U.S. Core Data for Interoperability Task Force

Transcript
April 4, 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. We will call the meeting to order, starting with roll call. Christina Caraballo?

Christina Caraballo – Get Real Health – Co-Chair
I'm here.

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

Arien Malec
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? Ken Kawamoto?

Ken Kawamoto
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valerie Grey? No Valerie. 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
Hi, Laura. Leslie Kelly Hall?

Leslie Kelly Hall – Healthwise – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Nancy Beavin? Not yet. 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
Hi, Kim. Rich Elmore?

Rich Elmore – Allscripts – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Eric Heflin? Not yet. Dan Vreeman? Not here. Mike Perretta?

Mike Perretta – Docket – Public Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology -

Designated Federal Officer

And I do believe Rob Havasy is absent today. So, with that, I will turn it over to Christina and Terry.

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

Great. Hello, everybody and thanks for joining yet again. This is our final sprint to the finish. And what I hope we'll do today is make enough of progress, so that we can get you a draft of our recommendations for this week's homework. So, we'll try to put a draft together at the close of this week and then, spend next week going over the draft to make any last minute changes because our final product is due next Thursday or Friday. I can't remember which. So, we've got one week.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Are we out of business then?

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

And then, we're out of business. You're right, Clem. We're done. They're shutting us down.

Christina Caraballo – Get Real Health – Co-Chair

Don't speak too soon. You never know.

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

Yeah, all right. Well, they may revive us with a different charge. So, we're going to go through a bunch of topics today. And they're up on the board now. So, it's really to think some more about creating a list of data elements that ought to be associated with each data element, as it goes through the USCDI process, which, for the lack of a better term, called the biography of the data element. And we'll talk a little bit about that. We'll talk about feedback for the final recommendation. So, to start that off, can I have the next slide, please? So, I think we'll – let me go through the slides that we're going to look at very quickly and very high level, so we can then come back and tackle each stage in a little bit more detail. But I think it would be helpful if we just sort of get to see the scope of what we're thinking about today rather than dive into each particular stage.

So, with that for our intro, let me go through what we're proposing. Again, we're proposing, so far, a six stage process for moving data classes from a stage of being proposed through to final, recognized, national deployment. So, six stages overall. And the first stage is the one of having the data element or data class proposed by any stakeholder or stakeholder groups. And the intent is to open the process of proposing data elements to the broadest group of stakeholders possible without any barriers for making a proposition. And to support this process, we're going to need a shared platform that allows any user to take a look at what's been proposed, by whom, with what value, what data set, what data elements. And, basically, allow coalitions of stakeholders to form around groups of data elements, or a data class, in order to support the value of that class moving forward.

So, that's sort of a summary of Stage 1. Stage 2 is once you've got a group of data elements yet to be a real data class, it's identified with sufficient value, then, it moves into sort of the

preparation phase. And then, this is the phase in which a lot of critical work has to be done. and the critical work includes specifying what actually is in the data class, clearly defining the data elements to be included, and then, identifying the standards that can and should be associated with that data class. And then, finally, some work of harmonization that there are similar data elements or data classes that are used by multiple entities. Think clinical care versus regulatory versus quality reporting versus what public health needs. They may all need similar data elements but may define them differently.

So, the process of harmonization, the single set, can meet the diverse population of needs that's done in this stage. And a lot of work. This is a very complicated stage. Can I have the next slide, please? Were we just going to talk about Stages 1 and 2, or are we going to go through all four? I guess, Adam, that's a question for you.

Adam

It's totally up to you. I thought it might be easy to give the full six stage picture view at the beginning, and then, go back and have a discussion.

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

Good. So, do we have slides for Stages 3 – yes, we do. Great. So, emerging status. This is the old – one of the originally statuses proposed in the initial ONC draft. And this is, basically, a sufficiently defined data class that it can be tested in limited settings. And the idea is to road test it, find out where the gaps are, do the modifications, revise, retest, revise, retest, until the data class is sufficiently tight that someone can deploy it, essentially, in Stage 4 in that commercial – really, in a broad commercial setting. And once it gets fully tested at Stage 4, with, again, the same issues as identifying gaps, identifying issues, mitigating them, making changes, retesting, the data class is bullet proof and ready to be handed over for anyone who finds value in it to deploy it.

So, those are some of the stages. That's Stage 5. That gets you into the USCDI. And the way you get out of the USCDI is when it's recognized that the data class has been widely deployed. And we've got some suggestions about how that might happen. The most promising one being that we use the RCE under TEFCA to measure data flow and just sort of measure it remotely. So, that's the overview of the six stages. So, let's go back to the beginning. There we go. So, let's pause here for a minute and entertain comments from anyone about anything. What do you think of those Red Sox? Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member

So, it looks like the Stage 5 is the point at which they might be pushed. You're saying, possibly, it's used to promote widespread adoption. And so, that is what is an important stage. And so, depending on how hard the first five stages are, I might like them or not, the first four stages. Now, if there are such high bars that it's already done before there's an encouragement, then, I might try to soften them. But anyway, it's at least as clear on five now.

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

And let me explain. So, once we go through Rich's comment, then, I'll come back to something we need to discuss. And that's thinking about different levels of interoperability, which may get to your point about the bar being too high. So, keep that thought. We'll come back to it

immediately. Rich?

Rich Elmore – Allscripts – Public Member

Yeah, thanks. So, good job on this. Just a couple of thoughts. One is that the use cases, which are proposed in Stage 2, I think it's important that there be the same sort of rigor around the use case as there is around the data class. And, ultimately, in a later stage, that is determining of which developers need to implement this. I mean, if it isn't applicable to a use case you support, or if it's – you know what I mean. So, that was Point 1. And then, later on in the discussion, I think it was Chart 4 maybe or Stage 4, there was reference to maybe one commercial system. I'm just wondering if this is to be used for interoperability, if we don't need to broaden that slightly to more than one system.

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

Great. Good comments. And I guess let's just toss that back out to the group. Is it getting enough testing and enough exposure or too much testing? And I don't know what the balance is. So, your proposal makes perfect sense to me. Anyone else with thoughts on that?

Clem McDonald – National Library of Medicine – HITAC Committee Member

This is Clem. So, it's not just the number of entries. It might be some sort of industry agreement. I don't know how to say it though. And these are the testings from these edges where there's some actual push. On one hand, we don't want to make it so hard that you don't push them until they're all already completely used everywhere. But you don't make it so each that it gets stuff people can't really use. There's maybe something, just not the industry applying it, but some support from professional societies or industry, in general. So, certain things that are going on now with fire and that seems to be industry support. And it wouldn't have to be tested necessarily. Do you know what I mean? There's an additional dimension, if people are cheering it on, or they want to have it happen. Although, you want to see it working somewhere.

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

Yeah. Anyone else with thoughts? Leslie?

Leslie Kelly Hall – Healthwise – Public Member

Yeah. Thanks. I think what Clem is trying to get to is a good idea. It's sort of an endorsing body that's not the sponsoring organization. So, someone has vetted this within another industry organization to just say that they are also an interested party.

Clem McDonald – National Library of Medicine – HITAC Committee Member

It might be federal agencies, too. CUC – CU something.

Leslie Kelly Hall – Healthwise – Public Member

Yeah. Or quality improvement organization to say, yeah, we're moving towards this but not sponsoring.

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

Basically, the idea that not only are you enthusiastic, but you go out, and you kind of meet with your colleagues and other interested parties, and you sort of drum up support, essentially, co-sponsors.

Leslie Kelly Hall – Healthwise – Public Member
Right.

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

Leslie Kelly Hall – Healthwise – Public Member
Perhaps not as much as a sponsor but an endorse. Yes, we agree with this direction.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
You guys are all raising a very interesting point. It points to how political, political in the sense that it requires consensus among multiple parties at multiple stages. It's a political process, in that it requires consensus to move ahead.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Consensus is stronger than having support. Consensus means everybody agrees. By that time, it will already be being used. So, this challenge about trying to encourage it because standards hardly ever happen without a little bit of push because everybody is busy doing something else. On the other hand, you don't want to have some raw thing that's no good being pushed. There are a whole lot of standards in the first round of it being used. They weren't being used. It was the meaningful use made them use. And none of this stuff Medicare pushes was being used. They just said this is what you're going to use and get used.

Rich Elmore – Allscripts – Public Member
Yeah. That just shows you one of the barriers to adoption is pushing standards that have no value to anyone.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I wasn't saying that, no. They got done. More that, if there isn't a push, you're just going to have kind of concurrence to get enough value out of them.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. So, anymore comments? This is very helpful.

Clem McDonald – National Library of Medicine – HITAC Committee Member
There are some other things that aren't on that section. It's like I'm not sure what you mean by elements. I'm not sure you're saying they should – say if you got some **[inaudible] [00:15:52]**, you're going to say you've got to list the whole set of SNOMED codes that you want to use. I'm not sure what you mean by these elements and definitions.

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

Let me respond to that, and then, Rich, we'll come back to you. So, the idea of separating data elements from data classes is that is you recall in the proposed data classes, some of them are single data elements. Gender, sexual identity, age, name. So, the point was that you could propose a data element, aka a data class. And that's fine. And I can go into this big, long list and place where people can look at it. But there might be a group of people who come by and say, if we took several of these data elements together, we could create a data class with broader value to a broader number of stakeholders. So, that's the reason sort of parse data class into its component parts.

And I think, as you mentioned, the implication of that is that you're going to build a composite data class built of many data elements that does each data element has to be highly specified, if it's going to be interoperable. And so, the answer to your question is yes, there probably does have to be a listing of the SNOMED codes or the long codes.

Clem McDonald – National Library of Medicine – HITAC Committee Member

And let me clarify. I wasn't really asking that question. I was asking what you meant by elements. And I think you answered it. So, an element could be the attributes. It's got a – I mean, there's attributes within coding systems. And I wasn't sure which element you meant. But, on the other hand, I don't think you should encourage much single element because if you want any other diagnosis, the answer is go to SNOMED and get it put in. So, it's an issue about how much we encourage one offs when a class has been accepted and serves some organization that deals with them. If you want to put a new drug in, go to RX Norm or something like that.

Rich Elmore – Allscripts – Public Member

Right. And I think what's going to happen, if we have data elements, the meaning of which is the universally shared that what we end up creating, in a sense, is a data element library that people can go back to and re-combine to create data classes, most of which have already been standardized. You might need another 15 percent of new data elements standardized, in order to create a new class with new value to new stakeholders and not requiring all of the rework of the original class.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Can I ask also if they've looked before they request a new one?

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

Yes. I think that gets in Stage 2. I think that's part of the huge work that has to get done in Stage 2. Exactly.

Clem McDonald – National Library of Medicine – HITAC Committee Member

And going back to elements, elements have got so many specialized needs. You might be better off with data items or data terms or data something else than elements. And I'd like to hear other people speak to that.

Leslie Kelly Hall – Healthwise – Public Member

Would data fields or data attributes work?

Clem McDonald – National Library of Medicine – HITAC Committee Member

Well, attributes are like part of a record. And these things are the record instances, I think, that we're talking about.

Leslie Kelly Hall – Healthwise – Public Member

Okay.

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

What does someone need to know, in order to share a piece of information that can be understood and reused by the receiver? Are you calling that items, attributes?

Clem McDonald – National Library of Medicine – HITAC Committee Member

I'd call it a term – well, in survey instruments, they call them items. The piece to be separate questions in survey instruments. But you've got drugs, which may not be called items. I don't know. It might be useful to have sort of an introductory discussion about what's there and what things – drugs, prescribable drugs are considered a class probably by everybody. And list some of the things that are there and encourage folks to go to those organizations and support them to get more of them or something like that. Of course, you can't just get any drug you want, but just what's available legally.

Leslie Kelly Hall – Healthwise – Public Member

When I want information on a medication like I may want the medication name. I may want the ingredient level. I may want the strength, the dose, the frequency, the start date, the stop date. To me, those are all of the additional items that go with that class. Where did the data come from? Did it come from the bill from the pharmacy? Did it come from prescribing – does all of that go into this? Or is that another phase?

Clem McDonald – National Library of Medicine – HITAC Committee Member

Good question.

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

Yeah. I think the way that I've been thinking about that, which may be wrong, is that there may be sort of nested use cases that we're talking about. And each use case requires slightly more specification than the preceding one. So, a list of drug names without doses or ingredients or administration times or lifetime use, whatever else you want to know that might be one use case. And another one might be no, we need to make this available, so we know what the next dose is that we have to give because we need to know the time and the amount and so on. So, I've been thinking about it as sort of nested use case rather than as all **[inaudible] [00:22:40]** data.

Clem McDonald – National Library of Medicine – HITAC Committee Member

This also gets back to introductory sort of educating the users. So, we're talking about the first case. We're talking about the decoding systems. And now, we're talking about message structures, I think, effectively, or data structures. So, I really think it would be important to say, if you really want to see about data structures and medication, go to the script standards, go to the HO7 inpatient V2 medication standards or the fire standards. Those are sort of done. And that takes care of all of that complexity. The coding system is what I thought we mostly were thinking of, when we were talking about data classes. But I don't know.

Kim Nolen – Pfizer – Public Member

This is Kim. I guess I'm struggling with this a little bit because let's just take the medication example, and you just have the medication name. And whether you're using this for primary use or secondary use, let's say it's for primary use, you get the medication name. But it was a medication that's not even active on the patient's profile anymore. That's important to know. So, I'm confused with what we're saying with these data classes and what to exchange, if we can't give all of the context that needs to go with them for people to make decisions off of them, either at a primary point of care or from a secondary analysis.

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

Sorry, this is Lauren just quickly. Terry, I just want to jump in. I see Rich and Leslie have been in the queue, so just want to acknowledge them have a comment or question.

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

Oh, okay. I'm sorry. For some reason, I'm not getting the queue anymore.

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

I believe Rich was first and then, Leslie, and then, was that Nancy who was just speaking?

Kim Nolen – Pfizer – Public Member

It's Kim.

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

Okay. So, then, we can go Rich, Leslie, and then, Kim.

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

Okay. So, I wanted to get back to the conversation that we were having a little bit earlier. There was some discussion about stakeholder and political support for particular data classes and whether to move them forward. And I just want to make sure we don't conflate that with technical feasibility established and proven. And that's where I was thinking the one commercial vendor ought to be something more. And I don't think we nailed that down. But I think that's important that there's – or maybe it's not commercial vendor. Maybe it's two different developers just generic that are approving this. So, it's not just a single instance. All right. And Leslie, are you up next?

Leslie Kelly Hall – Healthwise – Public Member

Mm-hmm. So, the way I think of this is we're not replacing standards organizations. We are allowing someone to pick up a bucket of standards or data class of standards and say this is ready to be considered for prime time. And we're not going to come back and ask for USCDI to take – I think as few times as possible, we want to say this is a single nit in all of the standards. We want to say there's a class of services called drugs. And the use cases that have been reviewed indicate all of these fields are necessary in one or more use cases, as Kim just described. So, this class and these definitions and these use cases are ready for prime time. We want to pick it up, stick it in the USCDI process.

And we can demonstrate that we not only have a sponsor, and it might be Kim's organization, but she's already spoken with several other organizations that have those primary and secondary uses of that data to gain support. And then, after that's gone through a process of technical feasibility, and it says yes, we're ready to have that considered for regulatory needs, it might get through once, and then, it evolves because that use case that was part of that data class recommendation gets some new needs. And that new evolution might skip to Stage 4 that says that class called drugs now has a new use case. As a result of it, they have four more data elements involved. We still have the primary sponsor. And those who have both secondary and primary interest in this use case are in support of this. That's ready for prime time.

So, I'd hate to have us be a replacement for standards but more as a place to consider that standards are ready for regulatory consideration. And, therefore, we're not approving or not data elements and definitions. We're proving whether or not this data class has met technical, political, and sponsorship needs, in order for it to be ready for regulation or rule.

Clem McDonald – National Library of Medicine – HITAC Committee Member

I like that.

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

Right. Let's hope that's recorded. Thank you. And I think we'll be a consumer of standards, but we're not going to be a creator of standards.

Leslie Kelly Hall – Healthwise – Public Member

Correct.

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

Yeah. I couldn't agree more. Anybody else out there? Okay. And let me throw something else by you and see if this makes any sense, any value, or whether we just want to scrap it. But for a variety of reasons, a couple of – it seems to be we're thinking of interoperability as really operating in three different levels of sophistication based on sort of what the stakeholder needs, their access to IT, the cost of acquiring, storing, sharing data. We're thinking of sort of three levels of interoperability, so basic, intermediate, and advanced are the three. And for basic interoperability, we're saying this is a group that, essentially, uses facts and email as their

primary exchange modes. And what they really need is they just need a document with unstructured data.

All they need is to know that the document is containing what they think they're getting when they ask for the document. They're getting a document of medications. And the expectation is the medication document will contain XYZ. And they're not going to use semantic standards. They're not going to use fancy transport standards. But they derive huge benefit from the data and from the unstructured data but really derive no additional benefit from any structure. We'll call those people the basic users. And that's really all of LTPAC, home and community based services, most likely the individual for a while. So, there's huge value in the data, but not much value in the structure, which adds cost.

And then, there's a group of intermediate users who can benefit from structured, semantically standardized data that they know means what they want it to mean because they've got to share it with regulatory bodies or payment systems or quality improvement reporting. So, they need some structure around their data. That needs to be specified and well defined. But they may not need the type of transport exchange that allows them to manipulate the data further than just knowing that they have data in a standardized form. And then, the third group are sort of the advanced folks. These are all of the meaningful use people who spent billions of dollars putting in certified EHRs who have the capability of producing and consuming machine readable data or data that they can parse into their systems. And they really need the whole ball of wax.

They need the applicable standards, both transport and semantic, and they need to have them constrained enough, so that what they're receiving is actually interoperable. So, that's the overview of sort of a world view about interoperability. And the implication of this is that there is a big class of folks who are going to be happy with unstructured data. And to the extent that we can facilitate that data moving rapidly, it puts things like clinical notes and radiology reports and anything that can be shipped as an unstructured text or picture, it puts that, essentially, on a fast track and says, okay, let's move this along because it has value to a bunch of stakeholders. And it may not take as much work as all of the semantic stuff, or the standards work that we're going to have to do otherwise. So, I want to throw that out there for the group.

Clem McDonald – National Library of Medicine – HITAC Committee Member

So, I agree with what you're saying, but I don't think that it's quite right. That is, if you're talking totally unstructured, it's done. People are sending email, or they're getting faxes. We have nothing to deal with that. You're talking about getting notes and reports where the payload is unstructured, you can't get away without having some structure on top of it to know who the patient is, this file that we're going to put it, to know what the test is, if it's a radiology report. You won't know where to put it, unless you're just doing it all by hand. Then, I'm back to why do you need anything? Just take it in and read it and put it where you want to. So, help me with that, getting that distinction. But I like the idea of focusing in where the payload is unstructured. It is fast tracked.

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

All right. Let's think some more about what – how can we advance interoperability moving

unstructured payload? And what would it take? What's the structure that it would take to do that?

Clem McDonald – National Library of Medicine – HITAC Committee Member

They exist.

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

I'm sorry, I do see a comment or question from Kim.

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

From Kim?

Kim Nolen – Pfizer – Public Member

Hi. Yeah. So, Terry, the way I heard what you were saying, and correct me if I've misunderstood it, was that you were saying the data classes could look different depending on the user. And so, I would almost flip that and say, if the data class wants to take medications because that is in a fairly structured format with standards today, if that's already there, then, it should be in that structured format, no matter who the user is. But then, there are other data classes that you were talking about like with radiology, those patient goals, and things that are important for other users to receive. And it would be good to have that payload, as you all were talking about, to be able to have that exchange for different users to view and use, if they needed it.

So, that's kind of how I see it. If the data class is already structured, everybody should be doing that because, if you don't, then, you're going to have somebody who has it unstructured. And then, one day, somebody who needs it structured. And they're not going to be able to send it that way. Do you know what I mean?

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

I think so. I guess the question would be are there broad swaths of healthcare where a structure doesn't add a whole lot, and B) they're not in a position to structure the data necessarily, unless they just copy what they get from somebody else who did structure it. Again, thinking about LTPAC and home and community based services, primarily.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Terry, since I don't see that we have a slide on this, can you reiterate what your middle stage was?

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

Yeah. And, again, this is probably the fuzzier of the three stages. The first one is properly defined. And that was a group of users who need standardized data but structured semantically standardized data but don't really have a way of manipulating it because they just don't have the IT capability. And, again, you can think of a lot of post-acute care where they have limited IT capability. And that includes LPACs and IRFs and home health agencies. And there's a benefit to them because they can reuse structured data to meet a bunch of their

reporting needs but don't really have the systems like the eligible providers who can parse that data, reanalyze it, run sufficient support off it.

Kim Nolen – Pfizer – Public Member

But it seems like you're setting up two different levels for the data classes to be stored just based on the user. So, let's take the LPAC one. So, maybe they don't have it in a structured format, but they, at some point, may need to send information to another provider or to a hospital that's taking care of that patient. And it's going to be in a text format. Or if a researcher wants to do research on that, and it's all in a text or a block format, then, they're not going to be able to do what they need to do. So, you're setting up two different standards for the data classes, right?

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

Right. And the reason for that is receiving unstructured data has more value than not receiving any data at all. I think that's the tradeoff. Would you rather not receive it?

Kim Nolen – Pfizer – Public Member

Yeah. I agree with that. But if you have a data class that's been defined in a structured way, why would you allow some people to do it in an unstructured way, and some people are forced to do it in a structured way to where you're getting two different levels of data? I'm getting confused on that.

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

Well, it has to do with how they are able to exchange that information or make it available. And that's part of it. They may not have any more sophisticated way of making the data available than secure email attachment, in which case, it's whatever structure is in the payload. It's not what they've done to manipulate the data. Am I answering your question? I'm not sure.

Kim Nolen – Pfizer – Public Member

Well, you're helping me understand what you're saying. I'm still drawing a little bit of a blank. And I guess, are you considering the LPAC? They're care providers, right?

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

Yeah.

Kim Nolen – Pfizer – Public Member

But I don't know. In my mind, I'm thinking of them that they would need to have their medications in a structured format with an RX Norm code and using the same standards to be able to exchange that because they're part of the whole care team. And if you couldn't exchange that in a fluid way, that seems to be going against where we're trying to go.

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

Yeah. No, I think, in the ideal world, everyone would have everything structured and have wonderful EHR platforms that enable all of this. But I think the reality is that that's never going to happen. I think there are going to be parts of healthcare that are providing clinical care that will never acquire the IT sophistication needed to either create or send structured data. I just

think that's a reality.

Eric Heflin – Sequoia Project – Public Member

So, this is Eric. I had my hand up. I just want to chime in that I couldn't agree more that structured data are imperative. Non-structured data is difficult to parse, to understand, to make sense of. And it is, bottom line, not interoperable. So, I couldn't agree more with the opinion that all data possible that can be structured should be structured period. If organizations cannot provide that, then, they already are not interoperable.

Christina Caraballo – Get Real Health – Co-Chair

This is Christina. I think Kim brings up an excellent point. And when I was originally thinking of this, I was thinking, if data is available, we should make it available. But now, this is a kind of different path in the discussion. It's not as available. So, I think this is important. You guys just made me think because, Terry, I think we were thinking let's get it out there in how it's available today. But then, we still need to continue to progress forward. And if there are more robust ways to exchange, then, those should be the requirements, right?

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

Well, it all comes down to, I think, the use cases. Again, if our use cases allow data to be processes and read by humans for human consumption, for individualized treatment, then, a fax or an email or unstructured content achieves that, to an extent, not efficiently. But if our use case is personalized medicine, population health, analytics to try to determine new optimal treatment pathways, then, those objectives are not accomplished, in my non clinical opinion, unless the data is structured and augmented by non-structured data, only to the extent that additional information cannot be conveyed in structured format.

Christina Caraballo – Get Real Health – Co-Chair

So, Leslie has been patiently waiting. So, Leslie, do you want to chime in?

Leslie Kelly Hall – Healthwise – Public Member

Yeah. This is a hard one. I struggle with this because, by nature of saying it's all structured, then, we have a have and a have not society in a process that is designed to serve as many people in the country as possible, whether it's the single guy in Rupert, Idaho that takes care of 500 patients, or whether it's Beth Israel **[inaudible] [00:44:18]**. So, there is a natural tension here that I think Terry's point is trying to acknowledge. Look, they're going to have varying degrees of technical capacity. Eric's point is well, then, it's not ready for prime time for regulation. And perhaps what this identifies, rather than us making the black and white decision about this, to say that part of this preparation would indicate the capacity to adopt across the continuum in today's technology as part of the due diligence process because, sometimes, the government will choose the floor.

And sometimes, government will choose the ceiling. If we have a Zika catastrophe, they're going to choose the ceiling. If we have something that says this is a nice to have, they might be choosing the floor. And it might, actually, be a direct message with a consolidated CDA payload that has to be manually ingested in to the EHR. So, we have an obligation to accommodate the

floor and the ceiling as part of due diligence and not state that it has to be one or the other, if our objective is to serve all in a country.

Kim Nolen – Pfizer – Public Member

I like the way you said that, Leslie. I guess, with that being said, with we know there's going to be different technical capabilities with different caregivers. But then, I think there's also the thought of, with the data classes, some of them, today, have very structured formats through standards. And some of the things only have a blob or have text that can be sent. And I think it's good for us to say, if it can be sent as a blob, and that information is helpful, we should help, as this group, facilitate that being possible through a standard, with all of the attributes that Clem was talking about earlier to day who it's from, what it is, to identify it in the proper way, so that it can be consumable to the end user. And I think it's important that we do have unstructured data that we could push through here, but it does have to be encapsulated with a standard somehow.

But I don't personally feel that, if we have a data crunch that has standard with structure that we should be pushing it to be sent in an unstructured format.

Clem McDonald – National Library of Medicine – HITAC Committee Member

I don't know whether there are other hands up, so let me know if I can join in.

Christina Caraballo – Get Real Health – Co-Chair

You're next, Clem.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Okay. So, I think we're getting some things confused a little bit. So, I think what Terry was pushing for was having payload that's just narrative. And there's no problem with that. But I think, if you think of it as people have no technical capability, they can't do any of this. You can't send stuff. You'll never get it in. They can either send faxes, or they can send emails. That's all done. We don't have to help. But you got to have a standard, as we just heard from Kim, anyway. And, probably, it can also take more structured stuff. But that's not the big issue. But if we just declare these are in between people and somehow, they don't have much capability, and somehow it will work, it won't work. There's got to be a floor in the capability before they can do anything with the payload being unstructured.

Adam

So, this is Adam from ONC. This is a terrific discussion. It is 4:20. I would recommend that we, perhaps, move on to the next slides on Stages 3 and 4. And also, note that I think there might be a loud typer who is not on mute. So, if you wouldn't mind putting yourself on mute while you're not talking, that would be great. Thank you. Terry, back to you.

Christina Caraballo – Get Real Health – Co-Chair

Hey, Terry, do we want to focus on the seed slides or go more through the biography of a data element, which we probably haven't discussed yet as much? Did we lose Terry?

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

No, you didn't lose me. I was just talking on mute. But I wasn't typing this time. Sure. That's fine. So, let's take a look at the biography because that's sort of another new concept. And the question is, if we're going to create this shared platform where we house data elements and data classes that are advancing through this process, is there a set of information about each data element that should travel with the element? And, again, it's biography, for lack of anything else. And these couple of slides are just a real fast draft of what, for example, some of those elements might be. But you could imagine a data element making it all of the way through as part of a data class that then becomes available for reuse.

And it has a pedigree attached to it. So, again, and does this help the process, or is it just sort of a needless detour? Eric, you got the floor.

Eric Heflin – Sequoia Project – Public Member

Sorry, it took me a second to unmute. So, the one item that struck me as being helpful to maybe add onto this excellent first draft would be the associated really use cases that is assigned to support. And you do say, in here, value. Maybe those concepts could be merged together asking what's the value or what's the value to certain use cases that this proposal is intended to augment or enhance or enable.

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

So, add use cases to the pedigree.

Eric Heflin – Sequoia Project – Public Member

Yes.

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

Or whatever we want to call this.

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

Clem and then, Steven.

Clem McDonald – National Library of Medicine – HITAC Committee Member

I think we need a lot more specification around this. So, what I think we're talking about is a list of records that represent the instances of the thing you're talking about in the class. And then, you're talking about the pieces of that instance, or the fields in that instance record, that would specify it or say what you mean. And so, you're going to get a whole different record and fields if you're talking about drugs, and you want to talk about drug instances. Or if you're talking about labs, you'll get different fields. So, across the space of things you're talking about, you get different record structures. And I think we need to start with some class names, actually, and then, specialize within them, if you want to go at this level.

And I think the idea of asking people let's say if it's something simple like a questionnaire, you want to ask that a questionnaire should be included. I don't think the average person will have

any idea of how to specify. You need answers for the questions. If you're doing things numeric, you need units of measure. So, I think we got to think about how we want to do this. And I think you might be better off saying this is what's out there. And if you want to know one of these kinds of things, use the standard that exists to ask for another one. But I think this is very, very diffuse, right now. And I wouldn't know how to use it.

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

Okay. Stephen?

Steven Lane – Sutter Health – HITAC Committee Member

I'm not sure I'm answering the same question that Clem was answering. But I think you asked is this a needless detour, or does it make sense for us to kind of flush out this biography, this history of each of the data elements? And so, I'll answer that question. And I think it does. I think this is a good idea. I think, for every element that makes it into USCDI, that it makes sense to kind of have a whole set of references that talk about how it got there, who supported it, what was its journey in getting there. And, frankly, I would even say, even once it's up in full use that there should be an opportunity to collect metrics on how much it's being shared and how it's being utilized, and what have been the successes. I think the idea of if you say a biography of the data elements makes sense to me. And I like the way you're approaching it.

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

Okay. Thank you. And Leslie?

Leslie Kelly Hall – Healthwise – Public Member

The points were well said. And I would just add that, in this biography, we have a biography that includes expanding an existing approved member of the USCDI or expanding new stakeholders to an approved class. So, making sure we have those tracks as well, when we're finished.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Can someone do some examples of what they're talking about? Are we going to say I want to put penicillin in, and I'm going to describe penicillin?

Leslie Kelly Hall – Healthwise – Public Member

It could be that. What I'm suggesting is let's say there's a data class that Kim described for drugs. And that data class and all of the use cases around it didn't meet a whole new group of drugs that are coming in. It could be related to new precision medicine initiatives, for instance. And so, now, that class has to be expanded with these new use cases. Or that same group has said, gee, now, the PDNs are going to be part of this interoperability network. It's a new stakeholder that wants to participate directly with the EHRs. We've already defined these classes of service. Now, we want to add these new stakeholders. So, that's my example. If those new stakeholders, by virtue of adding to this, create change to USCDI or change that needed support regulations.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Okay. Well, the advantage of saying you're adding something is there's already a structure of framework for knowing what the things you're talking about.

Leslie Kelly Hall – Healthwise – Public Member
Right.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, in your particular case, I think that's all done. I think the whole pharmacy stuff, I think it's pretty well done.

Leslie Kelly Hall – Healthwise – Public Member
I was giving examples. I'm not saying drugs are not, just as an example.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. Any other thoughts, guys? You might see this in the draft.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Maybe someone would create a flushed out example set of something that can really be done with this and might make it clearer and easier. Or, if they can't, then, we got a problem.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I had marked up a set around immunizations. And I can't remember who proposed the immunizations of a use case.

Mike Perretta – Docket – Public Member
Oh, I think that would have been me. This is Michael.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Oh, okay.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But I think that's done, too. There's a couple of coding systems for immunizations. There are some message structures for immunizations.

Leslie Kelly Hall – Healthwise – Public Member
But it is regulation, Clem. The issue is not whether the standard has been used but whether that standard is acknowledged enough to be in regulation.

Clem McDonald – National Library of Medicine – HITAC Committee Member
It is. It actually is. It's in meaningful use. But the question is –

Eric Heflin – Sequoia Project – Public Member
Here's an example, Clem. This is Eric. Right now, one of the issues I face in a real world project

was that experimental cancer medications are not codified. They're named based on the conventions of the study. And they're not shared, at least to my knowledge. And so, one proposal could be that cancer studies that are perhaps, hopefully, going to be within the scope of an interoperable data exchange, actually, include codification of the administration or the medications as part of the project. The value would be that cancer researchers can collaborate and identify more readily around the experimental therapies being given to patients. This brings something out of the scope of non enterable data into something that's not interoperable, etc. So, that's one kind of example I would actually like to see.

Clem McDonald – National Library of Medicine – HITAC Committee Member

But do you have an effective procedure for getting there? Because the vendors, you've got randomized. There's either a placebo or the real drug. You can't reveal that.

Eric Heflin – Sequoia Project – Public Member

Sure, easily accomplished, I would think in that, when the study is funded, part of that includes a map from an arbitrary identifier, which acts as the anonymized characteristic for the given medication. It maps back to the actual medication being prescribed, whether it's the placebo or the actual medication under a study.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Okay.

Eric Heflin – Sequoia Project – Public Member

I'm surely not a cancer researcher or a clinician. But that's just one example that occurred to me that that was a real problem because the project I was involved with, they wanted, from multiple hospitals, they were administering the same medication to be able to identify if the same medication was being given to the same person at a different facility. And they couldn't reconcile this.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Okay.

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

All right. More comments? And Adam, where are we on our journey through the slides?

Adam

I believe that up next was discussion of Stages 3 and 4 on the following slide.

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

Okay. All right. So, three and four are two of the original USCDI process stages. They're really the testing stages. And I may be wrong, but I've really been thinking about them as there's really differences in testing scale rather than differences in process. But happy to hear other thoughts about that.

Christina Caraballo – Get Real Health – Co-Chair

Clem? Clem, did you have a comment?

Clem McDonald – National Library of Medicine – HITAC Committee Member

I did, but I was talking through a muted speaker. I'm not sure we need three and four separately because they could be planted. But I also wanted to add a couple of things about the biography, after I was critical of it. I think we need to say something in there as to whether these are coded data elements and whether they've looked to see what's around. And there was another dimension. There are a couple of things like the higher level process things would tell people what they're asking about.

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

Great. Okay. To your comment about are these the same stage, I think one of the other purposes of Stage 4, in particular, is to give the vendor community a heads up with as long a lead time as possible. And there are going to be candidates that – there are going to be data classes that take a long time to get out of Category 3 because they're going to go through multiple cycles of testing and retesting. So, telling industry that they're coming dilutes the impact of knowing that, once you get to Stage 4, you really are, basically, one process step away from being a national priority. So, if it's a value of providing industry with as long a meaningful timeline as possible that let us to keep the two stages.

Christina Caraballo – Get Real Health – Co-Chair

Eric, you're next.

Eric Heflin – Sequoia Project – Public Member

Thanks. So, I like the overall idea behind Stage 3 and 4. But what I would like to suggest we do is improve the how to get out language. Right now, it seems very subjective. And I would respectfully suggest we make that objective. For example, some standards bodies will use criteria for their equivalent of a Stage 3 that says this has been piloted by three different organizations using different technologies. And that, perhaps, could be extra criteria for Stage 3 and Stage 4 more objectively Perhaps, they could have criteria such as it has been implemented in production by at least three organizations using different technologies with some similar, less subjective measure for the extra criteria.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Along that line, I think there is a formal maturity level that goes from one to five in FHIR. I can't spit it out what it is. We should probably look at the actual published levels of –

Eric Heflin – Sequoia Project – Public Member

Yes, there is indeed for I think for FHIR. I know there is for IT. And it actually is based on something similar to what I just conveyed, which is that we actually have subjective threshold based on organizations that are known to have achieved a certain level of implementation status. Otherwise, my concern is, on three and four, I don't know how to measure that or how to test that.

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

This is, actually, a proposal that Adam has been advocating. It makes a lot of sense that we make the exit criteria very explicit and using the maturity models that are out there as examples may help us find the right vocabulary to describe objective exit criteria.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Let me highlight though, even when you make it objective, people exaggerate or overstate or understate. And I think **[inaudible] [01:06:04]**, but I'm not sure, which doesn't have maybe as high objective spec. But at least you know, with the mass of industry and people and who thinks it's ready.

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

So, you're suggesting we ask the stakeholders or interested parties to opine?

Clem McDonald – National Library of Medicine – HITAC Committee Member

Well, I actually think what we ought to do is get the written specifications for these maturity levels from a safety and standards organization and think about what would work the best. Or maybe many of them would work equally well. If the standards body says it's a five, maybe that's good enough, rather than us having to do it. I don't know.

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

Yeah. The comment I made back to Adam was that the maturity standards for standards is different than so, the data class readiness to move on to the next stage, although they may be analogous, they're somewhat different.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Well, there's a lot of analogy in the fire one because fire applies the security to what they call a resource, which would be very parallel to a data class, I'd think, in our world. But people are digging a little bit.

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

Okay. So, the recommendation, Clem, you were saying is to take the fire resource standards and see how we can apply them to Stages 3 and 4 to add more objectivity?

Clem McDonald – National Library of Medicine – HITAC Committee Member

Yeah. But I would add in, as Eric suggested, look at IT. I don't think we have to target immediately just one, but just get a sense of what's there and how to use it, how it could be maybe used. Yes. I more or less said that.

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

Okay. And Kim, you're on deck. You're up.

Kim Nolen – Pfizer – Public Member

Yeah. I had something back on Stage 1 and 2, so I don't want to interrupt at Stage 3 and 4. So, when we're done with that, if you'll call on me again, I'll go back to that.

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

Okay. So, Leslie is the only other one in the queue, so Leslie –

Leslie Kelly Hall – Healthwise – Public Member

I think rather than say we're going to use or identify this maturity model as being the one we consider, we just simply state that, as part of this consideration, you've identified a maturity model associated with the standards need. When one doesn't exist, here is what the USCDI will consider.

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

Okay.

Leslie Kelly Hall – Healthwise – Public Member

But to the degree possible, we don't want people to redo work they've just done to get a standard elevated within the standards body organization. We want to be able to package it in a way that says it's ready for regulation.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Yeah, that's a good point.

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

Again, we're not advancing standards. We're looking for standards that support the data class to be advanced. Okay. Kim, you're back.

Kim Nolen – Pfizer – Public Member

Okay, thank you. So, I'm a little bit of a slow process, and I hope my processing capabilities are working right. But when I look at Stage 1 on Slide 4, it said proposed data element. And then, all the rest of them talk about the data class. And then, it defines the data element as part of the data class. So, is that the correct terminology on Slide 4 to use data element, or is it data class? And then, on Slide 5, at the title, it also says the biography of a data element. Shouldn't that be a data class? And then, the elements are just part of that class? I'm just thinking, if somebody else is looking at this, and they're trying to relate each of those things, I would get caught up on that.

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

Yeah. And I think that goes to a lot of Clem's points, too, as sort of what are we calling – what's a data element.

Clem McDonald – National Library of Medicine – HITAC Committee Member

I think she's got a good point. I would call them items because it's fairly generic. But the key is though that you've got to be careful with talking about the class and the child of the class as the same thing. There are such things as singles and classes. That's, I think, what Kim is pointing to. And we've got to be consistent.

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

So, we're talking about children of the class?

Clem McDonald – National Library of Medicine – HITAC Committee Member

Well, these items are probably children, but it just gets a little confused. You get like an [**inaudible] [01:10:52]** diagram, if they become the same.

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

Okay. All right. Okay. Good points. And we will take that under advisement. We'll see what we can come up with in one day. Eric, you're up.

Eric Heflin – Sequoia Project – Public Member

Just very briefly, to close the loop on the prior discussion about the exit criteria, I've included, in the chat, two links. One to an informal discussion of IHE maturity model for moving something from, essentially, trial to final tech status. Another one for the fire maturity model. These speak pretty much in terms of the lingo of the standards bodies. But perhaps it would give us some material to draw from. One criteria, for example, would be has this been tested at an industry test event. Another one is are there test tools available. Has it been deployed in production? Has it been deployed in prototype environments? Are significant change proposals issued against that where there's presumably a problem? And have those actually all been addressed? And so on. That might inform this work.

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

Yeah. That's great. That helps. And that might apply to Stage 2, as well, how do you get out of Stage 2. You may need to have some of those things in place.

Eric Heflin – Sequoia Project – Public Member

Exactly. This is just to inform what may be a little more objective entry and extra criteria for the various stages. And the good thing about basing our work, to an extent, on those particular items is they've been battle proven. These maturity models have been tested over many years and refined. And they work within those realms.

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

Right. Yes. I think that's a good suggestion. So, here we are. Maybe, at this point, if someone has anymore comments, just put your hand up and break in and make them. But perhaps we ought to take a look at the upcoming homework, which is going to be kind of daunting. Do we have a homework slide, Adam?

Adam

We do not have a homework slide.

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

Okay. Then, we'll make it up.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Does that mean it's not daunting?

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

Yes, that's right. That means it's not yet daunting. But it will be, when we make up the slides. I think, again, we've got to get our final recommendations in by the end of next week, which means our meeting on Wednesday and our homework are the last two times that we're going to be able to materially change the presentation. So, it means that whatever goes out on Thursday of next week is what's going to get presented the following week in DC. With that in mind, I think the homework for this weekend is going to be to take a look at the drafts, and get out your red pencil, and just sit down and mark it up.

And, again, it doesn't – things that bother you, things you think are missing, things you think are wrong, things that aren't emphasized enough or emphasized too much. Just have at it. And our job will be to take those comments and produce a redraft, so we can discuss – again, we'll try to get that out to you early next week, a redraft, so that we can discuss and make final changes on Wednesday. How does that sound for a timeline? Eric? Do you have your hand up, or are you on mute?

Eric Heflin – Sequoia Project – Public Member

Yes, I was double muted. Sorry. That sounds good. I just have two requests. 1) Can that be sent out to us sooner rather than later? And 2) can that be sent in editable format, so we can actually return it with mark up in place or something efficient like that? Thank you.

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

Yeah. That's a good idea. So, we can send it out as a Word file with track changes or whatever Adam and Stacy are most comfortable dealing with.

Eric Heflin – Sequoia Project – Public Member

Great. Thank you.

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

Thanks, Eric.

Christina Caraballo – Get Real Health – Co-Chair

Our goal is to try to get it out on Friday. But we've been working in just a Google Doc, and we have to put it into a template. So, just bear with us. I'm hoping Friday. And then, I was thinking, would it be helpful to send out the biography of a data element, for lack of better words, putting in data element, but would it be helpful to send that out to the group and get comments on that earlier? I think that's the only thing that's really new that we've introduced on today's call. And we can probably send that along with the immunization example out.

Clem McDonald – National Library of Medicine – HITAC Committee Member

But I've got to –

Eric Heflin – Sequoia Project – Public Member
This is Eric, yes.

Clem McDonald – National Library of Medicine – HITAC Committee Member
The immunization example is completely done. And if you're not at least referencing that, I think you're going to confuse everybody. We should know that kind of stuff, if we're representing HITAC.

Eric Heflin – Sequoia Project – Public Member
So, Christina, yes to your question. This is Eric. If you can send out partial information for us to start working on early that would be very helpful.

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

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
This is Lauren. If there's nothing else, we can go to public comments, or we could, if you need more time for discussion in the next five minutes or so, it's up to you.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Why don't we go to –

Leslie Kelly Hall – Healthwise – Public Member
This is Leslie. Could I make one comment? I think that what's confusing is like to Clem's point, we say this class **[inaudible] [01:17:39]** and that's already done. Maybe use case is something like, oh, quality measurement organization, CNS have been collaborating to determine this particular change for maybe it's half of patient safety. And so, there's new quality measure being initiated. This quality measure has data elements that are already in standards bodies, and here's what they are. And here's the use case today. We think this use case could be applied to this new need. And, therefore, we're bringing this in, so that regulations can be considered at a future date. I think the process has to be one that aligns with a use case need.

There's a new business need. And I think we keep trying to say is this the right data element to consider, or is this the right data class to consider, when what we're really saying is there's a new business need for the government that may be considering regulation. And there are rules. And they want to align that, so that standards can be promoted, adopted, and used to scale.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I like that clarification.

Christina Caraballo – Get Real Health – Co-Chair

Excellent point. And remember, when we originally sent out the homework assignment to go through the different stages, and Michael sent the immunization, we weren't asking where it was. It just shows that it's going to be further along, probably making it more towards Stage 6. So, keep that in mind, too, as you're looking at the immunizations. It's just an example of how it would work in the process, not something that we need to propose.

Clem McDonald – National Library of Medicine – HITAC Committee Member

Because there's going to be a whole spectrum of people looking to load this in. And I want to come back to why can't we give them like a couple of paragraphs of what exists and where they can look at it to see if it's sufficient.

Christina Caraballo – Get Real Health – Co-Chair

So, Clem just raised his hand to draft that for us.

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

We'll send you out a reminder tonight. All right. If there are no other comments from us, why don't we go to public comment, and then, any time that's left, we'll fill doing something.

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

Okay. Operator, can you please open the line for public comments?

Operator

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

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

Thank you. And just to remind everyone to please keep your comments to no more than three minutes. While we're waiting for folks to dial in, I just want to go back to **[inaudible] [01:20:41]**. Do we have either Brett, Valerie, Nancy, or Dan on the line? Okay. We'll just record them as being absent. And, 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. Thanks. So, with that, I'll turn it back to Terry.

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

Okay. All right. We got six minutes for anymore comments on anything that's still top of mind.

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

If nothing else, we can adjourn for today. Just to remind everyone that our next call will be **[inaudible] [01:21:41]** at 3:30. I'm sorry, we got a comment? Okay. Maybe not.

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

Great. Thank you.