U.S. Core Data for
Interoperability Task Force

Transcript
March 28, 2018
Virtual Meeting

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

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

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

Rich Elmore – Allscripts – Public Member
Present.

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

Steven Lane – Sutter Health – HITAC Committee Member
Good afternoon

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?

Brett Oliver – Baptist Health – HITAC Committee Member
Here.

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

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

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Valerie Grey? No Valerie yet? Laura Heermann Langford? No Laura? 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
I'm here.

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

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

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

Rich Elmore – Allscripts – Public Member
Here.

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

Eric Heflin – Sequoia Project – Public Member
Present.

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

Dan Vreeman? I believe we should have Dan on. We'll circle back to make sure. Mike Perretta?

Dan Vreeman – Regenstrief Institute, Inc. – Public Member
Here, I'm here. Can you hear me?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Yes, we can hear you now.

Dan Vreeman – Regenstrief Institute, Inc. – Public Member
All right, great. Thanks.

Mike Perretta – Docket – Public Member
This is Michael Perretta. I'm here.

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

Rob Havasy – HIMSS – Public Member
Here.

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

Christina Caraballo – Get Real Health – Co-Chair
Great. Thanks, Lauren. So, we have a big agenda here today. We have about three meetings left to finalize our recommendations before we give them to ONC for the HITAC meeting on April 18th. So, today, we would like to go over and finalize the three task force sub-charges, which include the USCDI expansion, the frequency of publication, and the USCDI process for stakeholder feedback, and then, time permitting, we'd like to move on to discuss the value criteria in preparation for next week, moving from Stage 1 to Stage 2 of our criteria, and then, in next week's discussion, also look at the technical criteria. Could we move on to the next slide?

Valerie Grey – New York eHealth Collaborative – HITAC Committee Member
Christina, this is Val Grey. I just wanted to quickly let you know I joined.

Christina Caraballo – Get Real Health – Co-Chair
Great. Welcome.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thanks, Valerie.

Christina Caraballo – Get Real Health – Co-Chair
So, on this slide, I want to point out that you see some red here. What we've done for each of the three sub-charges that we're going to look at is we've incorporated – we've taken what was presented

during last week's HITAC meeting and added input from the Task Force call last week and from the homework. So, for everyone who submitted their comments via the homework on each of these three sub-charges, those have been incorporated into this. Hopefully, all of those have made it in.

So, moving on to the USCDI expansion, let's just go through this to begin. These are our consolidated recommendations to date. First, we have that data classes should be added to the USCDI based upon successful progression through all prior stages. This means meeting the criteria that we still need to be determined and finalized. There should be no limit to the number of data classes added. Some people noted that there should be no limit on the "Who" or "What." Individual organizations can propose these data classes, whether it's public or private sector, commercial enterprise, or nonprofit.

Also, someone recommended that even international organizations can be proposed. There should be no predetermined timeline for advancement through Stage 5. Should there be a timeline of one to two years or no predetermined? We need to discuss that today. Is there a timeline needed to incentivize vendors to do this work? Progress through Stage 5 may be impacted by vendor and other stakeholder capacity and business cases.

A data class can move to Stage 6 as determined by the RCE, which will measure data exchange with associated standards. The ratio of available data classes in Stage 5 to those that have progressed to Stage 6 in the preceding 12 months should be used to review the process for prioritization and implementation. There was an additional recommendation that data classes should be available at minimum in both English and Spanish. Before I open it up to discussion, Terry, did you have anything to add to this slide?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, but it might be helpful if we just kick them off one at a time. So, start with the first bullet and hear people's comments. What do we think? The intent of this is to make it clear that you get into the USCDI having gotten through all of the other gates in the preceding stages.

Christina Caraballo – Get Real Health – Co-Chair
Great. Clem, do you want to kick us off?

Clem McDonald – National Library of Medicine – HITAC Committee Member
That's not one that I have any concerns about. I think we've created something like that story about it being harder to get into heaven than for a camel to get through the eye of a needle. I think we've created that here. I don't think anything is going to make it. This is a great way to stall standards. It's way too strict. Things like English and Spanish – are the drug names in Spanish? You've created stuff that may not be implementable. Sorry.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Clem, just to follow up, on the English/Spanish, I get what… Do you have any specific criteria in mind?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, they're way too strict. I don't think anything that exists would fit all these criteria. Then, when you go on to the additional technical measurements, which won't exist… This looks like something that will stall us ever doing standards. I think you should stop somewhere on Level 3 and say, "Now you can…" It depends on whether getting to the top means anything.

Christina Caraballo – Get Real Health – Co-Chair
Clem, I want to focus us on the expansion process right now. I think you're talking about the criteria to progress through the stages, which we will get to at the end of this call, but we need to focus on the other three charges so that we can knock them off, and then spend the remainder of the time getting down to that important piece.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, the first one says they must progress through all prior stages, so I'm right on target.

Christina Caraballo – Get Real Health – Co-Chair
So, meeting the criteria, which needs to be determined. I'm going to table that for now. Any other comments on the rest of the areas on the expansion process? Leslie, I see your hand up.

Leslie Kelly Hall – Healthwise – Public Member
Yes, thanks. I don't know whether it's here or at another level of expansion, but there will be evolution, and we need to allow for expansion to be in the breadth of stakeholders added to be using that or the breadth of function added to something that's been initiated. So, perhaps a new data class comes in that includes a new type of patient-generated finding, and initially, that stakeholder is the patient, but going back and expanding, we might have more things like findings and observations and results generated from the patient. That would be an expansion in the breadth of functionality. And then, we might add the caregiver and the plan. So, I don't think that every time expansion goes wider, it has to go through all of these steps. That might be a separate workflow that's established, but something we should consider in our recommendations.

Christina Caraballo – Get Real Health – Co-Chair
Okay. So, Leslie, do you have a specific recommendation that you would add to this set?

Leslie Kelly Hall – Healthwise – Public Member
Data classes should be able to expand in breadth of function and breadth of users or stakeholders. This expansion process might therefore have two tracks: One that's initiating a new addition to USCDI and another that's an expansion in breadth of stakeholder or function, which is fast-tracked.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Interesting. So, we may want to flag that one again when we talk about the stages because certainly, some of the initial stages – 2 and 3 – are more amenable to that sort of process. That might be where we want to tuck those in. But, we're going to put everything in the parking lot today.

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

Steven Lane – Sutter Health – HITAC Committee Member
I just wanted to revisit this English and Spanish. Clem touched on it. I must say, I don't get how it applies to data classes. It seems like the ability to translate words from one language to another is an entirely different discussion that doesn't specifically apply to data classes, in my mind. So, I don't know who recommended it, but I don't think it really belongs here.

Leslie Kelly Hall – Healthwise – Public Member
I agree.

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

Valerie Grey – New York eHealth Collaborative – HITAC Committee Member
I do as well.

Nancy Beavin – Humana – Public Member
Me, too.

Christina Caraballo – Get Real Health – Co-Chair
So, I guess we can take that one off unless the person that recommended it has a rationale. Please speak freely. Okay. Rob?

Rob Havasy – HIMSS – Public Member
Thanks, Christina. On the third bullet, which says that there should be no predetermined advancement through Stage 5, is that separate from a time limit? I think our intent is not to create an ever-expanding list of data classes that never make it through to the CDI or Stage 6, so at some point, if something doesn't move for *x* number of years – five years, maybe – should we just say it should be resubmitted? We allow resubmission, but at some point, we have to clean and purge the list so it accurately reflects current priorities, not what we hoped to do five years prior.

Clem McDonald – National Library of Medicine – HITAC Committee Member
That makes sense.

Mike Perretta – Docket – Public Member
Yeah, I think it makes a lot of sense.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Do you think five years? Two years? Three years? Four years?

Rob Havasy – HIMSS – Public Member
I just happened to be looking at something on my desk with the number five on it. That's where that came from.

Laura Heermann Langford – Indiana University – Public Member
I would vote for three years.

Leslie Kelly Hall – Healthwise – Public Member
I think it's two.

Laura Heermann Langford – Indiana University – Public Member
Yeah, short. This needs to happen, or it's not useful.

Rob Havasy – HIMSS – Public Member
I agree it should be shorter. I'm not married to the number five. It's in the middle of my telephone keyboard.

Steven Lane – Sutter Health – HITAC Committee Member
Two seems too short. I think it's going to take time for some of this to do, so if we're going to put a limit on it – which I don't think is really necessary because we haven't done it yet and I'd rather learn from the experience first, but if we are, I'd keep it at three to five.

Nancy Beavin – Humana – Public Member
I'm the one that put this comment in there. Stage 5 says that QNs and participants are required to update their technology to support the new data class, so my concern is if we don't have some kind of timeframe in there that makes them do that, it'll never become a priority to get it adopted enough to be able to be widely adopted in Stage 6.

Steven Lane – Sutter Health – HITAC Committee Member
I think putting a limit on the QNs step is very appropriate, but putting a limit on the entire process was the thing I was concerned about.

Christina Caraballo – Get Real Health – Co-Chair
So, what are thoughts on instead of having a specific year, having a recommendation that ONC – or whoever is going to govern this, possibly the RCE – looks at an annual review of what is in the current stages and just making sure they still fit?

Nancy Beavin – Humana – Public Member
And, should we say they're going to stay through Stage 4 for some long period of time, but they can't sit in Stage 5 for five years waiting for prioritization of actually doing the work?

Rob Havasy – HIMSS – Public Member
I think that actually makes a lot of sense.

Eric Heflin – Sequoia Project – Public Member
There's actually some precedent for that, too, which is that some standards bodies, like the IHE, actually include within their process a mechanism to determine if a standard has been adopted, or if not, to remove it.

Laura Heermann Langford – Indiana University – Public Member
I would support that. I think we might need to look at each stage and add a reasonable timeline.

Rob Havasy – HIMSS – Public Member
I think in Bullet 5, "Data classes will move to Stage 6 as determined by the RCE by measuring the exchange with associated standards" – that gets us how long something takes to go from Stage 5 to Stage 6, so it seems like if we accept these bullets, there's a process to make sure that something does move into actual use. I think putting a limit on things that are getting standards developed but not moving forward in the earlier stages is more appropriate to my comment.

Christina Caraballo – Get Real Health – Co-Chair
Clem, you're next.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I have a comment on one of the earlier comments, and I don't think it's necessary now. Thanks.

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

Rich Elmore – Allscripts – Public Member
The fourth bullet, "Progress through Stage 5 may be impacted by vendor or other stakeholder capacity and business cases" – I had one question. What was intended by "through Stage 5"? Does that mean applicability to that stage or Stage 5 in progress? That was the question. Certainly, vendor capacity could be an issue, but I'm concerned about the folks that actually have to handle the data collection. I want to make sure that we're explicit about workflow and capacity of the clinicians and the provider organizations to handle this, assuming that's who has to do the collection.

Christina Caraballo – Get Real Health – Co-Chair
Terry, was that you?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, but this was a rephrasing of something that I've gotten, and I can't remember who it was from, but it was to be sensitive to the fact that vendors are not going to necessarily pick up every data class to move forward. They're probably going to be selective based on what makes the most sense to them, and in that, them being sensitive to their customers in the sense that they're stakeholders. So, it was an attempt to acknowledge the fact that the process of getting through Stage 5 may be uneven depending on who the vendors are, what their business cases are, and whether the data class actually contributes to what they want to do. That's independent from any other incentives that get put in to do this work, like you don't get paid unless the MS gets the data this way.

Christina Caraballo – Get Real Health – Co-Chair
That was our way of looking at how the market is going to actually drive making it into Stage 5, and then actually being more widely adopted throughout the industry.

Rich Elmore – Allscripts – Public Member
We don't necessarily have to craft it right here on the phone. It may be worth thinking about how we could provide some greater clarity about that concept. It wasn't necessarily easy to read. And then, if I may, I had one other comment, which relates to expansion. I think this got picked up by Leslie Kelly Hall in her comments earlier, but we had this notion of something that was use-case-dependent and was also applicable to particular stakeholders. Terry, I don't know if that was part of where you were going with the uneven application, but it may be something that's critical to the behavioral health segment, but not to primary care. I think we need to allow for a segmented approach so that we're not trying to make an all-singing, all-dancing solution for every purpose.

Christina Caraballo – Get Real Health – Co-Chair
Okay. Steven, would you like to add a comment?

Steven Lane – Sutter Health – HITAC Committee Member
I was just going to say that I think the workflow considerations are real and valid, but I don't think that they should be limiting. I think we should let things in the front door and work out the workflow as we go. Just because something seems hard at the outset doesn't mean it's not worth looking into.

Rich Elmore – Allscripts – Public Member
No excuses.

Christina Caraballo – Get Real Health – Co-Chair
And, as we discuss the slides – Terry and I were talking about this last time – I know we have the hand raise function, but if anybody has a comment in response to another task force member, please feel free to chime in so we can create better dialogue.

Laura Heermann Langford – Indiana University – Public Member
I had one on the last one around "Progress through Stage 5 may be impacted by vendor," the fourth bullet point. I'm not sure that's really a recommendation. When you read the others, they read as recommendations. That one feels like it's perhaps a statement of reality, maybe an excuse. I'm just not sure that it belongs there at all. It sounds more like a criterion to measure the impact and capacity than it does an expansion recommendation.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I kind of agree. It's just a fact that will be influenced. I agree with what was just said.

Rich Elmore – Allscripts – Public Member
If that's the case, I just want to make sure we pick it up somewhere, particularly as it relates to the folks that have to do the data collection. I think that's the most important constituency here, to make sure we're not overwhelming them.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Along that point, I think we should make a sharp distinction between requirements for data that exists in electronic form versus that which is going to require manual input. That's been dropped. I think it was discussed a long time ago, but there's a difference of night and day between the issues surrounding those two.

Rich Elmore – Allscripts – Public Member
Agreed.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, do you want to propose alternative language or type it in eventually?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I just think that at a higher level, we should make a distinction between things that are sitting there but aren't coded well or being sent – lab tests, EKG tests, spirometry, you name it. If it's been collected already in many systems, that's easier and is not going to cause labor problems, whereas if you're asking another 65 questions for the nurse who's checking the patient in, that's going to choke the system.

Laura Heermann Langford – Indiana University – Public Member
This fourth bullet point plus what Clem has been saying – and perhaps Eric; I'm not sure who was the last voice – I think what we're talking about is some of the reality. We keep hearing Clem's voice of caution that this is too hard, we might not be able to get through this, and it might not be realistic. I feel like this fourth bullet point is part of our – this is kind of tough.

We're not sure how all this is going to go. I'm not sure what it captures. I'm not sure it's on expansion recommendations, but I do think there are several thoughts going throughout the group on wanting to

go back and revisit our stages and what we've put in there for the requirements, but also, there's the bit about our reality, saying this might not be easy, and it might take some time, and Clem saying that if it's electronic, it could be easier, but if you're trying to do something new, that might be harder. So, there may be another type of slide or document that talks about some of these realities that we realize.

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

Nancy Beavin – Humana – Public Member
I have already made my comments, thanks.

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

Clem McDonald – National Library of Medicine – HITAC Committee Member
It actually goes back to the expansion. One has to realize that a lot of these things expand automatically. In ICD-10, you get more stuff every year, often in response to realities, and I don't think we have to decide about that if that's a class that we're already accepting. Maybe people don't feel the same way.

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

Leslie Kelly Hall – Healthwise – Public Member
I would like to talk about what Clem just said. I do agree that expansion has to happen. Whether it's another fast track, or adding more stakeholders, as I recommended, or adding more functionality, there has to be an acknowledgement or fast track for organic changes. But, I'd also like to comment about the idea of regulatory harmonization and quality measure harmonization. For instance, let's say we were going to initiate a quality measure task force today. That would start at NQS or an organization like that, and they would develop measurement, and then look at studies to determine whether they're effective, then pilot that, and then say, "Yes, this will be adopted as a national measure."

In that process, it might be identifying data – highly likely identifying data that is not currently being collected and that would require a change in workflow. But, this process that I mentioned previously might be a five-year process. So, in our intake process, we should also allow for the idea that something might come in that isn't being collected today, but by virtue of this harmonization with ongoing efforts like NQS, ARC, and the rest, the intake process would acknowledge that these data classes from this pilot may be needed five years from today, so therefore, we have an awareness process built in that helps to inform the industry of impending or proposed regulation, quality measures, or other needs.

Without that, we end up with a quality measure that comes in where the data has to be manually processed and there's no process to get it through USCDI. So, I'd like to add to the expansion or intake process the ability to harmonize with regulatory and quality measures such that progression from manual entry to e-collection is in sync with those proposed measures.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Just to be clear on that, are you saying the USCDI process ought to be one in which quality measures move from manual to electronic recording, meaning the criteria along the process?

Leslie Kelly Hall – Healthwise – Public Member
Or that we harmonize the efforts so that the industry is made aware of future potential data requirements at a very early stage, so as it converts to electronic gathering, there is some harmonization in those processes. But, to just enhance – say we're not going to take it, it hasn't been – or, we have a bias against something that isn't already collected puts us in the position of always doing the same thing, but does not allow for evolution by informing the industry that these data elements need to move to an electronic gathering process.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay, I got it. This actually might sit nicely in the values discussion because there is certainly a value to pre-existing data that just needs to be attached to a standard but is already collected versus a new set that needs not only the process to collect it, but also the standards to attach to. There's a value in both of those.

Clem McDonald – National Library of Medicine – HITAC Committee Member
This list – I was not trying to argue against any new data. I was just saying there are some easy steps we should not have to go through 20 stages to get to.

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

Christina Caraballo – Get Real Health – Co-Chair
So, it looks like there are no more comments on this slide.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Let me raise a comment because we sort of threw it out there without a whole lot of detail, but that's Bullet 5. Implying a role for the RCE and measuring the adoption of a particular data class with its associated standards harkens back to a comment from Larry Wolf about two years ago. Why can't we use the system that helps us exchange this information to actually monitor the exchange itself? I'm going to toss that out. Is this reasonable, workable, possible?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think you could, but it comes back to if we're basically going to say it is a good standard when it's done, or are we trying to encourage them? I'm not clear on what it gives you to reach this stage. What's going to happen? Who's going to decide what when we reach a stage? But, if you've got to get to Stage 6 before anybody uses it, then you're not going to have anybody using it to get to Stage 6.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think Stage 6 is a recognition that you've gotten national deployment and a high level of adoption. Stage 5 is where the work gets done.

Clem McDonald – National Library of Medicine – HITAC Committee Member
But, what's the point of reaching these stages? Are you going to tell the baseball score after it's over or are you trying to influence the outcome? I think we have to decide that.

Christina Caraballo – Get Real Health – Co-Chair
Well, that was the purpose of adding this Stage 6. By adding Stage 6, it's saying we don't want to just get to Stage 5, where it's in the USCDI. We want to say, "Okay, it's in here. Now, let's evaluate that the market's actually using it, so let's get a Stage 6 so that it's not just sitting on the shelf." We added that Stage 6 to do just what you're talking about, Clem, and make sure it's being used, and if it's not, why?

Clem McDonald – National Library of Medicine – HITAC Committee Member
I had originally thought that if you got to a given level of support, people would be encouraged to use it. I don't know where that happens. I don't think it does happen in this sequence. Once you get to the place where it would be encouraged, you've already been doing it, so who cares? If you said you have to use ICD-9 in Medicare data, who cares? It's done. Or, ICD-10.

Laura Heermann Langford – Indiana University – Public Member
On Stage 6 itself, has a slide been prepared that talks about the purpose, how you get in, how you get out, et cetera, like we have for the other stages?

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

Laura Heermann Langford – Indiana University – Public Member
Okay.

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

Eric Heflin – Sequoia Project – Public Member
Yes. Back to Terry's question, I think you asked if we can use this with IHE. I was wondering if you could elaborate a little more on what the purpose of such an evaluation would entail.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
The purpose is just to get a measure of the extent of adoption without having to survey everyone. "What are you doing?" It's basically looking at the traffic.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I think that's a great idea.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, is it workable?

Eric Heflin – Sequoia Project – Public Member
Thank you, that's helpful. So, with respect to that, I think it might be technically viable, but I do worry about the privacy concerns. Is it worth looking at all of the clinical data in order to assess the maturity of the IHE, the QN, or the content being exchanged? So, to answer your question, it would ultimately be a matter of tradeoffs.

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

I guess it gets to the point of how we know this whole process works. How do we know it gets the outcome we're seeking, which is wide adoption of interoperable…?

Eric Heflin – Sequoia Project – Public Member
That's the point that you're getting to. I think it's a great point. Perhaps this is actually already accommodated by this process in that items that are not meeting objectives will go back into this six-stage pipeline as, "Well, we tried this version of the data class and found the following issues, such as that it was not expressive enough to represent the concept we need to express," and then it could go back into the stages of the process for a subsequent updated version of that specification.

Clem McDonald – National Library of Medicine – HITAC Committee Member
To get to Terry's point, I don't see any problem with privacy because you're not asking to hand-touch and look at all of that. You're looking for statistics as they go in and out of those systems. I don't see any privacy issues.

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

Eric Heflin – Sequoia Project – Public Member
The concern I have there is in order to get those statistics, you do actually have to look at all the data, so someone will have to analyze and snoop in to each clinical message going back and forth in order to capture whether or not that data element or data class is being used in order to compile the statistics.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, you picked a word that suggests bad things, but they're going into the system and some computer is looking at them now in some fashion to store and put them away.

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

Leslie Kelly Hall – Healthwise – Public Member
Back to the question of if we're waiting several innings to call the score, the difference between USCDI and an organic standards process that's driven by the industry is that this is to set the stage for potential regulation, rulemaking, certification, or some way the government says, "Yes, in fact, this can be used," or "We acknowledge that this can, may, or shall be used." So, I do think the outcome is that it's ready for consideration by the government in one way, and I'm not sure where that fits in our scale – is it No. 5 or No. 4? – but it is part of the outcome.

Clem McDonald – National Library of Medicine – HITAC Committee Member
That's what I was hoping for. And then, I think we shouldn't wait until it's done to encourage its use. It's sort of like putting the cart before the horse.

Christina Caraballo – Get Real Health – Co-Chair
Excellent points. In putting together what you just stated, Leslie, what we were trying to get at in Bullet 4 – so, it sounds like Bullet 4 might need to be revised because it's not as clear, but I think what you just stated was the goal of that bullet.

Leslie Kelly Hall – Healthwise – Public Member

Yeah. I don't think our goal is to replicate or compete with existing industry evolution of standards. Our goal is to have a mechanism to make it regulation-ready in a way that industry will acknowledge that that process is valid.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I take from that the implication that left to its own devices, the industry will not necessarily build the standards and the standard data classes needed for a wide range of use cases, such as quality and so on.

Leslie Kelly Hall – Healthwise – Public Member
Yes. I don't think there's any harmonization right now between the quality initiatives and data that's being collected. This could help remedy that. There are also no natural sponsors for patients as interested stakeholders that want to have data available to them and/or those they choose to be on their care team. So, in those two use cases or stakeholder groups, we see that there is a reason for regulatory readiness.

Brett Oliver – Baptist Health – HITAC Committee Member
What would a patient want that a provider wouldn't?

Leslie Kelly Hall – Healthwise – Public Member
I think it would depend on the stakeholder the patient is interacting with. For instance, perhaps the data collector and user – myself, as a patient – I might be doing my observations of daily living, my pain scale, here's how frequently Meals on Wheels comes, and here are my social determinants of health. Although that may or may not go into the detail in a medical record, it might go into the navigator, the coach, the social worker, or the payer system that's helping the patient. So, when we start looking outside the narrow scope of an EHR to the broader scope of a community-based system with a patient participating, then we have data that's new, and sometimes material to immediate care, sometimes material to a longer lifestyle and chronic care management. So, we don't yet know what kind of data might be important to the patient that isn't necessarily material to that episode of care.

Rob Havasy – HIMSS – Public Member
I'll add an example. We see the emergence of what some people are calling "social care data," things like fall monitoring, where a family member might monitor an elderly person at home and have monitors to determine what cabinets are opening, where food is stored, and things like that. The other thing that sometimes separates patient data needs from clinician data needs is frequency. Patients may look at their blood pressure daily or weekly whereas clinicians may want to see a summary monthly or quarterly. So, the frequency of the summary and the transmission is also something that differentiates.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Thanks. That was helpful.

Rich Elmore – Allscripts – Public Member
Can I just reinforce some points that were brought up several times? This is very use-case-specific. I just want to make sure that we're not coming up with broad requirements where the need itself may be more targeted.

Christina Caraballo – Get Real Health – Co-Chair

Yes, I agree with you, Rich. Getting us back on track on the expansion process itself, if there are no more comments on the actual expansion, we should move to the next slide. Leslie, do you have a comment?

Leslie Kelly Hall – Healthwise – Public Member
In general, expansion fits in that. We have yet to hear from ONC what kind of staff structure or what kind of support we can expect. We can design something that's not implementable because there are no resources available within the government to oversee, manage, and support this, so that is a "to do" item before we need before final recommendations go forward.

Christina Caraballo – Get Real Health – Co-Chair
Yup, and that is actually an agenda item that we have to talk about with the TEFCA co-chairs as well to see how we can fit that into the work that they're doing. Clem?

Clem McDonald – National Library of Medicine – HITAC Committee Member
You've heard this story before – it's an old song – but I think before we decide all this stuff, we've got to decide whether this is really to encourage the use of some that are pretty good or to wait until they're all done, and then I think we have a totally different question about at what stage we declare victory. As I said earlier, we're not going to get anything through this for a long time if we stay so strict all the way up to Stage 5.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I hear your concern. I think things are going to move quite quickly. An example is a clinical note, which basically needs a wrapper so you can see what's in the container, but no one is going to specify what's in a clinical note. That should move very quickly tied more to transport standards than semantic standards.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I'm with you, but I think if you look at the details of these thresholds they have to jump, it's got to be used everywhere before you can decide it should be used.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
No, it has to be tested – so, Stage 4 gets to testing in a commercial venue, real heavy-duty "Let's kick the tires and get it running," as opposed to the stage before that, which is more like a draft standards for trial use sort of process, where we try this, identify where its failure modes are, and fix it, and then it will move on.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Okay. So, maybe we should just tweak the thresholds. I read them as being pretty high bars.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. Well, we'll come back to that. You're absolutely right. The purpose is not to make this a tighter series of filters, it's to make sure that what's ready gets moved along.

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

Christina Caraballo – Get Real Health – Co-Chair

And remember, it's the floor, not the ceiling, as the ONC team has said multiple times – specifically for the USCDI. I think we can go ahead and move to the next slide. This is the frequency of publication. There's nothing in red here, but we did look at everybody's input from the homework and revised these recommendations to incorporate it. The first one is that we should publish the USCDI annually with necessary details of new items added, provide periodic bulletins to announce the addition of new data classes to Stage 5 as they become available, provide periodic bulletins to announce the addition of new data classes to Stage 4: Candidate, and our overarching rationale is to give the industry as long of a lead time as possible – so, really, transparency and awareness. Steven, go ahead and kick us off.

Steven Lane – Sutter Health – HITAC Committee Member
I was just going to say on that first sub-bullet, in addition to details of new items added, I suspect there will be clarifications and refinements of items as they move along through the stages, so I think part of the annual update should include a refresh of existing items with the latest content.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Just to amplify or clarify that a little bit, we had added Stage 4: Candidate, so this is a group that's being commercially tested. Do you think we ought to be going back even farther to give a preview of coming attractions at each stage?

Steven Lane – Sutter Health – HITAC Committee Member
When I read this, I assumed that when we were publishing the USCDI – and, maybe I shouldn't have assumed it – that we were not only publishing what's made it over the line, but everything that's in the pipeline as well. Again, it was just to give everyone in the industry a sense of what was coming and where it was in the process. If that wasn't other people's assumption, maybe that's worth discussing and clarifying.

Christina Caraballo – Get Real Health – Co-Chair
That's my assumption, too.

Laura Heermann Langford – Indiana University – Public Member
I'm going to jump in because I have a question around some of the process. I can understand publishing, especially around Stage 5, and I can see your point of highlighting what's in Stage 4 on an annual basis, but would the candidate stages and what data elements are in each stage be available at all times? Would you be able to go and see it? Anybody who's interested should be able to go and see what's currently proposed and what's in Stage 1, 2, 3, et cetera.

Steven Lane – Sutter Health – HITAC Committee Member
I agree. Again, I just thought if there was going to be an annual event, a publication, a communication, a press release, whatever it was, that it would be the whole thing. "This year's refresh." But, I agree. In an ideal world, there is some living website where people could go and see whatever's in the pipeline.

Laura Heermann Langford – Indiana University – Public Member
I would agree. An annual publication could just be drawing a line in the sand, saying, "At this date and time on an annual basis, this is the State of the Union," not an evolving and moving thing online that people can see on an ongoing basis, but I think having that annual report would probably meet that need.

Christina Caraballo – Get Real Health – Co-Chair

Yes, and that has been discussed. I think we took out the bullet, but it was a similar process to the ISA, where it's living and breathing, and there are places for online comments, but then you have a "reference guide" or "reference edition" annually.

Rich Elmore – Allscripts – Public Member
If something is published to the USCDI or is a new data class in Stage 5, what do we expect the industry response to be?

Christina Caraballo – Get Real Health – Co-Chair
"Let's get moving to support it."

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah. So, ONC has said that what they will do for data classes that have made it into the USCDI is to point to those data classes and hope that the entire regulatory and payment might of the U.S. government goes behind them.

Rich Elmore – Allscripts – Public Member
But, it wouldn't necessarily be through a mechanism – "You shall implement a data class." It's going to be through a mechanism like you were describing last time, Terry, which is that we want to do something which involves applying that data class, right?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Well, I don't know. It depends on how badly ONC wants to push it through. That's a good question. I don't know.

Rich Elmore – Allscripts – Public Member
Otherwise, it seems like a very academic exercise if it's not tied to a real, purposeful use.

Christina Caraballo – Get Real Health – Co-Chair
The way I see it is it's going through the whole process. You get to Stage 5, and it says, "This is ready now," and that's when the regulatory drivers come in and say, "Now, industry needs to adopt it and support these data classes to be used to get to Stage 6." I don't know that we can really write those recommendations in this, but I think that's the goal – to have a place where we say, "This is ready, and this is why, and it's moved through here, and these are the business cases that support it, and here it is starting from the beginning from the value." It has a use case and business case, moving all the way through to the technical requirements being ready.

Rich Elmore – Allscripts – Public Member
But, Christina, based on what you just said, though, it sounds like the "You must do this" is not coming from the USCDI, it's coming from some regulatory overlay that references some part of the USCDI.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
That's my understanding.

Christina Caraballo – Get Real Health – Co-Chair
Yeah, that's my understanding.

Rich Elmore – Allscripts – Public Member

I think it would be good for us to be clear about that.

Leslie Kelly Hall – Healthwise – Public Member
And, what makes it different from the ISA in that case? So, being clear as to how our use cases are different.

Rich Elmore – Allscripts – Public Member
ISA is more of a list. It's not a funnel, and it's not targeting broad adoption.

Leslie Kelly Hall – Healthwise – Public Member
I agree. I just think we should make that explicit in our difference. Maybe that goes back to our charge.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Getting back to my old saw, are we not going to have most of what's in ISA for five years on this document set?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I don't think ISA really deals with data classes per se, Clem. I'm not sure if I understand your question.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Actually, there are a lot of parallels. It's how severe we make it to get to the point where the government will encourage the use. That is actually the driving force, from what I've heard, and if we have to wait until everyone is using it – and, I've said this many times – it's not going to have any effect.

Christina Caraballo – Get Real Health – Co-Chair
I think this is a great discussion, and maybe we can add some of these things to our recommendations or things that we've identified to move from Stage 5 to Stage 6, bringing us back to the publication frequency. Are there any more comments related to our recommendations on here?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, this says "Stage 4," and that's more suitable to my eyes than Stages 5 or 6. The third thing, "Announce the addition of classes to Stage 4" – I think that's as far as we ought to try to go before we encourage it.

Christina Caraballo – Get Real Health – Co-Chair
Yeah, and the rationale behind putting that one on here as an announcement is that once it gets to Candidate, it should be more on people's radar, so we want to pull that one to people's attention. And then, adding new items – the first one was just saying, "Hey, these things are getting put in here."

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I think there's a distinction between encouraging and requiring. Particularly as you think about smaller companies that have to be very careful – well, every company has to be careful, but smaller companies in particular are going to be challenged with many potential targets that aren't yet right in front of them as something that they have to do. I think being clear about requirements to use USCDI coming from somewhere outside of the USCDI process is important to be clear on, as well as perhaps encouraging things in Stage 4.

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

Eric Heflin – Sequoia Project – Public Member
I just want to support the first sub-bullet there, that the USCDI should be published annually. I think that's the right cadence.

Christina Caraballo – Get Real Health – Co-Chair
Great, thank you. Brett?

Brett Oliver – Baptist Health – HITAC Committee Member
I just wondered on the second and third bullets, where we're talking about providing periodic bulletins – do we need to be more specific about that, whether they're regular intervals or periodic bulletins after a certain number of data classes are added? I feel like if we had a regular bulletin – whether it's quarterly, semiannually, or whatever – that would make it easier for the industry to anticipate. Basically, we're putting it on them right now. "You'd better go check this website and see where the data classes are in the process every couple of weeks." If we provided those bulletins in a more regular period instead of just saying "periodic" – I don't know what that means. Any thoughts there?

Christina Caraballo – Get Real Health – Co-Chair
We didn't want to be overly prescriptive, but we're definitely open to discussion.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Maybe we should be overly prescriptive. I think that's a good point. If our goal is to give industry a heads up, we ought to make it as easy as possible for them to see what's coming, so maybe just a quarterly bulletin that says, "Here's what's new in the last three months."

Brett Oliver – Baptist Health – HITAC Committee Member
It could say nothing.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, "Nothing's new."

Brett Oliver – Baptist Health – HITAC Committee Member
But, that's as important an update to me in the industry than, "Here are ten new ones coming."

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, do we want to amend this to say "quarterly bulletins"?

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

Clem McDonald – National Library of Medicine – HITAC Committee Member
If we can afford it.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Again, we'll probably get into this when we discuss the stages because I think implicit in all of our discussions is some model in the background that allows all of these data classes to be tracked in their

various stages of progression. Were such a system to be in place, then doing periodic quarterly bulletins would not be a huge lift.

Christina Caraballo – Get Real Health – Co-Chair
So, back to a comment Rich made about things not getting the support even if they're in Candidate or are on people's radar – I'm sorry if I didn't translate that properly, Rich – it made me think about the fact that throughout this process, we have wanted to be very transparent on what these data classes will support and the importance and value they will bring to the industry. So, within this publication, maybe we should recommend that not only should the data classes be highlighted, but the reason they're being looked at is in there as well. That will also give insight for providers and developers to even think about their strategy of who wants what to start building tools that are desired.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Christina, that's a really interesting thought, and it makes me think that maybe each data class goes through this process and acquires a rap sheet as it goes, which starts off with who the stakeholders are that are behind it and the initial proposed data classes are. How did it do in Stage 3? How was it renewed, refreshed, or altered? Basically, at the end, when you get to the USCDI level, you actually have a summary sheet that says, "Here's the provenance of this data class. This is where it came from, why it got here, and how it got here."

Rich Elmore – Allscripts – Public Member
I like that idea. I like the idea of the history of the data class.

Nancy Beavin – Humana – Public Member
Me, too.

Laura Heermann Langford – Indiana University – Public Member
Agreed.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. We'll come up with a one-pager.

Christina Caraballo – Get Real Health – Co-Chair
I see no other comments on the frequency for publication. Any last-minute thoughts? Going once, going twice – next slide. So, next is the process for stakeholder feedback. Similar to the last slide, we took everybody's recommendations and revised our current slide to create this one. So, the preliminary recommendations are that there is an annual release of new USCDI followed by a public comment period of at least 90 days, that two annual opportunities for public comment, that we provide an open public forum for each stage in the process, and that we record all proposed data classes in a searchable, sortable resource that facilitates interaction through review and discussion among potential stakeholders and enables public comment. Feedback needed during each stage is to be determined as we build out criteria. That last bullet was kind of a placeholder. Leslie, go ahead and start us off.

Leslie Kelly Hall – Healthwise – Public Member
Thanks. I have two thoughts. One is that I'd like to see some sort of formal process to act as the patient sponsor for stakeholder feedback. Without that deliberation, it's hard to get that kind of due diligence process as part of the stakeholder feedback. And then, the second is as a result of doing this, we're

saying that something is ready for regulation, ready for rules, et cetera. We should ask that stakeholder feedback also seeks to see where there is complementary, synergistic, or harmonized opportunities beyond the stakeholder who submitted it, especially regulatory.

One of the arguments we hear often is that the burden for data collection is exacerbated when many different regulatory bodies ask for the same data in different ways under different standards, so as part of this process, I'd like to make sure there is a burden for the submitter to make sure that the stakeholder feedback includes other regulatory bodies that would be positively or negatively impacted by that data class recommendation.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Do you think putting that into one of the earlier stages would make sense? It's really a –

Leslie Kelly Hall – Healthwise – Public Member
Yeah, I think it might, but I think that for the stakeholder feedback – my first comment on who is acting on behalf of the patient needs to be here.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Do you have a recommendation on who that might be or how that might get done?

Leslie Kelly Hall – Healthwise – Public Member
I think it depends on what the governance structure ends up looking like. If the governance structure is the current RCE structure, for instance, although the recommendations have included placement of patient sponsors on there, it doesn't get to a body that says, "Our sole purpose is as a stakeholder," and it might be a group that's convened by ONC across many different patient organizations or advocacy groups. It really will depend upon the governance structure.

Christina Caraballo – Get Real Health – Co-Chair
So, I just wrote that bullet – to summarize what you said, Leslie, is that you recommend active engagement with a variety of stakeholders and making sure we include the patient sponsor and patient voice.

Leslie Kelly Hall – Healthwise – Public Member
It's not just including the voice, but actually, there really isn't a body that represents…there's a body that represents the EMRs, there's a body that represents different stakeholders, but there isn't one that represents patients collectively. So, we all say we're all about the patients, but in general, it doesn't happen without deliberation and due process that includes that.

Steven Lane – Sutter Health – HITAC Committee Member
I agree, Leslie. On some level, something similar could be said about different clinician stakeholder groups that don't really have a body. Does home care have a consistent voice? Does ambulatory nursing have a consistent voice? I think the idea that stakeholders need to be engaged and input needs to be sought out from various groups that aren't otherwise well-enfranchised is a good point.

Christina Caraballo – Get Real Health – Co-Chair
Thank you both. Valerie, go ahead.

Valerie Grey – New York eHealth Collaborative – HITAC Committee Member

I think the previous conversation covered a lot of what I was going to comment on. I was very focused on how we can make that public comment period as broad and meaningful as possible, and I agree with some of the earlier changes that were recommended.

Christina Caraballo – Get Real Health – Co-Chair
Wonderful. Laura, you're next.

Laura Heermann Langford – Indiana University – Public Member
Thank you. I'm reading this, and I'm thinking about it, and I'm thinking that…these are all nice statements and I agree with the comments that have been made, but how this really works is still confusing to me. We've talked about the stages, and timelines of things staying in each stage, and whether that would need to be addressed separately in a future conversation, and the different kind of feedback that we've put into an annual release and into annual opportunities.

So, I agree with the statements that we need the opportunities, we need the public comment, we need the public platform, and it needs to be open, but some of the timing that's related in this is…confusing to me – I'm not sure what the word is – because we're worried about things lingering too long in our stages, we don't really know how long things should be in stages, we're saying that we need feedback on this…almost a timeline, and I don't know that we're all lined up here. And so, I think we need to be careful about the timing that we're talking about here and look at it a little more carefully.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I agree with you 100 percent.

Laura Heermann Langford – Indiana University – Public Member
I'm not even sure two annual opportunities for public comment… "Opportunity," yes, but maybe there should be more. Maybe there should be a different way they can get it.

Christina Caraballo – Get Real Health – Co-Chair
To share what we were thinking with that bullet, it was more about the two annual drives where we're trying to actively solicit feedback. So, yes, I agree, we're creating this document where people can constantly provide feedback and it's a living, breathing document. Then, two times a year, we were thinking that's when ONC or the RCE puts out a set of questions they want feedback on, and there's sort of a campaign of awareness, and it gets the industry discussing what's in the USCDI at – for lack of a better term – a draft reference, and then, at the annual, for public comment.

Laura Heermann Langford – Indiana University – Public Member
So, maybe you're talking about things like two annual campaigns, but ongoing opportunities for public comment.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
We'd like people to be able to comment 24/7. What ONC does with those comments, how they roll them up, and how they report them out might be a separate issue.

Christina Caraballo – Get Real Health – Co-Chair
I like the idea of two annual campaigns and ongoing opportunities. How do other people feel about that?

Steven Lane – Sutter Health – HITAC Committee Member
Christina, that was what I was going to chime in on. I think two is sort of unrealistic. Everyone has a day job. I like the idea of an open wiki-like opportunity for people to constantly provide feedback, but realistically, to expect anyone to collate all that, whether it's ONC, the RCE, or anyone else – to me, we're talking about a 90-day comment period. I would do that once a year and link to the annual release of the updated document. I think two campaigns a year seems unrealistic.

Leslie Kelly Hall – Healthwise – Public Member
I agree with Steven, and I would also add that when a regulation is named, that has to indicate a data set associated with that regulation. That in itself has a public comment period, so it would have two avenues: One in the publication of the document and one opportunity for public comment when it's designated for use. So, I think we're covered.

Laura Heermann Langford – Indiana University – Public Member
I'll just add one more thing. We still need to look at each of our stages, understand timing within that, and then look at the feedback needs for those timings. If we think that they would have different rates at which they might go through a stage, that might influence some of the feedback, which could get a little bit undoable as well. So, like I said, it's something we need to look at together in tandem.

Dan Vreeman – Regenstrief Institute, Inc. – Public Member
I was thinking that same thing, which is probably why at one level, we need to think of the opportunity for feedback as being continuous and open, and potentially… I can think of a handful of things where we could anticipate a particular data class jumping stages quite rapidly, actually, because it's ready. People are using it.

Laura Heermann Langford – Indiana University – Public Member
I think we're hopeful for that, but in order not to jump too fast, we'd probably need to have some guardrails in place to say, "There is this amount of time for public feedback," a minimum amount that they stay in the stage, that it's published, and that it's ready for feedback. Maybe it can go quickly in the earlier stages, but later stages take a little more time. I probably haven't thought through that well enough, but…

Clem McDonald – National Library of Medicine – HITAC Committee Member
Do they always have to go through all the stages? Could they jump to Stage 3 or 4 if they look good? What's the point of doing all those other steps if it's obvious that it's already made it?

Laura Heermann Langford – Indiana University – Public Member
Well, we have criteria set up, so… I think you're right – you could have something that comes in as a candidate that has met all the criteria to start out at Stage 3 or 4, perhaps, but what does that mean for any kind of a public feedback and stakeholder comment?

Christina Caraballo – Get Real Health – Co-Chair
I'm going to get Adam from the ONC team to chime in and comment.

Adam Wong – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thanks, Christina. I'll chime in quickly that one of the reasons we were thinking about these two opportunities for public comment was to account for that possibility, where a data class goes into

lightspeed and moves through categories or stages particularly quickly. So, if it enters Stage 4 very soon after the annual release of USCDI, and six months later, it has advanced really quickly and progressed a lot, then there's another opportunity for us to get that information and reassess where it lies in the process.

Christina Caraballo – Get Real Health – Co-Chair
Thanks, Adam. Steven, do you have a comment?

Steven Lane – Sutter Health – HITAC Committee Member
Yeah, I did. Thanks, Christina. I forget who it was that mentioned the whole notion of governance and made reference to the idea that perhaps the RCE would assume governance of this whole process. I don't know that any of that has been discussed or is even on our plate to discuss here within the task force. I'm just curious – did I miss that part of the conversation, or is that still an open topic?

Leslie Kelly Hall – Healthwise – Public Member
I was just citing it as an example. No, we have not discussed it, nor do we know if it's in our purview, but there has to be some governance structure.

Steven Lane – Sutter Health – HITAC Committee Member
I just wasn't sure if I'd missed that because I think it is an interesting topic of conversation, but don't want to distract us with it if this isn't the time.

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

Nancy Beavin – Humana – Public Member
Sorry, I don't have my hand up.

Christina Caraballo – Get Real Health – Co-Chair
I see no more hands up.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, we'll keep this topic open as we go through the criteria for each individual stage, and perhaps give thought at that time about what the feedback opportunities are, or which ones are required.

Christina Caraballo – Get Real Health – Co-Chair
Thanks for that reminder, Terry. So, as Terry just said, during each of the stages, we wanted to add this as a piece of discussion to add to our final recommendations. Are there any other comments on this slide?

Mike Perretta – Docket – Public Member
I have a quick question, and this is sort of open. Do we have anything in mind for the second to last point for a web-based application? Is there an existing platform, or is this something we'd have to explore later on?

Christina Caraballo – Get Real Health – Co-Chair
I believe it would be something to be explored later on.

Mike Perretta – Docket – Public Member
Very cool. I don't have anything beyond that. I was just thinking about it and what could work. Thank you.

Christina Caraballo – Get Real Health – Co-Chair
Okay. So, can we move to – do we have time to move to the next slide?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Yeah, Christina, we've got another five minutes before public comment.

Christina Caraballo – Get Real Health – Co-Chair
Okay, great. I guess we can go ahead and begin to discuss the value criteria in more detail. The upcoming slides are going to be value, and we have to whom the evidence and measures for the tiers as well as some questions. So, what we have on these slides now is really a dump of – Adam and Stacy went through and aggregated all of the comments that we've received through lots of homework – all the ongoing homework – and put them all here, so this is very much in a draft format, but we wanted to go ahead and get some thoughts.

So, the "value to whom" Tier 1 we had as the patients, both current and future, including individuals as a population, public, and community, and then, providers with clinicians, caregivers, and clinical support staff. And then, Tier 2 was really everyone else, including the researchers, technology folks, payers, the ecosystem, and others. Nancy, go ahead and kick us off on this one.

Nancy Beavin – Humana – Public Member
I would really like to add "quality reporting" here to "payers." I think the value of this is way beyond payment for payers. The word that comes to my mind is "quality," but maybe someone else has a better word. Can we add additional information under Tier 2?

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Is quality one of the pieces of regulation? Is there a broader… Do we need a government stakeholder for any of this?

Nancy Beavin – Humana – Public Member
It could be. That's another way to address it.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Yeah, that's a good one.

Leslie Kelly Hall – Healthwise – Public Member
That is the primary sponsor of the USCDI.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yes, we should pay attention. Okay.

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

Steven Lane – Sutter Health – HITAC Committee Member
Other things that come to my mind – public health is clearly a key stakeholder in terms of the reporting and sharing of data. Potentially, we could link the criminal justice system under "providers," but I think they've got some other needs that may fall outside of that. And then, I think community services that may not immediately fall under "providers" – schools, other service providers, Meals on Wheels, food kitchens, homeless shelters – those all come to my mind as potentially missing. I don't know if that falls under "ecosystem." I don't know which ecosystem we're talking about there. The rainforest?

Clem McDonald – National Library of Medicine – HITAC Committee Member
Your forward community.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Maybe "ecosystem" has to go up into Tier 1 to make sure that – with that caveat that that's what we're talking about.

Christina Caraballo – Get Real Health – Co-Chair
Yeah, I think "community" is Tier 1.

Steven Lane – Sutter Health – HITAC Committee Member
It's calling out community services.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Community services? The implication of the slide is that the value is worth more in Tier 1 than it is in Tier 2.

Steven Lane – Sutter Health – HITAC Committee Member
I don't know. The value to payers is pretty high.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
But then, the question is why are there two tiers? I'm destroying our slide. It's the value to whom, and are we ranking different stakeholders as having intrinsically different values?

Steven Lane – Sutter Health – HITAC Committee Member
Well, I think we have a bit of a directive – I don't know if it's from Congress, CURES, or Don Rucker – to have a primary focus on patients, clinicians, and caregivers, but maybe that is artificial. In my mind, it makes sense to push some of these payers and researchers to another tier, but it's a gray line.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
What's going to happen with this tiering is that we're going to have choices to make about value to the system as a whole. And then, to bring in Clem's point, if you've already got it and it's easy to move, doesn't that have value in and of itself at the recipient end regardless of who you are?

Clem McDonald – National Library of Medicine – HITAC Committee Member
The other thing – I'm jumping in; I guess I shouldn't – is that it's the first movement that's the hardest. So, if you can move it to the clinicians who aren't getting half this now – people have the idea that this is all done – you can move it anywhere. I think we may get it all blended and mushed up if we don't get it out to somebody, and you can get it to everybody else. That's the "it" we're talking about – which data is the most valuable?

Steven Lane – Sutter Health – HITAC Committee Member
What you're saying is use patient access and caregiver access as the first use case, the one that we focus in on, and you believe that the rest will flow more easily thereafter.

Clem McDonald – National Library of Medicine – HITAC Committee Member
Well, I've done it, and it's a ton of work to set up the standards, build the codes, and make sure everything's working right, but it's just text. It's just like an email. You can just pass it on, except for some of the privacy concerns and tangles. So, if you can get it out of the places that have it, you can get it to everybody, considering what other constraints there are that are independent of getting it out. You can't just send everybody's data to the public and things like that.

Christina Caraballo – Get Real Health – Co-Chair
So, Leslie's been waiting, so Leslie, go ahead, and then we need to open it up to public comment.

Leslie Kelly Hall – Healthwise – Public Member
Okay. So, we talked about value, and I think that we talked about getting the data out. I think there's new value, which is getting the data in, and that might be more in line with the patients as the primary tier. But, I do think that payers are playing more of a role, and if we get to value-based care and we're talking about the partnership between payers, patients, and providers, that might be a consistent way to group it. And then, Tier 1 is value-based care and beneficiaries and Tier 2 is everyone else.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Christina and Terry, I think we need to break here for public comment. If we don't have any, we can always come back and close up on final discussion points. At this time, operator, would you please open the line for public comment?

Operator
If you would 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 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 *.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. I'll remind everyone to keep their comments to three minutes or less. While we're waiting for everyone to dial in, I'll just remind everyone that our next USCDI Task Force call will be a week from today on April 4th at the same time, 3:30 Eastern. 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. With that, I will hand it back to Christina for the last few minutes.

Christina Caraballo – Get Real Health – Co-Chair
Great, thank you. Nancy, I see that you have your hand up. I don't want to lose the conversation of Leslie's proposal that Tier 1 is value-based care, so are there any comments on Leslie's last comment? If not, Nancy, go ahead and chime in.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
I'm just anti-Tier 1/Tier 2. I don't know if that helps us. That's my comment to Leslie.

Christina Caraballo – Get Real Health – Co-Chair
I kind of agree.

Nancy Beavin – Humana – Public Member
I agree, and I wanted to support Leslie's comment. I don't think there should be tiers at all. I think the list makes priorities in and of itself, but convening the groups together for value-based care makes a lot of sense to me. The third thing is isn't all of this the ecosystem? I'm still confused about that particular bullet.

Leslie Kelly Hall – Healthwise – Public Member
Agreed.

Christina Caraballo – Get Real Health – Co-Chair
I think the ecosystem was a reference to say we know we haven't included everyone. There's a bigger ecosystem. If you remember the first homework that had it, we had so many that the list kept going on and on.

Nancy Beavin – Humana – Public Member
To me, that makes "ecosystem" and "others" duplicative.

Christina Caraballo – Get Real Health – Co-Chair
I'm going to take that back. My statement should be toward "others."

Terry O'Malley – Massachusetts General Hospital – Co-Chair
To get back to Steven's comment about healthcare providers that are on the fringe of healthcare, like schools, and – the police are the largest mental health provider in the country. How do we include those folks that are not quite healthcare, but have an impact on it?

Steven Lane – Sutter Health – HITAC Committee Member
I liked "community service providers." On the one hand, you've got a school nurse or jail physician who are providers, and on the other hand, you've got other service providers in those same systems that may have a need to exchange data.

Clem McDonald – National Library of Medicine – HITAC Committee Member
I would think we should not include criminal justice or police because that may have a negative reaction to readers. We're giving the data to people who are sometimes perceived as not being friendly in certain neighborhoods. I agree that they need them, but I don't know if we should highlight them.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
I see that we have two more comments before we wrap up, from Nancy and Rich.

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

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Maybe not. Maybe she put her hand down.

Nancy Beavin – Humana – Public Member
I'm talking on mute. I think I've covered all my comments. I totally support removing the tiers and value-based care. I do think there's a role in here somehow, if it's through the value-based care arrangement. I think that's fine from a quality perspective and quality reporting. I think "community services" – without calling out police or any others – pretty much covers some kind of wording around community services, supporting all those other caregivers that should be in this overall ecosystem.

Christina Caraballo – Get Real Health – Co-Chair
Thank you, Nancy. I see we're over, so Rich, go ahead and make your final comment.

Rich Elmore – Allscripts – Public Member
I just think that if we were doing really well on the fundamentals, then extending the breadth makes sense, but I would just ask about what the purpose of the slide is if it isn't for us to provide some guidance on where priorities should be. If not, what are we trying to achieve here? I think that's a pretty important part of this. There's a limitless number of things that we don't do, but I think we have to help the large community to make some decisions and make some progress on the priorities that we do want to achieve. So, if we just make it a broad list, I don't know how it helps us.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
So, Rich, you'd be in favor of – instead of keeping the tiers, saying we're going to focus on patients and providers, and hopefully, everyone else benefits?

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

Laura Heermann Langford – Indiana University – Public Member
I can agree with that.

Rich Elmore – Allscripts – Public Member
Terry, to your point, that made sense to me, but I think what's important is that we are helping to provide a process for selecting out, not bringing a long list in.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Okay. So, within the context of helping us focus on work that needs to be done, not doing all work, we'll start here.

Rich Elmore – Allscripts – Public Member

Right.

Leslie Kelly Hall – Healthwise – Public Member
As long as "community" stays in, right?

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

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Christina, I would say for any other thoughts relative to this last slide or just in general, feel free to send your written thoughts or edits to Christina, Terry, Adam, or me. If there are no final comments from Christina or Terry… Do you have anything else to add before we close?

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

Christina Caraballo – Get Real Health – Co-Chair
Look for homework.

Terry O'Malley – Massachusetts General Hospital – Co-Chair
Yeah, do your homework.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Thank you, everyone, for your time today, and we'll talk next week.

[End of Audio]

Duration: 93 minutes