U.S. Core Data for Interoperability Task Force

Transcript
April 11, 2018
Virtual Meeting

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Good afternoon, everyone, and welcome to the USCDI Task Force meeting on April 11th. We will call the meeting to order, starting with a roll call. 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? Not yet? 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? Not yet? Ken Kawamoto? I do believe I saw Ken on the Adobe. We'll circle back. Valerie Grey? Laura Heermann Langford?

Laura Heermann Langford – Indiana University – Public Member
Here.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Public Member
Good afternoon.

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

Nancy Beavin – Humana – Public Member
Yes, I'm here.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Great. 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
Okay. Rich Elmore? Not yet? Eric Heflin? Dan Vreeman? 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.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Great. Okay, Christina and Terry, I turn it over to you.

Christina Caraballo – Get Real Health – Co-Chair
Great. Thanks, Lauren. So, am I sharing my screen already? So, thanks, everyone, for joining. We are in the home stretch, and thank you so much for the amount of work that's gone into everybody's recommendations so far and the comments over the weekend. This is our last meeting before our final

recommendations are due, which will be on Friday, so we're going to do things a little differently today. I'm going to share my screen and we're actually going to go through the Google document live.

We do want to direct the task force's attention to a couple things. So, just so everybody's aware, things that we want to discuss today are the definitions that we added at the beginning of the recommendations. We want to hone in on the overview. We did a big revamp after seeing task force comments on the overview. We want to discuss the inclusion of the term "data class work group," and we want to note that we have replaced all of the references to "data elements" with "data items" and "data classes."

At the end, we also want to go over our recommendations related to issues and our issues raised but not addressed, and in total, there are nine of them. So, as we go through this document, just keep in mind that we have nine additional recommendations that we also want to make sure that we've reviewed with the task force to ensure that we want them in there. Terry, did you have anything else to add to that?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, I think that's a great list. Just a word of caution: Let's not worry about wordsmithing unless something is so unclear that it needs to be changed. We'll try to do good editing, but what we really need your thoughts on are whether the concepts expressed really match your thoughts about this whole process. Tell us what you think, and if you don't like it, tell us that especially. But, let's go.

Christina Caraballo – Get Real Health – Co-Chair
Sounds good. So, I can't see exactly what you guys are seeing. I think it probably just has my full screen on. So, right now, I have it on the definitions section that was added right at the beginning. Can everybody see that? Perfect. So, was everybody able to read through – well, first, read through our new draft and then go over the definitions? I can certainly give people some time to read.

Kim Nolen – Pfizer – Public Member
I just had a quick question because I think I keep confusing myself on this. Last week, in my mind, I was thinking "data item" was an attribute of a data class, but this definition is a little bit different. It says it's about a patient versus the data class, so I just want to make sure I'm clear on that and that this is correct.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I can take that. This is thanks to some comments from Clem that, hopefully, I've managed to adequately reflect. Think of a data item as a child of a data class. The data class is the parents. The data items fall under the data class. It's meant to represent that hierarchy of scale.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I might be able to help out. So, the distinction was between – it's not just a field, it's usually some kind of a structure, and it's usually something that is used to talk about an instance of a particular person or patient rather than a single standalone code.

Christina Caraballo – Get Real Health – Co-Chair
A data item would not be a child to a condition or a drug. It's always about the patient.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, this is meant to send data around about patients. That's how I thought of it. It's not just standalone vocabulary. It's really an object, and there are many instances of that object – say PHQ9. There are nine critters in that panel or that set. A drug would be a prescription, which would be a structure with the patient, the time, that stuff. It wouldn't just be a list of drugs. I said that wrong. It wouldn't just be a drug table, like a master table of drugs. Now, I may be wrong, but I thought that's what we were trying to send around – patient information of various kinds, and it belonged to different classes. Holler back. That's just how I thought of what we were talking about.

Kim Nolen – Pfizer – Public Member
Clem, if you take a medication, and you have the ingredients, the strength, the dose, the frequency, the route of administration – that's not a data item by this definition, correct?

Clem McDonald – National Library of Medicine – HITAC Committee Member
No, no, that's sort of the object. That's the table. That's the fields in the table, but an instance of an item in that table is what we're sending around, and we want all items that are talking about drugs with those kinds of attributes. So, "drugs" doesn't work as – you can't find as many classes for drug information, but I'm trying to distinguish between information in the abstract about a drug – "These are drug interactions," or "This is a list of the names of all drugs" – rather, something about drugs related to people and data for those people being sent in this class.

Kim Nolen – Pfizer – Public Member
So, it would be like an active or an inactive status of a medication?

Clem McDonald – National Library of Medicine – HITAC Committee Member
That's an attribute of the object – the prescription record or whatever script – there's dispensing; there's more than one class related to drugs: Dispense, prescribe, blah blah blah. I thought of the data class as being either like a data object or a table, with specific items in it that then talk about something about an individual patient.

Christina Caraballo – Get Real Health – Co-Chair
So, I think we have a couple others who may want to chime in on this. Mike and Laura, do you want to clarify the definition here?

Mike Perretta – Docket – Public Member
Yeah, I just thought that if we're inferring a hierarchy here, it might be helpful to explicitly call that out, that data items are in data classes, et cetera. Also, if you're interested, I would love to volunteer my time to create some sort of graphic to represent that as well.

Laura Heermann Langford – Indiana University – Public Member

I can add on that. I would appreciate some sort of a graphic, if that's possible. I think that would be helpful. Also, because we've been talking about how data item is part of a class, then just as we say "data class work group," I would call it "data class item."

Clem McDonald – National Library of Medicine – HITAC Committee Member
The way we were talking about "item" is it was a single instance, and you're usually talking about more than one kind. If you're doing disability class, you might have 10, 15, 20, 100, or maybe 1,000 specific things you'd say about a patient regarding disability.

Christina Caraballo – Get Real Health – Co-Chair
Right, and remember, the data item is really that Stage 1 where it's identified. The data class work group is to get us to the data classes in the stages that follow. So, we just had "data item" in there for Stage 1 to really get that bucket of all data items that people could possibly want, but then, the work group forms the actual data class.

Laura Heermann Langford – Indiana University – Public Member
But then, there are specific pieces that are in a data class that we were saying were items. So, if you're saying a data item is something coming in pre-formed, then maybe it needs a completely different name. But, if it's a child of a data class, then perhaps calling it "data class item" would better imply that it's a child.

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

Christina Caraballo – Get Real Health – Co-Chair
So then, is the recommendation to change "data item" to "data class item"?

Laura Heermann Langford – Indiana University – Public Member
If it's the child of a data class. If you mean that the data item is something that comes in an early stage and it may not be known yet if it's a data item or data class, then it should have a different name because it's not completely formed or understood. If it's supposed to be this premorphous unknown, then I wouldn't call it a data item. I think we can come up with a different name. I'm just not being very creative myself at the moment.

Mike Perretta – Docket – Public Member
If I may interject, would you all agree that if, for example, "prescriptions" was a data class, then "dosage" might be a data item?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I would think of that as an attribute of the record. The item would be "penicillin prescription." Better to get off into something that is an observation. Items are what you call survey instruments, the things inside of them.

Kim Nolen – Pfizer – Public Member

So, should we have a data class attribute? I just feel like we need a different definition.

Clem McDonald – National Library of Medicine – HITAC Committee Member
The attribute is the dose or something.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
But, I think we also might want to avoid the HL7 techy language about classes of items and attributes as much as possible. I think my simple-minded construct is that a data class includes a bunch of observations that you're going to want to make about a patient, all of which potentially have a subheading. That data class is what you're trying to figure out the boundaries of. You want to know what observations you want to include in the data class. Perhaps we want to say it's a data observation instead of a data item. Would that clarify things for people?

Kim Nolen – Pfizer – Public Member
Well, what I just heard you say is within "data class," maybe we should add that this includes observations around the data class. You could give an example with a medication like the dose, the route of administration, the ingredients – I don't know.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think you're right on it, but the challenge is that the word "observation" – at least, in the message world – is different from a prescription. It's a different object in the message context. I think we're talking about – if you think about it as a table, the columns are the attributes and the set of rows you might talk about for a given person would be what we're calling the items. Clearly, if you do a survey instrument, you call each of the questions an item, and I think that's where that word came from. But, you send all the answers to all those questions as a package as a data class, and you might have a bunch of stuff that is sent sometimes and not sent sometimes as part of the data class. I've said too much.

Christina Caraballo – Get Real Health – Co-Chair
Mike, did you have a comment?

Mike Perretta – Docket – Public Member
Did you mean me? Sorry, I didn't hear the name. I think it would be great if we had a simple hierarchy drawn out from data classes all the way down to the most specific level. It doesn't have to be terribly complicated, but I definitely think we can make this very simple graphic and clear this up right away. Please reach out to me and engage me with that. I'd be happy to help out and volunteer my time to do that.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. Let me encourage us to agree with that approach and move on. We'll seek clarification around "data class" and "item," and what we're going to call it, and how we're going to describe it. So moved.

Christina Caraballo – Get Real Health – Co-Chair

Mike, if you could actually send that to Stacy and Adam with a pretty quick turnaround, that would be great.

Mike Perretta – Docket – Public Member
Absolutely.

Christina Caraballo – Get Real Health – Co-Chair
Thank you. Then, scrolling down – are we ready to scroll down? I can only see so much of my screen without it being too small. I'm happy to go back up and take a look at the USCDI process and structure as well. Are there any comments?

Clem McDonald – National Library of Medicine – HITAC Committee Member
What number is that? Is that 2.2.11, or is that above that?

Christina Caraballo – Get Real Health – Co-Chair
We're right at the beginning. Right after the charge, we have the definitions that came out from the original.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
It's 1.2, and then, there's the set of bullets.

Kim Nolen – Pfizer – Public Member
The only thing I might add in here – as I was going through it, I felt like the word "standards-based" was used loosely, and sometimes, it was a transport standard, sometimes, it was a semantic standard, and as I was reading through it, it confused me a little as to what the intention of "standards-based" was, so I think it might be good to put a definition around that up here, too.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Good idea.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, a definition of "standards-based" referring both to semantic and transport standards?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Maybe we should distinguish them.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Separately? Okay.

Kim Nolen – Pfizer – Public Member
Yeah, and then, I think you would want to read through because there were a couple of places where I got a little confused, where I thought maybe it was only a transport standard that could be needed at that point in time versus the actual semantic standard. I marked a couple of places in there, so that as we go through, I can point out some of the points where I was confused, but it may just be me.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Even there, we need some clarification because "transport" can be down at low levels and "semantics" can include codes and the structures. So, maybe an example would help if we have to mention a real standard.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay, good point. You're right, they are kind of mashed together.

Christina Caraballo – Get Real Health – Co-Chair
Okay. Everybody, I'm in the Google doc if anybody wants not to be dependent on where my screen is. I'm trying to think of a good way to go over the next thing that we wanted to go over, which was the overview. Basically, what we've done here is identified the top things that prevent data from being shared, all the way from the top, where it doesn't exist, to where it exists but is not collected at all, to where it's collected but there are no standards for regulating it, it's collected in appropriate standards, but they're not necessarily being applied, it is collected in standards that are mostly applied within the organization, but they are not being applied to data shared outside of the organization, and then, the sixth is detailed in reliable workflows to share the data outside the organization have not been established. After that, we've gone through each of these challenges and identified why it matters and what we're trying to do to address this in the USCDI as best we can. It's a very high-level overview.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Kim is up.

Kim Nolen – Pfizer – Public Member
Thank you. This goes with some of the standards stuff that I was talking about. It says, "It is collected but there are no standards," No. 4, "It is collected, and there are appropriate standards, but they are not being applied." But, at least, in some of the core data elements that were in the proposal, there were the transport standards, but it was a text or blob. So, you could exchange it and it could be human-readable, but not computable. So, is that also captured here in that scenario? I didn't feel like it was, but maybe I'm not reading them.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think you're right. I don't think it was.

Clem McDonald – National Library of Medicine – HITAC Committee Member
That gets back to the long discussion that – my assertion would be that if there's complete blob, there's no structure anywhere, nothing can be done with it. Do you really mean stuff that has a payload that's text, but you still have who the patient is in the structure, and you have some other kind of information? Which kind do you mean?

Kim Nolen – Pfizer – Public Member
I mean that it has the attributes with the patient and everything with it so you can do something. The history of physical illness – if somebody wanted to send that…

Clem McDonald – National Library of Medicine – HITAC Committee Member
That should fit. That belongs. But, I actually had suggested some discussion about that, but I don't know whether… In one of my written comments, I said we should make a distinction about what we're talking about with "unstructured" so that we can agree on it.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
That's a good point, Clem. I think that's going to come up a little while later. Essentially, I think the authors adopted your term of "minimally structured data" to recognize that you need structure to identify who the patient is, who the recipient is, and what the content is minimally.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I don't there's any disagreement with that being appropriately valid stuff. That kind of thing is set around all the time.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I was thinking that maybe we should start this section – so, there are six ways that data doesn't move. Anybody got a seventh, or care to kick something off?

Clem McDonald – National Library of Medicine – HITAC Committee Member
There are some you might not need. Do coding systems exist to remedy these? Items… Never mind. It's all right.

Christina Caraballo – Get Real Health – Co-Chair
Laura, you had something.

Laura Heermann Langford – Indiana University – Public Member
I don't know if it's No. 5 that I don't understand, or if I might have a seventh. So, "Data is collected, and standards are mostly applied within, but are not being applied to data shared outside." That doesn't entirely make sense to me. It kind of does, but doesn't entirely. What I'm thinking of that I don't know if it's No. 5 rewritten or a new item is – so, data standards are applied, but they're applied inconsistently. So, one institution applies the standard with one definition as a code and another institution applies it with a different coding, and then they're not interoperable. So, the standard is applied, but not applied consistently.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think you're right. I don't think we need that one because if it's really applied well inside, there's no reason they wouldn't be sending it outside.

Laura Heermann Langford – Indiana University – Public Member
If you have it inside, you would use the same thing outside. But then, my issue is if I have it inside, but I have it differently at two different institutions, then when I send it outside, I'm not interoperable.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Well, then they're not really standardized in the first place, probably.

Leslie Kelly Hall – Healthwise – Public Member
No, you can apply a standard differently. You might have different rules that are trusted inside, so you accept a direct message with a consolidated CDA payload, and you ingest it automatically. But, now, when you're going to send that using the same standards externally with someone you don't know, you might have a very different process for sending and a process for receiving, and different levels of automation.

Laura Heermann Langford – Indiana University – Public Member
You can appropriately apply the FHIR standard, but there are interpretations within the FHIR standard, such as selecting a LOINC code, that are completely acceptable, but if I choose different ones, then they won't be interoperable. I applied the standard, and I applied it along all the rules, but I applied it differently. That's what I'm getting at. Like I said, I think No. 5 may need to be rewritten because I'm not sure it really exists. I don't know that I understand it.

Christina Caraballo – Get Real Health – Co-Chair
That's a good point, Laura. I think you bring up two different things, where it's applied within the organization, but not necessarily…universal standards.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Maybe not across organizations.

Clem McDonald – National Library of Medicine – HITAC Committee Member
The reality is in most places, they might have a standard HL7 message, but they use their own local codes. That's the biggest problem. So, that wouldn't count as standardized.

Laura Heermann Langford – Indiana University – Public Member
Even if you used a LOINT code – you use the example of heart rate or blood pressure. There are so many different heart rates in LOINT that are accessible and could both be applicable to the way that institution uses it for an adult cardiac care patient, but they choose different codes.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I'd be happy to get messages with codes in them instead of local codes. You can do your own…

Laura Heermann Langford – Indiana University – Public Member
That's true.

Clem McDonald – National Library of Medicine – HITAC Committee Member
We built 1,500 messages, and our only Death Star was trying to map all 3,000 lab codes. Otherwise, it was a day or so. We could tweak them.

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

Let me go back to Item 5. Christina, you've got the… Maybe take out "mostly." Just say, "The standards are applied." The issue is that they're applied, but they're just not necessarily shared among other entities.

Christina Caraballo – Get Real Health – Co-Chair
I'll clean this up. I was just trying to capture it.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Laura, does that take care of Nos. 5 and 7, or do you have a 7?

Laura Heermann Langford – Indiana University – Public Member
I think that takes care of No. 5. That's the one I was saying is the inconsistencies of implementation of the standards. It's still a valid use of a standard, they're just inconsistent. So, I think that takes care of it there in No. 5.

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

Laura Heermann Langford – Indiana University – Public Member
The seventh or a sub-part of No. 5 would be what Clem was saying. So, there are standard codes and local codes. Again, you can essentially implement a standard and be within the rules of a standard, but if you use your local codes, that's even more broken than using an inconsistent code of the standard codes. Did I just confuse everybody?

Clem McDonald – National Library of Medicine – HITAC Committee Member
No, that's a common thing.

Laura Heermann Langford – Indiana University – Public Member
The local code used could still be considered implementing the standard, but then your interoperability is broken. An inconsistent use of international codes also creates lack of interoperability, and so, there are an A and a B to No. 5.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, interoperability is not… There is no perfect one definition. We were sort of stuck with a little bit of gray zone in reality. We can tweak things a little bit differently. That would be so much better than the world we have now. You could actually get the data and use it. But, if you've got a blood pressure sitting and a blood pressure standing, they're different codes. They actually mean different things, but that's separate. So, you get them both, and you can store them in a proper place, and you can actually decide whether you wanted to do further manipulation.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
But, only if they're not a local code.

Laura Heermann Langford – Indiana University – Public Member

It's a lot easier to do if you do that with a standard code base as opposed to using your local code base.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, how are we going to get people to make that change?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Government!

Laura Heermann Langford – Indiana University – Public Member
Yeah, we have ideas, but do we really want to cover the "how" now?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, no, no, but it's something that – we ought to be thinking about the "how" when we're talking about the "what."

Laura Heermann Langford – Indiana University – Public Member
Well, the "how" – I have to plug some of my own work right now. That's kind of what HSBC is all about, getting professional organizations and clinicians together to say, "Let's agree on some codes here. Let's agree on a common instantiation of the standard to improve our interoperability."

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

Laura Heermann Langford – Indiana University – Public Member
So, the "how" is in place, but I'm trying not to plug things that I'm too involved.

Christina Caraballo – Get Real Health – Co-Chair
Right, and I think that "how" is a perfect example of what would be picked up and taken through the USCDI process that was ready for prime-time regulatory consideration.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, we should remember that Medicare standardized everything in an instant without getting full agreement before, and actually, the e-prescribing pretty much happened that way, too.

Christina Caraballo – Get Real Health – Co-Chair
As we describe these in more detail and why it's important for USCDI, maybe we can add something to this – and, why we thought it was important at the very beginning of the process for the data item harmonization, which comes up later in our recommendations. Maybe we take some of this content and put it into the document down here. Sorry, I'm not sure of the most efficient way to share my Google doc here. Thoughts?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Where are you in the document now? What number?

Christina Caraballo – Get Real Health – Co-Chair
I think you guys are just looking at the overview with 1 through 6. I can scroll down. Feel free to direct me.

Laura Heermann Langford – Indiana University – Public Member
I guess I lost context of what your question was to help answer with the overview. What were you referring to?

Christina Caraballo – Get Real Health – Co-Chair
If you read this overview – so, it's got the recommendations, the overview, we've identified these six areas, and then, underneath, there is a synopsis of why each of these different areas matters and what we're trying to do within the USCDI to improve upon it and break down some of these barriers.

Laura Heermann Langford – Indiana University – Public Member
And then, your question was related to what – do we need in that section? I think we do. I really lost context on what your question was.

Christina Caraballo – Get Real Health – Co-Chair
We're building out and putting on these bullets at the top. We're saying we may need sub-bullets. So, what is the most important high-level bullet for the overview, and where do we need to expand within that actual bullet versus within our written overview below?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Just to clarify, there are no bullets in this section. Do you mean 1 through 5?

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

Clem McDonald – National Library of Medicine – HITAC Committee Member
And, the second, I didn't hear anybody pushing that, but maybe I misheard.

Laura Heermann Langford – Indiana University – Public Member
Sorry to break in without raising my hand, but I think what I'm understanding is that the wording for the numbers is short and succinct. No. 5 gets a little bit longer. I think what you're asking is do we need to put more description in the 1 through 6 when we do have more description in paragraphs below? Is that what you're asking? Do we need to put sub-bullets?

Christina Caraballo – Get Real Health – Co-Chair
Yes, perfect. With No. 5, because we were saying there needs to be sub-bullets, what's the most important thing to put in this bullet, and is there other stuff that we want to call out in our overview below?

Clem McDonald – National Library of Medicine – HITAC Committee Member
What I heard is that No. 5 needs to be mutated, not added to.

Christina Caraballo – Get Real Health – Co-Chair
Definitely mutated. We're going to clean up what was just added here.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, if you're saying the standards – both codes and structure – are applied internally, it isn't a big deal inside or out that. It's just choices being made. There was a second there – so, it needs clarification, I guess.

Laura Heermann Langford – Indiana University – Public Member
I would clean up No. 5, but I don't think that there will need to be any other sub-bullets, but it will need to have a clarification or a descriptive paragraph of the others down below.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, that – you want to take a shot at changing No. 5?

Laura Heermann Langford – Indiana University – Public Member
I'm happy to help. I'm not very good – if I could have a few minutes tonight or in the morning, I can look at that. As Mike volunteered on a diagram, I'm happy to help on No. 5 and the short timeline.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think it most needs what you said.

Laura Heermann Langford – Indiana University – Public Member
So, sign Laura up for No. 5 in the descriptive paragraph. I know we have a tight deadline.

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

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Thank you, Laura. I think the next big section that we really appreciate the feedback on is the whole concept around the data class work group, which really formed the heart of the next stage that we envisioned – the preparation stage.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Identify it by number.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I'm sorry. 2.2.1.2. There we go. 211 – next one is…

Christina Caraballo – Get Real Health – Co-Chair
There it goes.

Clem McDonald – National Library of Medicine – HITAC Committee Member

"Preparation."

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Basically, the process – let me take a minute to quickly walk through the process that seems to have merged, but we haven't really discussed it, and I want to get some consensus on it. If we think about Stage 1 being everyone throw what they think is valuable into a pot, and we'll see what we can pull out of it that's worth moving forward, to then be cleaned up, and out of which, comes a data class.

The group that's responsible for the cleanup – meaning type definitions, finding the appropriate standards, harmonizing the data items with other work groups, harmonizing them across as many of the stakeholders as they possibly can, and creating a data class that's then sufficiently clear and well-defined enough to be pilot-tested. That's the job of Stage 2. To do that, we thought we really needed a very formal structure because it's a lot of work, and it's work that's not going to happen without a clear charge, direction, and support. Let me just stop –

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think that's pretty good as it stands.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Does anyone think that this stuff is going to get done without some direction?

Laura Heermann Langford – Indiana University – Public Member
Sorry I'm not raising my hand well, but the – are you getting at funding? Are you getting at because this is a bit of work – and, I'm not sure it's even just direction. Is it that in order to accomplish this, it has to be funded so it gets the time and attention it needs?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Not so much getting into funding as it is getting into the concept of support of the process, kind of like the way ONC supports ISA, or the proving ground, or… It needs to support a process, and the process that came to my mind was the SNI framework.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Terry, I assumed they were going to do that same level of support. No?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I hope so. I think we should –

Christina Caraballo – Get Real Health – Co-Chair
What you're saying is it may need to be called out as a suggestion. We've seen things as important as that.

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

Christina Caraballo – Get Real Health – Co-Chair
I can agree with that.

Laura Heermann Langford – Indiana University – Public Member
It's a condition of going forward that there has to be an oversight and governance structure provided, and therefore funded. So, it's not just a recommendation, it's a condition of the USCDI existing.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I might say it a little differently, but I think there is very – if they wanted to create a new one, they could imitate the SNI framework, and that might make it easier to see what's needed. Otherwise, it sounds like we've got to create a governance and start all over what the process is.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
We could call out the SNI as an example, but it sounds like I can call a vote. Is everyone in agreement that this needs to be supported, or the process doesn't move forward?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Do we raise our hand?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Just say no if you don't. Good work, guys.

Christina Caraballo – Get Real Health – Co-Chair
So, does that move us along to our related – our additional recommendations? Before we do that, is there any other area that we didn't call out for discussion today that any task force – Clem, I see your hand up.

Clem McDonald – National Library of Medicine – HITAC Committee Member
No, I was just voting yes.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Christina, although we've never really asked – it's just been assumed – the six stages… So, we blew up the draft from three to six stages. I know it's kind of late, but does anyone have a strong allergic reaction to the six stages?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, I've been consistent. I've always thought it was too many.

Laura Heermann Langford – Indiana University – Public Member
They make sense to me, but I agree with Clem that at times, it's complicated, and I'm not sure it's doable. I share his concerns on whether this is going to be implementable at the scale that we're asking it to be done, so I have concerns about that. It makes sense to me if I know that it has the support that Terry says it's going to need. The entire process is going to require some support.

Clem McDonald – National Library of Medicine – HITAC Committee Member
If it's too heavy, it might not get enough support.

Laura Heermann Langford – Indiana University – Public Member
Right. I share Clem's concerns that he's voiced all along about how the entry and exit criteria may be too high of a bar. I feel like a test and a pilot of it – I always joke within my own head. I really like it, but how do the existing items fall into this?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think if we did the exercise of taking some of the existing items – or, certainly, the ones that have been proposed – we'd find that some of them are already knocking on the USCDI door and are already there, and some are going to be stuck back early in Stage 2 because they're great ideas, but there are no semantic standards that corral them.

Laura Heermann Langford – Indiana University – Public Member
So, there is the idea of piloting this to see how it works. I get it, and it makes sense to me, but is it doable? I'm not sure. Could there be a trial phase before it's mandated?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
That was what Stage 3 was all about, the trial –

Laura Heermann Langford – Indiana University – Public Member
No, not about the trial stage of the data elements. I'm talking about the whole process.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Oh, I see. Take the process out for a trial run.

Laura Heermann Langford – Indiana University – Public Member
Right. Before we come out and say, "All of USNA – here's the USCDI, and here's how you must work with it," I think we need to try it.

Clem McDonald – National Library of Medicine – HITAC Committee Member
The other problem with pilots is that who would buy a phone if only 20 people own one? It's a real challenge to do when you have to have both ends working to find out what it does.

Christina Caraballo – Get Real Health – Co-Chair
This is great. Kim, did you have something to add to this as well?

Kim Nolen – Pfizer – Public Member
Mine was a different comment on another section, so I'll wait until we're done here.

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

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, let's add a section – it almost comes under "governance," but not quite – here's our proposal, but our proposal is to try this process in pilot. I think that's a great idea.

Christina Caraballo – Get Real Health – Co-Chair
And, in that, we can also put in some of the concerns that were just raised.

Laura Heermann Langford – Indiana University – Public Member
Yeah, and that's why we need to be doing the trial. We see the value, we see the need, we think this could work, but we're concerned about these areas, and let's suggest a trial.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Could we allow some sort of higher power to do the final shaping, like ONC? They're going to have to figure out how to fit it in the resources. We can't architect the whole thing out with the little bit of time we've spent.

Laura Heermann Langford – Indiana University – Public Member
And, they'll also have a public comment period on this, too, so there'll be responses to that.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think we're sketching out the process. There will be a lot of feedback on it. This is a good thing. So moved: Six stages with caveats and the need to test. All right, Christina, I think we're at our out-of-charge recommendations, or related, but not specifically to the charge.

Christina Caraballo – Get Real Health – Co-Chair
Yeah. On this, we have – let me go down. Sorry. So, one thing I want us to think about as we go through this is can we merge these two? We have "Recommendations on related issues," which has six recommendations, and then, we have "Issues raised but not addressed," which is No. 3, and I'm wondering if we can just put them all as additional recommendations or things to think about. So, as we go through them, I'm going to ask that again at the end of this.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Could you specify the paragraph number again?

Christina Caraballo – Get Real Health – Co-Chair
We are on 2.3, "Recommendations on related issues."

Clem McDonald – National Library of Medicine – HITAC Committee Member
Thank you.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Kim, are you…? We forgot you.

Christina Caraballo – Get Real Health – Co-Chair

Sorry, Kim.

Kim Nolen – Pfizer – Public Member
That's okay. I had one. It was closer to the beginning under No. 2, "Recommendations," which I believe is on Page 4. I just wanted to make sure something was correct in a paragraph.

Christina Caraballo – Get Real Health – Co-Chair
Am I going up further?

Kim Nolen – Pfizer – Public Member
Yes. Wait, go down a little bit.

Christina Caraballo – Get Real Health – Co-Chair
You said recommendations with the overview, and then, "Summary of recommendations."

Kim Nolen – Pfizer – Public Member
It's in between. It's above that.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
It's in the word part of the overview – right here.

Kim Nolen – Pfizer – Public Member
Okay. The paragraph that says, "There is a substantial body of data" – that one. If you go to the very end of that paragraph, "Examples of data that is currently collected but without necessary standards include nursing quality measures, some federally mandated assessment instruments, and billing data." Billing data – we have X12. I didn't want to ruffle anybody's feathers if they read that. Is X12…?

Christina Caraballo – Get Real Health – Co-Chair
These are examples, so if we question it, do you want to just delete it?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, just delete it.

Laura Heermann Langford – Indiana University – Public Member
Or, use the words "some billing data" if it's true for some, but I agree, you wouldn't want to do too much of an umbrella there.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Billing is very standardized. We'd be delighted to have things standardized in clinical as well as in billing.

Laura Heermann Langford – Indiana University – Public Member
But, remember, we're saying whether – is that standard ready for prime-time regulatory action? X12 standard and billing data could be.

Clem McDonald – National Library of Medicine – HITAC Committee Member
It's more than that, it's been mandated by law –

Laura Heermann Langford – Indiana University – Public Member
But, not for particular EPQM uses, not for research uses, not necessarily ready yet for an open API for patients. There are other use cases, and X12 has great information.

Christina Caraballo – Get Real Health – Co-Chair
So, do we have another replacement example that we want to put in that is a better example?

Laura Heermann Langford – Indiana University – Public Member
I would just put "some billing data."

Clem McDonald – National Library of Medicine – HITAC Committee Member
This is the first paragraph on Page 3? I've lost the actual reference.

Christina Caraballo – Get Real Health – Co-Chair
It's the second paragraph. Let me look it up.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, there's no example in Paragraph 2 on the top of Page 3.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Paragraph 1 on Page 3. The first paragraph, the one that starts, "There is a substantial body of data…" Maybe that got –

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. Well, I'd take out federally mandated assessment instruments as well. I can send you the specs. They've got to be followed or they won't get paid. OASIS and all the rest of those?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, they're tightly specified, but they're just recently getting some LOINT codes attached to them and being mapped to HL7. You'd think they would have been done a long time ago, but this was literally within the last couple of months.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, I like your position, but they really are standardized. Medicare does it with their own way, so it's slightly different thread, but I like what you said.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I guess that gets back to Kim's comment on what we mean by "standards." CMS has tightly specified what goes where.

Laura Heermann Langford – Indiana University – Public Member
But, it's not necessarily for all the use cases envisioned.

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

Laura Heermann Langford – Indiana University – Public Member
So, what happens is – let's say we have a great standard that's already been adopted, that's widely spread, and now there's a new use case, and that use case says, "Boy, we need to pick that bucket up again and assign it now for this new use case and this new regulation." So, we're not saying the standards today that are already in place and already have regs shouldn't be excluded, it's just that they would be on the fast track for a different use case.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, I worry that this could be really confusing to the industry as it's stated now. Ideas are all good, but… I might just come out and say it –

Laura Heermann Langford – Indiana University – Public Member
Could you say the bullet number? I'm having a hard time keeping track of where you are. You said you're at 2.2.1.1?

Clem McDonald – National Library of Medicine – HITAC Committee Member
No, we're above 2.1. The first paragraph on Page 3, last sentence.

Christina Caraballo – Get Real Health – Co-Chair
We're under the overview. Page 3-4.

Laura Heermann Langford – Indiana University – Public Member
All right. When you are looking for comments on other things, let me know.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Maybe we should come out and say that high formality, but not part of this SGO process, Medicare standards should be embedded in the SGO process. They're working toward it. That might be what we really are saying about the billing things.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I would certainly go with that recommendation.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Call them ad hoc standards, but they're locked down.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
They're tight standards, they're just not accessible to anyone else for any other use cases, as Laura said.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Did you know CMS is – I don't know if you guys all know it. They've announced this thing where they're going to let people into their chronic disease database using FHIR – patients, I mean – their own data to pull.

Christina Caraballo – Get Real Health – Co-Chair
So, can we move on to the additional recommendations just to keep us going? We've got 30 minutes left. Does anybody have anything else? Group, if you guys have comments, please feel free to put them into this document in real time. That's completely fine.

Clem McDonald – National Library of Medicine – HITAC Committee Member
So, you're on Page 11 at the bottom?

Christina Caraballo – Get Real Health – Co-Chair
I'm going there. I don't know which page it is, but…

Clem McDonald – National Library of Medicine – HITAC Committee Member
Page 11 on my printout.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think we're going to 2.3.

Christina Caraballo – Get Real Health – Co-Chair
There we go. So, the first of our additional recommendations is to explicitly address barriers to interoperability. I'll give everybody a second to go over this.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I don't understand the first bullet. So, if everybody doesn't like it, we shouldn't do it? Is that what it says?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, I think the flip side of that is that there are some stakeholders who don't have data classes that meet their use cases. It's not that.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. We should say it that way, then.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay, fair enough.

Clem McDonald – National Library of Medicine – HITAC Committee Member
It's not a general barrier to interoperability, but some stakeholders haven't got a stake yet. I think Bullet 2 is either a truism or an adulatory statement. It's not going to get us anywhere to say it's hard.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think the point of that one is that it's not only hard, it may be impossible for some organizations to get very far along with interoperability even though they have information of high value to the rest of the system, with the implication being that if you want them to get over that barrier, you may have to invest in their capabilities.

Clem McDonald – National Library of Medicine – HITAC Committee Member
So, why don't we say that? Well, it's really the smaller, less rich organizations. Valuable community organizations that are struggling – the safety net hospitals may be in the same situation.

Laura Heermann Langford – Indiana University – Public Member
The patients themselves.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, wait until you see what's coming from Medicare – today, I saw three people with iPhones looking at all the records from two hospitals with Apple Health. It was easy as pie.

Rob Havasy – HIMSS – Public Member
Are we trying to say complex interoperability schemes are a barrier to market entry or participation?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think what they're saying here is there are some places that don't have the resources to get on board, and they need them. That's the second bullet. But, this could get a lot simpler.

Laura Heermann Langford – Indiana University – Public Member
I'd like to add to what Clem says about resources. I think it has all to do not with the technical aspects, but with the workflow. I think that in our practice of medicine, we're not used to incorporating data from other places. In some ways it's been implemented, it is not easy to fit into a workflow, but in fact, it burdens the clinical workflow. And so, that immersion – I'm thinking about allergies and not having a separate allergy list that you have to consult, but that they're actually integrated with a problem list. There's something in here related to interoperability and current workflow, and also, it's just the cost of getting through how we create the technical solution to fit the clinical workflow. I think that's been one of our barriers.

Christina Caraballo – Get Real Health – Co-Chair
Laura, would that fit into this last bullet, or not?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Are you on Page 12 now?

Laura Heermann Langford – Indiana University – Public Member
Are you thinking of the link interoperability to a compelling business case?

Leslie Kelly Hall – Healthwise – Public Member
Yeah, for each stakeholder. That's a broad way to address each stakeholder's concern.

Clem McDonald – National Library of Medicine – HITAC Committee Member
This is a network economy. Single stakeholders will never make a network economy work.

Laura Heermann Langford – Indiana University – Public Member
I know – telephones haven't worked because they're assigned to individuals. Of course it'll work.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Not individuals, but everybody's got one. That's why they work. So, I think picking out the fact that one stakeholder is having problem isn't going to help anything, unless we can identify that problem and target it. So, the one with the resources – let's get them resources.

Laura Heermann Langford – Indiana University – Public Member
Or, get them a proportionate share in governance and structure or a named sponsor from government. For instance, who represents the patients? There's not someone who's going to sponsor them to go to standards meetings. So, that's one stakeholder that always needs to have governance assigned and deliberate processes that will include them.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, I think we should propose some kind of mechanism that's directive to the problem.

Laura Heermann Langford – Indiana University – Public Member
I put some in my comments. I'll send them again.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, I never saw such a buzz with this Apple Health. They're all walking around with their iPhones. No work at all. It just shows up. There will be some –

Leslie Kelly Hall – Healthwise – Public Member
That's a different conversation, Clem. It is.

Clem McDonald – National Library of Medicine – HITAC Committee Member
All right. It's happening.

Leslie Kelly Hall – Healthwise – Public Member
It is, totally. Yesterday, we spent a lot of time talking about that.

Laura Heermann Langford – Indiana University – Public Member
That's a great point, and that's another industry that might not be participating as a named sponsor, or the typical folks attending, but now have Apple. So, they aren't following this same thing. They are introducing a new standard.

Clem McDonald – National Library of Medicine – HITAC Committee Member
No, they're not. They're using FHIR.

Laura Heermann Langford – Indiana University – Public Member
They are using their iPhone and their iKit. They're using FHIR, but you have to be running it on an iPhone, so that's different than using the standard.

Leslie Kelly Hall – Healthwise – Public Member
It's within iOS that we've put that.

Laura Heermann Langford – Indiana University – Public Member
Correct. So, for instance, would Apple and Google Play be able to participate in the USCDI for standards in a sense that they want to see? So, we want to make sure our process accommodates those coming to the industry and those inside the industry.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Yeah, okay.

Laura Heermann Langford – Indiana University – Public Member
The point that I'm still trying to get to when I talk about the clinical workflow – so, I think we're meeting with the OCDI and trying to do more structured data interoperability so that the data will end up in the right place, but I believe it's almost a practice issue because there's the trust and the value of this data coming from somewhere else, and the utility of it, and if you want to bring in the patient thing – the trust and the value that the heart rates that the patient submits from their home spreadsheet or their Apple Watch – how does that fit into the decision-making of a physician? It's a completely different thing that – in the past, the way we've done interoperability is that you have to go somewhere. "I'm in the ER and I want something from the other thing. I have to click three other ways to get the CDA document, and then I can have my interoperability and read through the pages."

Leslie Kelly Hall – Healthwise – Public Member
As you add more stakeholders, you're going to move from reconciliation to curation because there's never going to be – as many people who can be now on a care team as a patient defines – a way that says we all have a standardized workflow or a standardized trust. And, just because a patient has conflicting information doesn't mean it isn't true. It just means it's true to them, and I would quote Carrie: "Patients will always be adherent to a plan they create." It's the same kind of thing. This is true to me, so perhaps the conflict in information isn't the most useful discussion to have.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, getting back to the physician getting stuff unsolicited, there's a deep problem because they can't spend the time to read it all. You can get – it's a deep problem, and they're really worried about getting sued for something they haven't totally digested, and it's flying in at every moment, and they have to go home and sleep sometime.

Leslie Kelly Hall – Healthwise – Public Member

I think there's workflow to be addressed there, but at Kaiser, 51 percent of their patient interactions are now digital. So, there's always a competence, and an appreciation, and an embracing that has to take place with any technology. The same thing would apply to a phone. I think our job is to make sure that whether the stakeholder is the patient or the industry, that there's consideration that can be given, and the diligence that determines whether the use case is applicable is not part of the USCDI. The USCDI says a group is coming with a use case, it's ready for prime time, and to follow these six steps.

Rob Havasy – HIMSS – Public Member
I think we addressed a little bit of the trust issue, and I've been flipping through pages here to try and find it. I think Stage 3: Emerging, or somewhere where we talk about moving forward with data that is not yet fully structured. A lot of patient-generated data falls into that category right now. Again, I'm trying to find the words for it. I'll keep looking. But, we talk about having sufficient – we didn't use the word "metadata," but that's what we meant – having sufficient structure to understand the source and the provenance of the data, which should allow whoever gets it to use it in their workflow however it's appropriate. They can trust it or not trust it, but they can make their own decision. So, I think we've handled a lot of that in the statement we made about making sure that even data that's not fully structured and fully standardized with full semantic interoperability has, at least, sufficient data to judge its provenance and decide whether to use it.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think you're right. Could I speak to Bullet 2 on the top of Page 12 – "Failure to enhance sharing of unstructured data"? I don't believe this –

Christina Caraballo – Get Real Health – Co-Chair
Where are you?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I'm on the top of Page 12. It's one of the six bullets that's spread over from the previous one.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Right where your cursor is.

Clem McDonald – National Library of Medicine – HITAC Committee Member
If we're talking about unstructured data as something with some provenance, there's something complex about that. It's all over the place. Every note in the hospital that kind. Someone was talking about something different than just an ability to deliver unstructured data as payload. We should get to the heart of it. There's some other problem that someone was talking about, but if we are not completely unstructured with nothing anywhere, then it's quite available. In V2, it's available, in FHIR, it's available… I don't know about X12, but it's just around. If you've got it and you can send it, it's unstructured data. The problem is getting it and putting that little provenance around it.

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

That goes back to the earlier comment about sufficient provenance to be able to trust the source or know what to do with it when you get it. So, perhaps we can eliminate this bullet and come back with something more akin to "sufficient provenance."

Clem McDonald – National Library of Medicine – HITAC Committee Member
I go back to the little value from unstructured data – I don't think that's true, either.

Laura Heermann Langford – Indiana University – Public Member
I agree.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Unless it comes through encrypted, if you see blood pressure with the units and all that, how's… In fact, if it's structured, you can deliver it very easily as a text report.

Leslie Kelly Hall – Healthwise – Public Member
I think we did talk about the floor and the ceiling earlier, that depending upon the situation nationally, there could be an issue that needs to be communicated with, and government wants to step in and say, "Here's the floor for communication, and we're putting this at the floor because we realize the constituents involved are going to be those that aren't necessarily as technically mature as other organizations or don't have the capacity." In some cases, the groups that we're trying to address are organizations and stakeholders that are largely mature in their technical capability, and therefore were coming in at a higher level. I think we should make sure this accommodates the needs of both when the situation allows.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, if you have to accept this upper-level structure, it's no problem to take the payload. If you can't do that, you can't play, really.

Leslie Kelly Hall – Healthwise – Public Member
Right, but for instance, you might take a consolidate CDA that just has the header function, and now it's followed with notes – that's perfect, that's great.

Clem McDonald – National Library of Medicine – HITAC Committee Member
That's allowed.

Leslie Kelly Hall – Healthwise – Public Member
Or, it might be something that's generated by a fax that's converted into a consolidated CDA, and that's great too. I'm just saying that there is going to be a variety of technical capacity, and that the government will choose the floor or the ceiling.

Christina Caraballo – Get Real Health – Co-Chair
Okay. We've got 11 minutes. I love this discussion. Can we ask that any additional bullets – since these are some of the identified barriers – be sent to us or put into the Google document? We've got eight

more of these to go through. Sorry to cut you off, but are we good with moving on? Everybody should send their –

Clem McDonald – National Library of Medicine – HITAC Committee Member
Are they numbered? I don't see eight more things. What pages are we supposed to get to?

Christina Caraballo – Get Real Health – Co-Chair
I've got notes here. We will send a follow-up email – or, Adam and Stacy and Lauren – and point people in the right direction on some of these things that we've identified that people want to add more comments to.

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

Christina Caraballo – Get Real Health – Co-Chair
So, the next recommendation is to highlight the interdependencies between the TEFCA and the USCDI. Are there any comments on this, or are we missing anything?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, the third bullet – how do we know… "The RCE should promote the voice of the individual and provide that voice." I don't think that's stated in terms that can be actuated. What's really wanted? Do want to get a seat? Do we want to get funding for patients? I don't know that that's going to be actionable the way it's stated.

Leslie Kelly Hall – Healthwise – Public Member
So, the RCE should have a proportionate number of patients' voices in governance that is equal to other stakeholders' gravitas.

Clem McDonald – National Library of Medicine – HITAC Committee Member
The problem is that other stakeholders often have companies that send them to meetings, and the individual parties often don't. But, there usually are people that claim the voice of the patient – or patient advocates – in a lot of meetings.

Christina Caraballo – Get Real Health – Co-Chair
Yeah. We identified exactly what you just said, Clem, in the earlier recommendations under the data class work groups, so maybe we just revise this bullet a little bit to incorporate what Leslie just said. Any other comments on this section? Okay. Seeing none, we can move on to the next one. This is, "To ensure the voice of the patient is represented and heard." Okay. Am I giving people a chance to read, or can we move on to the next one?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Move on.

Laura Heermann Langford – Indiana University – Public Member

We can move on.

Christina Caraballo – Get Real Health – Co-Chair
Great. So, the next one is, "To endorse two criteria for data class prioritization and advancement," and we've identified value and technical requirements as those two main criteria with a little bit of a caveat after that.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I don't know that people could disagree with it, but it's not very actionable.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
We can eliminate it. Some of these were just placeholders. I think we've probably covered that.

Christina Caraballo – Get Real Health – Co-Chair
So, does anybody want it kept in, or is this something that we just want to delete?

Laura Heermann Langford – Indiana University – Public Member
I think you can delete it, but if we put anything in later around the idea of piloting, I think this is the type of stuff that – how do we know and measure the value, and are the technical requirements doable? I think this is why I was suggesting that we suggest that we pilot the process. The actionable pieces of these things are what raise questions.

Christina Caraballo – Get Real Health – Co-Chair
So, Laura, when you send us the recommendation for the concerns and the trial, why don't we incorporate this, take some of this language, and add it where we see that value and technical requirements are important?

Laura Heermann Langford – Indiana University – Public Member
Okay.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
The next section – 2.3.5, "Establish a biography" – it's sort of… Anyway, it's essentially the provenance of the data class. It's everything we learned about the data class moving through the USCDI process.

Clem McDonald – National Library of Medicine – HITAC Committee Member
It's not a bad idea, but can we –

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Can we afford it?

Christina Caraballo – Get Real Health – Co-Chair
We're giving our recommendations for everything we want.

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

That's right.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Be greedy.

Christina Caraballo – Get Real Health – Co-Chair
Remember, this is in our additional as well.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
And then, on 2.3.6, we talked about the process of harmonization in Stage 2, and sort of called out here – that was such a difficult piece of the S&I work, and it wasn't always successfully done, I must say. I just felt the need to call it out again because it's so critical to interoperability.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Again, it's worthy, but I think it needs to be spelled out. I'm not sure what exactly is meant. Is that trying to find how you represent gender when you've got…?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, and is there a value, or isn't there a value? Maybe that's a testable hypothesis. Is there a value of specifying things like that? So, we all use nine categories of gender, or however many there are now.

Clem McDonald – National Library of Medicine – HITAC Committee Member
It's worthy, but I don't know how you write it such that it's being done.

Christina Caraballo – Get Real Health – Co-Chair
I'm just wondering if this is something we add to the overarching recommendations as opposed to these additional, and then tweak it a little bit, because we have addressed it throughout the stages – this importance of being cognizant of the data item harmonization.

Leslie Kelly Hall – Healthwise – Public Member
Christina, did we get to the harmonization efforts that were brought up between the government agencies?

Christina Caraballo – Get Real Health – Co-Chair
It's coming.

Leslie Kelly Hall – Healthwise – Public Member
Okay, good. Thanks.

Laura Heermann Langford – Indiana University – Public Member
I think it probably does more in the appropriate stages so that harmonization is happening along the way, and that should just be part of the process, not an issue that we put out here.

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

So, we'll drop it into Stage 2, Stage 3.

Laura Heermann Langford – Indiana University – Public Member
It may need to be a little flavor in both. I'd have to look at those as well, but I think it's a constant thing as things are developing and evolving.

Christina Caraballo – Get Real Health – Co-Chair
I was wondering if we move that toward the beginning where we just say some of our larger recommendations, in Section 2, I guess.

Laura Heermann Langford – Indiana University – Public Member
I think we need to look at the stages themselves and refer to harmonization as you progress through the stages. It may be in one stage or a couple.

Kim Nolen – Pfizer – Public Member
I would definitely agree with that as well.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
And, under 2.4.1, "Data class issues," I'm wondering if this doesn't fit under Laura's proposal for testing. I think the first four – well, first three, anyway – might be part of the testing rung. And then, the last two were our wish list of things that we thought someone should think about, but we weren't going to.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Sorry to jump in, but we should probably go to public comment soon, and if we have any remaining time, we can come back if that works.

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

Christina Caraballo – Get Real Health – Co-Chair
Great. Operator, please open the line for public comment.

Operator
If you'd like to make a public comment, please press *1 on your telephone 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
Thank you. While we're waiting for folks to bow in, I'll just do a quick roll call. Did Steven Lane join? Brett Oliver? Valerie Grey?

Valerie Grey – New York eHealth Collaborative – HITAC Committee Member
Hi, Lauren. You've got Val on the line.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Hi, Valerie. Rich Elmore? Eric Heflin? Dan Vreeman? Okay. Operator, do we have any comments in the queue at this time?

Operator
There are no comments in the queue at this time.

Lauren Richie -– Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Terry, I'll hand it back to you for the last few minutes.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
And, back to Christina.

Christina Caraballo – Get Real Health – Co-Chair
Leslie, you had mentioned – I'm going to jump down a little bit in the interests of time – this last part, "To harmonize the USCDI efforts with the cadence of likely participants." This is an area where we needed a little more examples. Leslie, we've inserted your example, but if others have other examples that they would like to add – I think the CMS data element library was also mentioned – but, we realize this is not an extensive list, so we'll add this to the email that we sent out for specific things that we would like feedback on. Sound good, everybody? Would anybody like me to capture anything now?

Leslie Kelly Hall – Healthwise – Public Member
Okay.

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

Christina Caraballo – Get Real Health – Co-Chair
Sounds good. And then, the last two data class issues – if anyone has any comments or that, or if we want to look at the governance structure, I'll leave it up to the group to decide.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
We didn't try to propose a governance structure, but we proposed the suggestion that they have a fairly robust one.

Christina Caraballo – Get Real Health – Co-Chair
And then, this is where we put the crossover to the RCE.

Laura Heermann Langford – Indiana University – Public Member

I think that's fine and sufficient.

Christina Caraballo – Get Real Health – Co-Chair
Sounds good. With two minutes, anywhere else we would like to go in this document? Terry, go ahead.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
We had time to spare. My goodness.

Clem McDonald – National Library of Medicine – HITAC Committee Member
How'd we do that?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
This has been a spectacular piece of work, guys. I wish we had another five months to do it, but there's some advantage to being forced to do things quickly. But, we can't thank you enough for all the time you've spent, and all the thought you've given, and the expertise you bring to this – I think this is a document we can be proud of.

Laura Heermann Langford – Indiana University – Public Member
Well, thank all of you for your hard work there, too.

Christina Caraballo – Get Real Health – Co-Chair
I just want to echo Terry's comment. Thank you all for your hard work, time, and commitment. I know there's still a pending meeting on the calendar for next week, and we still have a couple of items to clean up on the document today based on the conversations, and we'll surely go back to the full group if we need to keep that meeting, even if only for a brief time.

Laura Heermann Langford – Indiana University – Public Member
Sounds good.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I just wanted to say thank you to everybody. This was an amazing experience. I'm looking forward to the next chapter.

Christina Caraballo – Get Real Health – Co-Chair
We're not done yet, though.

Leslie Kelly Hall – Healthwise – Public Member
We'll see you next week. Thanks for all your work, Terry and Christina. I appreciate it.

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

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

[End of Audio]

Duration: 87 minutes