overlapping, then there should be a determination as to whether this is an innovation that improves the data. One example that occurs to me that I saw last week was that the HL7 FHIR definition of an organization type is very inconsistent. It goes down to extremely fine-grained levels of details for some categories and organizations, and yet, for something like a government entity, it has a broad stroke of the category. Essentially, all government entities are one category. It seems like that certainly needs more resolution. In that case, someone could propose the organization datatype be included to have a more consistent level of granularity as an innovation.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Seeing no more hands up, unless Terry would like to make any more comments, I think we can move on to the next category.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Let's go.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. I had my hand up, but I didn't push the button light. Could I just comment quickly? I like this in general. I just don't know what we mean by "primary sponsor." Whose obligation is that? Is that the sponsor from the organization proposing it? Is that one of us? And then, the specific use case might be a little overburdened. We just have to say who is going to use it and why or how because some proposers may not know how to do the formal case business. I don't think of a single code system as a class. I don't know if other people do. That is what Eric was talking about a minute ago.

Christina Caraballo – Get Real Health – Co-Chair
Adam, can we move on to the next slide while I capture notes? So, the next category, Category 3, is "emerging." "The data class has been designed and its future applications demonstrated. The HL7 standard level is draft FHIR maturity level or equivalent model 0." To advance to Stage 4 or Category 4, which is "candidate, "The data class must do the following: Progress technically to be testable in production settings" – for example, testing at Dev Days or connect-a-thon-type events in the emerging level, not candidate level.

"Readiness for production testing requires that data can be tested for all mature transport standards in a curated list like FHIR and CCDA. It requires that it is being collected nationwide, and there are no barriers to collection where it may not be, and that known cost barriers to implementation and workflow issues have been theoretically mitigated." Then, we have the systematic standards as a placeholder here. Our thought process on this was that technical work is focused on preparing the data classes to be tested in the production setting and to meet technical requirements essential to interoperability. Going right into comments, Eric?

Eric Heflin – Sequoia Project – Public Member

One additional item for both Category 3 and Category 4 items – as well as for items transitioning to Category 5 – would be whether or not this is required by federal mandate.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Can you clarify that a little bit? Is that a good thing or a bad thing? Does it help or hurt?

Eric Heflin – Sequoia Project – Public Member
I understand your question. I realized as you were asking that I was ambiguous. So, one of the elements assessed to determine if a given data class goes from Category 3 into Category 4 would be whether or not that data class is mandated by federal requirements. If the data class is mandated, that needs to be taken into account as a positive factor as far as the item moving from Category 3 to 4.

Christina Caraballo – Get Real Health – Co-Chair
Eric, good point. In Category 1, under "proposed," we have the bonus points for relevance to government policy priority. Maybe we should put that as a bonus category or bonus points in each of the categories.

Eric Heflin – Sequoia Project – Public Member
Great idea. Agreed. This also may help address the excellent suggestion from Leslie Kelly Hall about some type of an expedited process for public health emergencies.

Christina Caraballo – Get Real Health – Co-Chair
That is a good point as well.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
I don't think that this process will ever serve the needs of a public health emergency. To the extent that there is an emerging concern about a particular disease or some other public health concern that needs to be addressed, this is still going to be a multiyear process. It won't be a fast process. It is a bit of a mistake to suggest… I think it is a gap in what is needed outside of USCDI, but I just can't see a way that if we had a real public health emergency that this is a vehicle for addressing an imminent public health emergency.

Leslie Kelly Hall – Healthwise – Public Member
I think the questions are going to be asked about whether or not it happens in days or weeks. Do we have this electronically already? Are there standards that can meet it? Do we have a de facto use case that can be applied? I think some of it could be. Maybe that is the test to see if it is valuable. Maybe that would be the process.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
I would welcome other opinions or comments later on this topic, which is what the cycle time on this is, but I think it is measured in terms of many years. That's the reality of going through these stages and getting out deployed systems to be able to take advantage of what is defined in the USCDI. That could be five years or eight years. I don't think it is weeks or months. I don't think that was what you were saying, Leslie, but I wanted to make sure that we are not confusing things by suggesting that a process in that kind of cycle time will address an imminent public health emergency.

Leslie Kelly Hall – Healthwise – Public Member
Right.

Christina Caraballo – Get Real Health – Co-Chair
Steven, did you have a comment to add? Steven, you may be on mute.

Steven Lane – Sutter Health – HITAC Committee Member
Sorry about that. Like Eric, I was involved in some work done locally in California around the emergencies. While it's very exciting and satisfying, I agree that this is a different process that we are talking about. Most likely, there is not going to be some new data type that will show up in a public health emergency. I get this notion of Disease X and being prepared, but I don't think that we need to confuse these two issues. We need to create a deliberative process that can move as quickly as possible. I agree that it seems unrealistic that this will be a process that will move in hours or days as opposed to months or years.

Christina Caraballo – Get Real Health – Co-Chair
I agree that this is an important discussion. I know we have identified it as a category or subcategory that we need to incorporate. We have about 20 minutes left and a couple of more things to get through. Seeing no hands up, I will move to Category 4, which is "candidates."

Clem McDonald – National Library of Medicine – HITAC Committee Member
There is something wrong with my hand wave. It says it is up on the screen.

Christina Caraballo – Get Real Health – Co-Chair
I saw you go up and then down. Go ahead.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Firstly, I agree with what Elmore said completely, but these three things here below "readiness" are way too severe. Why should it have to be tested on all mature transports? Heck, NCPDT is running now, and it doesn't run on all three transports. Or, if it's collected nationwide, by the time that happens, why bother going through this process? It's done. Some of these sub-bullets I think are too tough and should be softened if it is emerging. That is all I have.

Christina Caraballo – Get Real Health – Co-Chair
Any other thoughts on "emerging"? Can we move on to "candidates"?

Terry O'Malley – Massachusetts General Hospital - Co-Chair
I can't remember whose comment it was. We will come back with a format of how you get into the category, how you get out of it, and what are you while you're in it? I think that's a helpful frame. Sorry for interrupting.

Christina Caraballo – Get Real Health – Co-Chair
We have a lot to go through after this call. So, moving on to "candidate," "The data class has achieved a technical level that can be tested in production settings. HL7's standard level is trial-use FHIR maturity level or equivalent maturity model 1 to 5. To advance to Stage 5, or USCDI, the data class must do the following: Barriers to nationwide implementation have been mitigated and achieved normative status." The thought process here is that the data class has to be 100 percent ready to be implemented to advance to the USCDI. The initial placement is sooner candidate status. For example, in 2019 or later, it will depend on where the data class is in the testing maturity level process. Eric, you are the first with your hand up.

Eric Heflin – Sequoia Project – Public Member
I think this is good. I would suggest that on the second sub-bullet about "barriers to nationwide implementation have been mitigated," that that is actually defined. For example, "A test tool must exist to validate the structure of the data class and the value set associated with that data class."

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Again, I think we are being too mean. If you have achieved normative status, you're at 5 in FHIR, so there is an inconsistency there. Maybe we don't need four levels. You are basically saying – the other part about it is that if ONC doesn't push something, it may never achieve a real high status. I think it is pretty tough. "Barriers must be mitigated" – that definition might be helpful, but to achieve normative status is contradictory with what you say about how 1 to 5 is maturity.

Christina Caraballo – Get Real Health – Co-Chair
Thank you, Clem. Laura?

Laura Heermann Langford – Indiana University – Public Member
I wanted to agree with Clem on what he's saying. When I looked at what we have said on these last two with these barriers and how you must advance, we need to go back and look at the data classes that are already part of the USCDI and whether even they match this. I'm not sure they do. For, incoming things, we are making it very difficult.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Sometimes, I think we're mixing up the standard message structure specification and the content. Maybe not, but I just want to make sure that we aren't.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Clem, the reference to HL7 and FHIR on the maturity level was really an analogy ranking how data classes are maturing rather than meeting those particular transport standards. So, it is confusing.

Clem McDonald – National Library of Medicine – HITAC Committee Member
That is helpful, but 5 – you don't get to "normative" until you're at 5 or above, just to clarify that.

Christina Caraballo – Get Real Health – Co-Chair
Eric? Do you have a comment? Are you on mute?

Eric Heflin – Sequoia Project – Public Member
I'm sorry. To build on what others said, which also makes sense, maybe we could modify the first sentence to state that in Stage 4, they are receiving testing in pilot or limited production settings and in Stage 5, that they are in full production use for multiple organizations.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
If I understand that right, you are softening the steps to USCDI by saying you are going from test to some full production, but not necessarily ready to do it everywhere?

Eric Heflin – Sequioa Project – Public Member
Sort of. Kind of verifying more than loosening or softening. Right here, the language states that it can be tested in production settings. I am suggesting that it is a little harder and clearer than stating instead that it is being tested in pilots. For the next stage, it is in production by multiple organizations in production environments.

Christina Caraballo – Get Real Health – Co-Chair
Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think this is a backwards cause-and-effect problem. What the USCDI is going to do if it gets to a high level is induce this implementation of it across the country. More and more, it sounds like if you get it introduced across the whole country, then we'll say, "Yeah, you have done it." That is not necessarily what we want. I think NCPDT standards were hardly used at all until they were required. It's attention, but we have to be sensitive to the fact that we need to identify something that would be really good to have and how we can make it happen sooner by public pressure. If you have to have it done before that point, it is too late.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Leslie, I thought I saw your hand go up.

Leslie Kelly Hall – Healthwise – Public Member
Yes. I agree with Clem. I think one way to think about this is where there is a need for the data but there are many competing ways to do it, and someone needs to act as an arbitrator. That could be one other condition. I'm not sure which stage that fits in, but it could be this one. There are five different ways to do this same thing, and it is a burden on the industry as a result of those five. Let's come to some agreement.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. I don't see any more comments for this slide. In the interest of time, may we move to the next?

Rich Elmore – Allscripts – Public Member
Sorry, I didn't have my hand up. I just want to make sure – I think this is an area where normative status is one part of moving on to Stage 5, but having a clear, proven use in production settings across a large number of commercially available systems should be explicit criteria for Stage 5.

Clem McDonald – National Library of Medicine – HITAC Committee Member
If they have gotten there, why do we need any more encouragement? That is my contention on this stuff. Are we doing any good? It's like we are going to bless what has happened.

Rich Elmore – Allscripts – Public Member
Well, we're going to bless what's happened perhaps technically in terms of proof, but not necessarily what is being used at a national scale. I think that is the expectation of Stage 5, that you're moving from something that you know will work to something that is going to be used at a national scale.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. That is a good distinction.

Rich Elmore – Allscripts – Public Member
I don't think a normative standard is enough. I think we need to have great confidence that in production, across a reasonable number of commercially available – whatever the applicable systems are in this case, that it has proven itself before moves to Stage 5.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Laura?

Laura Heermann Langford – Indiana University – Public Member
I'm not sure I entirely agree. I am with Clem on this one. If it is already in use, what is the purpose of doing this? I understand the need about it being technically ready and that we're able to adopt it, but yet, I push the envelope on that. I think people can get to the point of ready to adopt if it is put out in a regulatory way. I don't think saying that it's already in use and that it's already assumed is very helpful, so I just wanted to push back on that a little bit.

Christina Caraballo – Get Real Health – Co-Chair
I wonder if it falls under one of our more specific criteria as we build this out for the technical requirements.

Clem McDonald – National Library of Medicine – HITAC Committee Member
If we had some clarity on what this was supposed to do, we may be able to resolve this better. I thought it was supposed to push a little bit on the envelope. There are some yins and yangs here, but if everybody is using it and it is very solid, it will all happen anyway.

Christina Caraballo – Get Real Health – Co-Chair
No more comments? Go ahead.

Rich Elmore – Allscripts – Public Member
I want to reemphasize that I think where we have failed as an industry is having taken all the steps necessary to validate this in production before we declare victory. We declare victory before we have gotten to national scale in terms of use. I think those are distinct steps that need to be followed. We can discuss which stage they fall into, but until you have something that you know works and has been deployed and implemented in a number of different, relevant system settings, you are not in a position to talk about striving for nationwide adoption. I want to make sure that we are not getting ahead of ourselves as we have done as an industry time and time again.

Nancy Beavin – Humana – Public Member
The other thing is consistency. For me, we have done a lot of things with standards, but we have not gotten to that last step of striving for consistency across the standard and how it's implemented. I want to make sure we don't lose sight of that in the process.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Hear, hear.

Christina Caraballo – Get Real Health – Co-Chair
Laura? Go ahead.

Laura Heermann Langford – Indiana University – Public Member
I'll be quick. I think we're onto something a little bit different here. I think there are stages to the point of implementation, but what the last couple of speakers are saying is to not claim victory until you know that it's taken place. Perhaps there's almost a Stage 6 that is not related to being ready to be implemented in real life, as our Stage 5 is currently saying, but that it is in real life, it has had uptake, and it is being used. That's almost a different thing, and I completely agree with saying that.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Do think that happens after it gets into USCDI, or before?

Laura Heermann Langford – Indiana University – Public Member
It could be after, but I think it is a stage that we need to recognize. I agree with this because I was saying that we often claim victory too soon, so we should acknowledge that and say that you can go so far, but until it is actually implemented, it has only gone so far.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Is the goal to help it get implemented or described what has happened in history?

Christina Caraballo – Get Real Health – Co-Chair
To answer Clem's comment, I think the goal – remember, it is something that federal agencies will point to for people to use in different initiatives. I am just answering that question quickly.

Leslie Kelly Hall – Healthwise – Public Member
I just think that what we are talking about is something that works, and now we wanted to go to scale. It goes to scale because it is easy to use and findable. New stakeholders can use it. So, I think it is a scale step that we are talking about. Maybe that helps us to differentiate from ISA, as it can be used as mature. It's done, and then the government comes in and says, "Good, let's move it to scale because the payers are now coming on board, or the patients are coming on board, or research is coming on board. This will be the item to scale?

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
May I just read a sentence from the draft USCDI ref document quickly?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
This is Lauren. Before we do that, we have to go to public comment now. Can you hold on that for one second?

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Sure.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Operator, can you open the line, please?

Operator

If you would like to make a public comment, please press *1 on your keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing *.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. We would like to remind everyone to keep your comments to less than three minutes. Do we have any comments in the queue at this time?

Operator
There are no comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Thank you. I am sorry, Adam, I will turn it back to you.

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. Quickly, this is from the USCDI draft document. "The draft USCDI and its proposed expansion process aim to achieve the goals set forth in the **Cures Act** by specifying a common set of data classes that are required for interoperable exchange in identifying a predictable, transparent, and collaborative process for achieving those goals." That's it. Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you, Adam.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
We are certainly transparent. I don't know if we're clear yet, but we are getting there.

Christina Caraballo – Get Real Health – Co-Chair
I am going to get as much as we can in. And we move to the next slide? That would be Category 5." The data class fully ready to be implemented in a real-life setting, HL7 standard level, normative FHIR maturity level 6." You guys can read that. Do we have any comments on this? Eric? I saw your hand go up and down.

Eric Heflin – Sequoia Project – Public Member
That is odd. I put my hand up and it went down on its own. I do like the model that **standards** bodies often use to self-assess the maturity of something. I think that can inform us, and I also like the model in the ISA where they talk about data classes and how they can mature, or what is the definition of them being in Category 5, in this case. That includes the factors that I mentioned before, which I won't repeat now, but for example, it includes adoption level, cost, test availability, and similar requirements.

Christina Caraballo – Get Real Health – Co-Chair
Thank you, Eric. Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member

It goes back to the same thread. If the goal is to get this stuff adopted, we either have to couch the description of what we're doing a little bit differently or we have to lower the bar a bit. We don't declare something ready to use until it has met all these criteria – although, 5 is actually less than 4, I think. It's fully ready to be implemented. 4 sounded like it already was. I think we have to tweak this so that we achieve some progress faster than normal inertia would do while still having some validity to the choices we make.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Do we have time for one more comment? I do see that it's 5:00. Laura, go ahead.

Laura Heermann Langford – Indiana University – Public Member
I will be quick. I'm playing tennis with Clem. I agree with what he says. We need to make this achievable and doable, but I don't want to make it just be that we rubber-stamp everything that is already being done. We need to make sure that it has just enough in there that can push and encourage people to get to a better operability than we already have.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I don't disagree.

Christina Caraballo – Get Real Health – Co-Chair
Thank you, Laura. We will be sending out a revised copy of some of what's been discussed and recommendations that we will be presenting next week. We do not have a call prior to that as of today, so look for that as homework. Terry, did you want to add anything else that we will be sending along, or anything else in general?

Terry O'Malley – Massachusetts General Hospital - Co-Chair
No. I'd like any suggestions you have for our draft proposal presentation. Any points that you think we should bring up besides the structure that we have discussed would be gratefully acknowledged and appreciated.

Steven Lane – Sutter Health – HITAC Committee Member
I think we should be very clear about the scope that we have taken on at this stage of the process. Again, I think it is more focused than what some people might have assumed we would be doing based on the draft USCDI that was posted.

Terry O'Malley – Massachusetts General Hospital - Co-Chair
Thank you.

Christina Caraballo – Get Real Health – Co-Chair
Lauren, I think we are ready.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thanks, Terry. Thanks, Christina. If there is nothing else, we will adjourn. We will talk soon.

Christina Caraballo – Get Real Health – Co-Chair
Thanks, everyone.

[End of Audio]

Duration: 91 minutes