U.S. Core Data for Interoperability Task Force

Transcript

May 17, 2019

Virtual Meeting

Speakers

Name	Organization	Role
Christina Caraballo	Audacious Inquiry	Co-Chair
Terrence O'Malley	Massachusetts General Hospital	Co-Chair
Tina Esposito	Advocate Aurora Health	Member
Valerie Grey	New York eHealth Collaborative	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Steve Ready	Norton Healthcare	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member
Sasha TerMaat	Epic	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Steve Posnack	Office of the National Coordinator	Executive Director, Office of Technology
Al Taylor	Office of the National Coordinator	Staff Lead
Adam Wong	Office of the National Coordinator	Back up/ Support
Johnny Bender	Office of the National Coordinator	SME

Operator

Thank you. All lines are now bridged.

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

Good afternoon, everyone. Welcome to the USCDI task force meeting. We're excited to kick off Phase 2 of this work. So, I'll call the meeting to order. Of the members, we have Christina Caraballo, Terry O'Malley, Steven Lane, Sheryl Turney, Ken Kawamoto, Valerie Grey, and Sasha TerMaat. Are there any other members that have joined the call so far? Okay. With that, I'm going to firsthand it over to Terry and Christina to review a few outstanding items from Phase 1 before we start the Phase 2 discussion.

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

Great. Hello, everyone. Christina, do you want me to take this or do you want to?

Christina Caraballo – Audacious Inquiry – Co-Chair

You can go ahead.

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

Okay. So, great work, gang. We got our recommendations all but two of them past the HITAC or with the HITAC's blessing, I should say. But we have our two amendments that were proposed during the HITAC session. And we're going to put some up on the screen and then, ask for a vote to accept or reject them. They're not highlighted, are they? I guess not. Here we go. All right. So, the first was under Recommendation 4.

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

I'm sorry, is it possible to zoom in a little bit? Thanks.

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

That's even better. So, the red text is what we are voting on. It's a proposed addition by Carolyn Petersen, which we shall consider. So, I'll give you a couple of seconds to read it. And let me ask if anyone has any discussion that they'd like to have about this.

Steven Lane – Sutter Health - Member

I'll just say I think it's a great addition. We've been cautious in terms of how much we've wanted to ask to pack into USCDI Version 1. But I think this is definitely one that's worth adding if HITAC agrees.

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

Great. Okay. Any other comments or discussions? Hearing none, we'll go on to our vote. All in favor say aye.

All

Aye.

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

And those opposed, nay. Those abstaining? The ayes have it so we will pass that on to the HITAC with the blessing of our task force. And then, Adam, if you can scroll us down to Recommendation 28 Charlie. So, a comment was made saying that some – we had previously where the red text is accreditation body. And we just made a change to professional body, which should include the accreditation bodies as well as non-accreditation bodies that may enumerate providers. This was just a clarification based on a recommendation from the HITAC. Any discussion about this item?

Steven Lane – Sutter Health - Member

I guess I'll just ask is accreditation, does that have a formal meaning? Clearly, licensure is very formal. I ask this question because my wife happens to be a healthcare provider who is certified in her field but not licensed and not accredited per se. So, I just wonder whether – sorry. I think professional is great. I'm sorry, I was backwards here. I think having professional instead of accreditation is good because it provides the flexibility that I think we need.

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

Thank you. Any other comments, questions, concerns? Okay. Hearing none, all in favor of making this change and then, move it on to the HITAC, please say aye.

All

Aye.

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

Those opposed, please say nay. Any abstentions? And the ayes have it and we will pass this amended recommendation back to the HITAC for next week's meeting. Thank you all very much. And Christina, do you want to do Steve's intro and where we're going from here?

Christina Caraballo – Audacious Inquiry – Co-Chair

Yes. I think we're moving on to the agenda. So, thanks, again, everyone, for the Phase 1 recommendations and all of the hard work echoing Terry. Now, we're going to go ahead and move on to Phase 2 for Steve to give us an overview. And then, at the end of the call, we'll leave it open for questions for Steve and then, start moving into our next steps. So, if we could

go to the next slide, I think it's just our task force, the same task force that we've had. Moving on to the next slide, here is our work plan. So, today is our kickoff with a discussion of the promotion model guidelines. And then, we're going to move into the promotion model lifecycle. Then, on June 14, we're going to discuss the data element submission criteria.

On June 28, we'll move to the Level 1 classification, July 12 Level 2 classification and then, July 26 we're going to discuss the overall USCDI classification and start with our draft recommendations. Then, on August 9, we are hoping to update and refine those and present draft recommendations to the HITAC in August. So, we're looking at an every other week cadence through August. Moving on to the next slide, I think I'll pass it to Steve.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

All right. Thank you very much. Greetings, everyone. Happy Friday. I appreciate your time as usual. Congratulations on getting through Phase 1. So, before we dive into some of the details, I wanted to level set a bit in terms of where you've been relative to your experience with US Core Data for Interoperability and where we're planning on taking you over the next couple of months or few months, as Christina mentioned. So, a little over a year ago, the draft USCDI and proposed expansion process were laid out in the context of the trusted exchange framework and common agreement. And since you are all part of HITAC, you got a chance to weigh in on three particular aspects. So, at the high level, the new data classes. At that point, we had not indicated the specific data to meet those data classes. A promotion model process and characteristics by which to judge the readiness for including something in the USCDI.

And if you recall all the way back a year ago, at the end of the document, we had kind of a rough estimation of the year in which a particular data element could be targeted for inclusion in the USCDI. So, you all gave us a bunch of feedback. The public gave us a bunch of feedback. We all got a lot of good feedback. And then, as the news of the USCDI death was greatly exaggerated, as the saying goes because as you know, we fully proposed a kind of flushed out Version 1 of the USCDI earlier this spring as part of our proposed rule to implement the Cures Act. And so, before we start the conversation related to Phase 2 for this task force, I wanted the level set on what's changed in the past year so you have a kind of full context for how to approach Phase 2 and the type of recommendations that we're looking for you now, at this point, given that we're all a year older and wiser.

So, all of the feedback that we received in the first release of the USCDI and promotion model were used to inform our thinking of what went into the proposed rule as well as how we were going to engage you all as part of this process. So, just to reiterate, again, we proposed the USCDI Version 1 in the proposed rule. So, that's one ingredient that you have to work with. And that's really what your Phase 1 recommendations are focused on. Then, the other ingredient that you need to keep in mind, and I'll cover how this is relevant is that as part of the proposed rule, we included a new process that we refer to the standards version advancement process for standards and implementation guides overall that we reference in a regulation.

And we also included the USCDI as a proposed standard to be part of that process, to be an

input to that standards version advancement process overall foreshadowing some things just to keep in mind, again, for how they relate to the promotion model that we talk about. So, your work on USCDI Version 1 and the specific discussion about the data itself is now done. And the next time you will see a final version of USCDI Version 1 will be when ONC issues a final rule. So, you can have your moment of Zen. You can take a deep breath for a few seconds until I get you ready and energized to take on Phase 2, which will focus solely on how ONC can work with the community at large to work through adding data elements to the USCDI on what we think would be an annual basis. And I believe you've gotten this in one of the materials a four page process document.

I'm going to cover a bunch of that document in the slides that I present to you today. So, don't worry about flipping to it right now. But, largely, it lays out if ONC had to implement a promotion model for the USCDI today, here's what we think would work. And your task put simply is over the course of the many weeks in meetings is it's essentially redlining the document and recommend updates to the process that ONC could then take and use to execute the process over time as we prepare to release the final rule and have a USCDI Version 1 as a baseline on which to subsequently iterate. So, a key point that I'd like you to keep in mind throughout the process as we've taken everybody's feedback into consideration is that it became clear that we needed to pursue a community driven process.

And so, you see a lot of what we try to lay out both in terms of transparency, predictability, and just overall understanding and clarity about what's necessary to get promoted through the USCDI process. It's something that we wanted to make sure that the community at large could understand. So, the approach on which we seek your recommendations really embodies that and we're really looking at putting something into place that democratizes the process of submitting data elements for consideration and lays out clear guidelines that a single entity or a coalition can focus on to, I'm going to emphasize this here, build a body of evidence around a readiness of a data element to be promoted and, ultimately, included in the USCDI.

So, a lot of what I'll walk you through just at a high level here and what you can read through in more detail in that four page document is what kind of evidence, what's the body of evidence, that needs to be built and attributed to a particular data element in order for it to get promoted further up along the line to get included in the USCDI. So, first, I'm going to show you a visual illustration of our vision for how this would work over time. And then, I'm going to walk through specific aspects of the process and timing. And lastly, we'll conclude with the formal prose of your charge and you'll be all ready to go after that. So, the way in which, hopefully, the slides have all flipped over for you, the way in which you kind of envision this is a step wise approach where, at the beginning, as I mentioned, we're looking to really democratize the process. Anyone could submit a data element for consideration.

And we expect to get a pretty large number of those at least to start. And they would sit in a space where we call the comment level. And I should probably also interject here. We intend to build out, in order to support these processes, a new section in the interoperability standards advisory that would allow for this type of online public engagement. So, keep that in mind that we have this infrastructure component that we intend to build out as well over time to support this community engagement. So, data would be submitted. And as you noted from the timeline that you got that Christina mentioned, one of the things that you'll be looking

at is what's the first set of information that needs to be attributed to a data element that gets submitted for consideration. And then, over time, as the cycles go, all of the data that comes in as comments will subsequently be classified into either a Level 1, which is less mature or a Level 2, which would be slightly more mature and potentially ready to be considered for inclusion in the USCDI.

You can kind of see that step wise process that would be on a kind of annual cycle as the data element could work its way up to the USCDI. And, ultimately, you can think about this like a funnel perspective. But really, that didn't get across the kind of visual that we intended or vision that we have for the process. So, largely, on the right side is an arbitrary kind of axes of how many data elements could be at a particular level at any point in time. So, we think at least to start we could get a lot of engagement that could be a few hundred data elements or so that people submit at comment level. But when it comes to the actual evidence and additional detail and information that would need to be associated with those data elements for consideration to be promoted, ultimately, to the USCDI, that's where we'd start to see some attrition and separation among the readiness of those data and the evidence associated with them.

So, when it comes to ONC's engagement, as data elements get submitted into that new part of the interoperability standards advisory platform, we would look through and classify, based on the characteristics you'll give us feedback on, where those data elements fit from a maturity perspective, promotability perspective. And they would either get classified into Level 1 or Level 2. At the point in time when data elements are at Level 2, there would be a role as we've identified here, for the HITAC to have an opportunity to weigh in as well as the public, which has an opportunity to weigh in on everything throughout the cycles that we have proposed. But more explicitly, when it comes to including something into the USCDI, we saw that there was a special role for HITAC to have an opportunity to issue recommendations and further consider what data elements may be applicable to include.

And at that point, there's only so much of new data that could be included in a version of the USCDI on a year after year basis for people to consider. But, ultimately, our hope is that on an annual basis, we'd be able to update the USCDI based on the subsequent characteristics that I'll cover, keep moving other data up their various promotion levels. And that would start to signal to the industry that there would be more clarity and more predictability around we've seen this data element now move and to have additional evidence attributed to its ability to get moved into Level 2. And in some cases, the industry would see a data element move from Level 1 to Level 2, which would be a signal that it's working its way up the evidence building and implementation testing, etc. And that it may be considered for the USCDI in the next year or two pending additional work by the stakeholder community.

So, it starts to lay out that same kind of timeline that I think a lot of people favorably reacted to about charting out a course and a trajectory for the future and giving more of a vision toward what data elements may be coming up and included into the USCDI. So, that's a visual representation of how things would work. You can go on to the next slide to start talking about the actual details in a little bit more of an approach here. So, at the start, we came up with a set of promotion model guidelines. And I'm going to touch on these in a bit more detail. I normally don't try to read through but I want to give you the bullet by bullet and what we're

thinking here. So, getting back to the first point that I made overall about this being a community drive process, we wanted to establish a way for any individual or entity to submit a data element to the USCDI process and contribute to its promotion.

And so, we have a vision that I may be the one that submits, originally, the information for a data element to be included in the USCDI but there may be a whole bunch of other members in my tribe that are really interested in advancing and seeing that data element get included in the USCDI in the future. And all of those people can easily participate in submitting additional evidence and other types of information about the data on its use in the field to help. Not me. Did we get put on hold?

Steven Lane – Sutter Health - Member

By somebody.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

It could be worse music. I'm not going to sing this to you. That's one thing for sure.

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

Are we able to mute? Oh, thanks.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

All right. Awesome. Very good. I didn't know it was karaoke time yet, right. So, getting back to Bullet No. 1. Our vision is that the person or entity or group that submits a data element to the process doesn't necessarily need to be on their own to advance it through. It can be a community effort at large. Anyone can help contribute to a data element's promotion. The second bullet, which kind of goes without saying is that we want the promotion model process, at the end of the day, in the four pager that you've got. We would, ultimately, make all of that publicly available as we are socializing it with you today so that the stakeholders that want to advance data on this know exactly what they need to do and how far they need to get data elements and the evidence surrounding them in order to get to a point where the readiness for inclusion to get promoted to the next level is visible to them.

The third bullet here covers that as the data element is submitted for entry into the process, we'll determine whether the data element enters at a Level 1 or Level 2 or requires more development before entering the process. So, it's possible that something could get kept at a comment level until there's more information that can really clearly sort out whether it belongs in Level 1 or Level 2.

Moving on to the fourth bullet, we thought, and this is subject to your recommendations as well, that if there's a newly proposed data element that's entered in as part of the process, it may have a wealth of evidence associated with it but we thought that it would be helpful for everyone from this public and transparent process that, even if we would directly classify a

data element based on the body of evidence that's submitted with as a Level 2 in terms of its readiness that a data element couldn't just be inserted directly in for consideration to the USCDI and that it would need to go through at least one cycle, so one year's worth of public comment HITAC evaluation and recommendations and then, subsequently reviewed by the national coordinator for inclusion in the USCDI. So, that seemed to be something that was not too timely of a way to slow things down but as a way to keep the predictability of the USCDI promotion model overall.

And then, we had this discussion internally about what do we do with data elements that kind of sit there and languish and perhaps the community that originally was energized to advance a data element gets focused on something else or priorities change. And, eventually, we want to have some way to archive and kind of keep the pipeline clean, for lack of a better word, after a particular period of time. And so, there are some notes in there and in the main four page document that covers when we think this cleanup process should commence. Move on to the next slide. All right. So, I covered some of this in detail already but I'll tell you what I told you already. So, as data elements get submitted, we would have a web based form approach. They would get submitted in as comments and then, they'll be classified into the particular levels.

As I discussed just before, we have suggested, as part of this document and prepared process, that each data element and the level at which they're at would have three submission cycles before they would be moved and cleaned up from an archive perspective. And data could certainly be resubmitted again. So, there's no prohibition on people resubmitting or groups resubmitting the data element if it were eventually moved over and archived or moved out of the main pipeline. But it's just to keep things clear in terms of what's making progress and what seems to be languishing. And, again, in terms of moving between levels, we have another three submission cycle kind of process that we recommended as well. I don't know that there's anything else. One last thing that we also thought that would be helpful to have some due process, sometimes there is misunderstandings about the evidence that could be submitted.

And since ONC would be the ones classifying data elements into Level 1 or Level 2, we thought it would be helpful to offer an opportunity for a stakeholder or whomever might be most passionate about that data element or had recently submitted some body of evidence to ask for a debrief on the classification decision that we came to. So, again, ultimately, some processing that you may have some feedback on as well. But, ultimately, we wanted to make sure that stakeholders had ample opportunity to make sure that all of the evidence that could be associated with the data element was rightfully considered and that the classification level was appropriately assigned. And that really is, again, to emphasize to you all as part of your Phase 2, I really see the meat of your work, again, if you remember a year ago, looking at what are the characteristics that are necessary for ONC to use to classify data elements that are submitted through this process as a Level 1 or Level 2 item.

And maybe I'll take one quick digression here to say you may remember that we had emerging candidate and other kinds of terminology. You all perceived some terminology as well as part of your first round at this a year ago. There are a lot of different interpretations and intent behind a lot of the meanings of the data or the categorization labels. So, we chose to just refer to things as Level 1 and Level 2. And then, Level 3, as you saw in the graphic earlier, is

equivalent to the USCDI. But we attempted not to cause any type of additional consternation around the labeling associated with the particular levels at this point, just to kind of keep it simple in terms of the promotion levels up to Level 3. So, move on to the next slide. So, when it comes to submitting data elements, we've tried to follow a kind of keep it simple approach.

And when the data element gets first submitted into the intake form or system that we would stand out, there's a set of informational questions that we would ask. And that's the first half of this slide. It's the top half. I'm not going to cover these in detail here because you're going to spend a lot of time talking about them amongst the task force members. And then, subsequently, as we start to dive into what would constitute a data element that has sufficient evidence to be classified at Level 1, we start to look at what do we need, what do industry stakeholders need to have greater confidence that this data is ready for prime time and can be promoted up the ladder into Level 2 and then, ultimately, into the USCDI, which would be, effectively, for nationwide exchange. So, to be formally entered into the process at Level 1 so after it's just submitted with its generic information, a data element would also need to identify one developed use case, including its relevance to nationwide exchange.

And then, identify at least one content standard or implementation guide with which it can be used. And then, demonstrate that its been tested for exchange. So, we start to see here, and you'll start to connect the dots as you look at what it takes to move something from Level 1 to Level 2, an increasing rigor in the testing and implementation experience that industry stakeholders have with the data elements. And so, we'd like to get to a place from a vision perspective that the community is driving the data elements that it prioritizes is clear based on these characteristics for what it takes to move something from the comments to Level 1 and from Level 1 to Level 2 and from Level 2, ultimately, to the USCDI. And if it means they need to do additional work and engage in a particular standards development organization that they know that they already have to go and do that and it's not something that is identified later on in the topic.

So, they can really map out a two year plan, a three year plan, a five year plan, whatever the plan is that they want to take to advance the maturity of a data element or set of data elements. It could be an entire data class using our USCDI parlance to advance something up the promotion model. So, again, ultimately, laying out the body of evidence and implementation experience that we'd like to see from the community and, again, having it be community driven. So, when we get to a point, perhaps this is my main point at the moment when something is considered for the USCDI, there is a ready implementation experience associated with that data element. And so, there's a little bit of a change in terms of where we've been but it's where we understand the industry would like to go, where we would like to go would be that as we consider including things that would eventually make its way into regulation that it's not regulation that is driving that data into the industry.

It's actually the industry moving this data element forward and having a clear, predictable process to see that data find its way into the USCDI and then, subsequently be used from a regulatory perspective. Let's go to the next slide. So, I've tried to give a couple of examples of where things were based on the prior version of the USCDI that we put out last year, things that would fit into the comment level. We, as you remember from that document that was put out a year ago, assessed where certain data elements are captured if they could be

represented today in Fyre or the consolidated CDA. And so, the two that I highlight here would be in the comment level where they don't currently have enough evidence built around them, enough standards work to associate or meet the Level 1 characteristics that I just covered on the prior slide. Employment status is one that seems like that it could at least have met the Level 1 criteria.

These are just illustrative. I'm sure there are bones to pick with all of them but, again, just for your reference, I didn't want to give you the full detail of what the characteristics were without giving you a couple of examples. And I'll try to do the same as well for Level 2 as we go forward. Next slide. All right. So, to move from Level 1 to Level 2, again, you'll see this kind of accumulative building of evidence as you work your way up those steps from the graphic that I displayed earlier. And to move to Level 2, we thought that it would be helpful for the evidence necessary to be that the data element has achieved sufficient technical development to be tested at scale. So, in this for something at Level 1, it could be relatively limited scale in its testing. And as we looked from a Level 1 to Level 2 classification then, we looked at making sure that there were technical representations in the content standard but has, as necessary, vocabulary bindings or value set bindings.

As you know, in the USCDI, you reference particular value sets, code systems, or vocabulary as necessary. Or you could have something like clinical notes where it could be unstructured kind of free text but it has a representation, which the syntax is structured around it such that the data can be exchanged, ultimately, if it were included in the USCDI. And then, we included I don't want to say arbitrarily but at least as a starting point that it would be good for two independent systems to have tested the use of this data element as a start. And this is certainly an area where I can expect us all to have many discussion and time thinking about what the right N number of systems or stakeholders for which the data should be exchanged in order for evidence to be clear that the data element is ready for promotion to the next level. So, that's Level 1 to Level 2. Let's move to the next slide.

A couple of examples in terms of what would fit into Level 2. So, you look here at the data elements that were included in the transition of the care certification criterion since 2012. And so, if you're students of our certification program and criteria, you are well aware that even though the aforementioned named MU common data set that subsequently changed to the common clinical data set have also had additional data attributed to particular certification criterion. So, for the transitions of care certification criterion, in order to support the CMS incentive program, we required the common clinical data set, as an example, plus a few other data elements that health IT developers needed to include in this system to meet the transitions of care certification criteria. And these are some that are listed in that certification criterion.

And so, they would largely get to the point where they would fit into Level 2 out of the gate because they're already implemented in production nationwide, effectively, by virtue of both the 2014 edition and 2015 edition. They just didn't happen to be included in the common clinical data set for various reasons at the beginning. But they may be considered now for inclusion in the USCDI as this process kicks off. So, we can go on to the next slide. So, there's a two part slide combo here. So, to move something in from Level 2 into the USCDI, again, another expansion of its characteristics and the body of evidence that would be associated

with that data element's readiness. So, there's one part around technical maturity. And so, here we've moved from being tested in two independent systems to being tested in four independent systems.

And that, again, is something for you all to discuss or some other alternative that you think would be a better characteristic for ONC to consider from classification. And then, the other thing that we thought would be helpful and relevant would be that there is formally published documentation for the data element's representation and exchange. So, typically, that would be through a standards development organization. But there could be other mechanisms by which that could be accomplished. Ultimately, though, there is documentation that would be available to the stakeholder community to implement and use that data element or data class as maybe necessary. And then, the second component that we added for consideration to move from Level 2 to the USCDI was, and this really gets at informing the prophecies that the HITAC would need to consider as well as ONC, the nationwide adaptability of that data element.

And so, we included some more qualitative information and quantitative information about that data element that the stakeholder community would need to represent to make sure that the data element is really ready and prepared to be included in the USCDI. I'm not going to touch on each of these in particular but they really illustrate the type of information that we would be looking for. I certainly welcome as part of your recommendation analysis, if you don't like any of the four of these, you could certainly recommend alternatives. If there is some other tweak or pivot for some of the language that you think would be helpful and make it easier to implement and administer then, that's certainly a welcome comment as well. Next slide.

So, in terms of where the HITAC would fit in, we think it would be the best use of the HITAC's time to weigh in on the inflection between Level 2 and then, data promoted into the USCDI. And so, that's really kind of a crucial policy determination and area where we thought that recommendations and evaluation from the HITAC would be important. And so, part of that process would be to look and say let's say there are 10 data elements that happen to be, just to make the math easy, at Level 2 when the cycle comes around for the HITAC review. You would get to look at the body of evidence associated with all 10 of those data elements that are at Level 2. And then, cumulatively, look at the impact as if let's say all 10 of them were ready to be included in the next version of the USCDI, what would be the cumulative impact of including all 10 of them.

And it may be that you determine or you would recommend eight out of the ten are the highest priority to include in the next version of the USCDI and then, the latter two albeit important should wait until the next cycle because accumulative impact of including the eight that you've recommended are significant enough that the industry would need some time to fully consider them as part of that new version of the USCDI. And you would be providing these recommendations to the ONC on an annual basis. and, ultimately, when something would move from Level 2 to the USCDI, ONC, the national coordinator, would consider the HITAC feedback, the public feedback, and these other similar characteristics of the cumulative impact related to including the data in the USCDI. We're getting close to the end of my stock presentation here.

Next slide. So, when I talked about the ingredients early on, I wanted to show you kind of a process timeline to have these things that fit together. And as I mentioned earlier, we won't see the final version of the USCDI Version 1 until we issue a final rule. And I can't predict when exactly that will occur. But we know, based on the cycles that we'd like to pursue for the standards version advancement process, which we expect to be annual and the USCDI process, which we expect to be annual that we couldn't run them at the same time cycle. So, we had to offset one from the other. And we determined that it would be best to have the USCDI process run on a July to July, so to speak, schedule from a 12 month perspective and have the standards version advancement process run on a typical calendar year schedule.

And so, the way that that works would be after the final rule comes out, there will be some period in between the start of the calendar year where we would expect to be able to start up the USCDI promotion model process. And then, at the beginning of the calendar year, whenever that subsequent calendar year would be, we would put out a Version 2 draft of the USCDI and the stakeholders would get an opportunity to comment on that, including the HITAC, which would be for the Level 2 items, which would be the ones eligible for promotion into the USCDI. And we would, ultimately, review those, subsequently go through any other internal processes that we have and then, we'd publish a final version of the USCDI Version 2. As I discussed earlier, in the beginning, that's not really the finish line for that next version of the USCDI.

It would get kicked into the standards version advancement process, which would have its comment period towards the back half of the year, towards he early fall, so to speak, where the USCDI next version plus all of the other available standards and implementation specifications that may be eligible for version advancement pursuant to the standards version advancement process would have an opportunity for consideration and ONC approval by the end of the year. And the important point to note as we've indicated in the proposed rule, as specifications are considered as part of the standards version advancement process, their ultimate approval or recognition by the national coordinator would not result in a compulsory or mandatory change on behalf of the health IT developers int his case for the certification program.

So, as you track through the Version 2 of the USCDI, if you were to hypothetically play that out and by the end of the standards advancement process, version advancement process Version 2 of the USCDI, you would have a Version 2 that would be out there available for use as part of the standard version advancement process. It would be a signal to the industry that there is a new version of the USCDI. And if health IT developers and others had already been building toward or contributed to the evidence associated with certain data elements or data classes then, they would be able to get a jump start on the USCDI Version 2. We could go through a number of these cycles just to kind of play this out hypothetically where we could get up to a USCDI Version 4 some years down the road. And at that point, there may require a subsequent regulatory cycle to formally update that version of the USCDI as the new baseline.

So, up until the point where another regulatory cycle would kick in, the industry would be on kind of moving on a voluntary basis to bite off the pieces of the USCDI updates that it so chose or was interested in doing fitting it into release cycles and other types of things up until the point where we would issue another regulation to update the USCDI as a baseline. So, our hope

getting back to the beginning is that this will, ultimately, lead to a more predictable, fully aware, fully transparent roadmap out aspect of as new versions of the USCDI start to cycle out then, the industry has a sense of here is where the regulations could be going in the future. Here is where data compliance and support requirements could be going in the future. And there would be an ability to be more planful and figure out how to integrate in those new data elements over time as part of the USCDI.

So, this is a timeline illustrative process to understand how those ingredients that I mentioned at the beginning fit together in terms of what we proposed. Obviously, we need to consider public comment. So, again, this is kind of hypothetical post final rule example given what we have and what you know and what we know. But I really wanted to make sure that we could give everyone on the task force a vision for how this would work out into the future so that you can give us the best recommendations possible. So, with that said, I believe I am at the end of my slide deck but we can go to the next one there. It may just be a request for questions. Yes. Back to the beginning. So, your specific mission, should you choose to accept it.

As I noted, we have requests for you to effectively, as I said in the beginning, redline, make changes, react to provide constructive recommendations on top of addition, subtraction, etc., to the four page document that we laid out, which is really the USCDI promotion model process. So, in this case, unlike last year where you kind of had green field, we've given you, effectively, a Version 0.9 of the promotion model process that we'd like your feedback on to the degree that you can get it to a place where you think industry stakeholders would be fully clear on what they need to do to participate and what ONC would need to do and our role to administer the process. And we would, effectively, go through after your recommendations, clean everything up and then, start on the investments that we need to make to update the interoperability standards advisory platform and other such investments that we need to do to lay everything out to get this ready post final rule.

So, that's about it. I appreciate your time and attention. I know it was a lot of talking but I'm happy to answer any questions that you may have. I'm certainly happy to come back and cameo as may be relevant. But you're in very good hands with my colleagues on my team, Adam and Al. And thank you, again, for your continued engagement on the USCDI task force.

Christina Caraballo – Audacious Inquiry – Co-Chair

Thanks, Steve. Do we have time to open it up to any questions that the task force might have for you?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Yeah, I'm here for you.

Christina Caraballo – Audacious Inquiry – Co-Chair

Great. So, let's open it up. Does anybody have any initial questions? Steven, go ahead.

Steven Lane – Sutter Health - Member

As always, first on the button here. Steve, thank you so much for that presentation. I wanted to maybe ask you to clarify, and I think you covered this, but I just want to be crystal clear to understand the task force's role in a couple of steps in the process. So, when new data elements come forward and they need to be assigned to Level 1 or Level 2, is that something that you're going to ask the task force to take a first stab at and then, bring back the recommendation to HITAC and to the national coordinator? And the same question about when it looks like something is ready to be promoted from Level 1 to Level 2, what is the specific role of our task force in being part of that assessment or making a recommendation?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Sure. I'll try to unpack this in a couple of different ways. At least from a time and administration process to engage with the HITAC and task force and subsequently work in that regard, we've laid out in this process that for data to get classified into Level 1 or Level 2 that would be done by ONC solely on the basis of the characteristics that you all will collectively weigh in on now for the type of evidence that would be necessary to classify data on a Level 1 or Level 2. So, that would be done on an ongoing basis by ONC because as data gets submitted throughout the year, so to speak, which is our expectation, we would start incrementally biting off each of the data elements looking at them against the characteristics for whether or not they fit at Level 1 or Level 2 and then, assign them to that particular level and they'd appear in that new section of the interoperability standard advisory platform.

So, the work of this task force or a child, so to speak, a new type of USCDI task force is what we envision in the future where its role would be specifically to weigh in on Level 2 data elements that are considered for promotion to the USCDI. Maybe I'll pause there to see if I answered your question.

Steven Lane – Sutter Health - Member

So, the initial assignment one versus two, that's going to be done by ONC based on the criteria that we're going to provide input to. And would the same be true for readiness to go from one to two there again we can weigh in on and contribute potentially to the criteria but ONC will be applying that to make the determination to go from one to two?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

That's correct, yeah. So, and this is perhaps why you're hitting the nail on the head in terms of your feedback now will be quintessential and important to our use and execution of the process going forward so that as we go through that annual cycle, say a bunch of stakeholders works together because they know that they need to independently test things in multiple systems, they do all of that and they submit the evidence to that data element's page, so to speak. When that gets in, we would look at it and say here are the characteristics for a data element to move from Level 1 to Level 2. It looks like, based on this evidence that's been submitted that that data element is ready to move to Level 1 and Level 2. And we would be doing that on kind of an ongoing basis.

Getting back to when it would be important to engage with the HITAC task force or HITAC

overall, again, we thought the most relevant time would be when data elements are in Level 2 already and are now considered for full promotion into the USCDI.

Steven Lane – Sutter Health - Member

Got it. Thank you.

Clem McDonald – National Library of Medicine - Member

This is Clem. I put my hand up but I don't know if I'm next.

Christina Caraballo – Audacious Inquiry – Co-Chair

Clem, I don't see you but I see a guest so that might be you. Go ahead.

Clem McDonald – National Library of Medicine - Member

So, two things. I want to say this is really a nice approach and it's vastly better than the one last year. I really want to applaud that. On those two additional things, you might think about adding to the questions about who is expected to answer it or get it. You might give some hint is that going to be the patient, the physician, the hospital service people. Somehow, that would be useful to kind of sort it. And the other thing is there is a concern but you kind of addressed it in something with levels that people will say very broad based things. And I think you kind of are dealing with that, instead of a single scale or number or question or set of questions. So, this business about sets of things like your whole history versus your height, if you had some description of that so people would characterize or at least stay away from just huge things and pick something that could be specified.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Yeah, thanks, Clem. Always ready to dig right into the tactical aspects. Yeah. So, one of the things that you all could consider, especially with some of the points that Clem mentioned, the focus that we have in the write up, which is a bit more prose associated with the slides that I provided is the USCDI is focused on data elements. Data elements will, ultimately, be part of a data class as we've kind of described things. And there may be various different data elements at different levels that may all associate with a data class over time as you can start to see the expansion playing out. But if there are particular characteristics, I keep using that term for lack of a better – I don't want to use criteria because criteria is overused.

Characteristics that are attributed to Level 1 or Level 2, getting back to Steven Lane's question that you all feel are relevant for everyone in the community stakeholder wide to know that this is an important factor in ONC considering moving something from the submitted level to Level 1 or to move from Level 1 to Level 2 or, again, ultimately, that HITAC would look at as well as part of its deliberations from Level 2 into the USCDI.

Christina Caraballo – Audacious Inquiry – Co-Chair

I do see some hands up but I think we need to move to public comment really quickly and then, we can come back.

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

Christina, we're actually scheduled to go to 4:00 so we weren't scheduled until closer to 4:00. So, we have more time for questions.

Christina Caraballo – Audacious Inquiry – Co-Chair

Missed that one. I didn't use it in the discussion. Sorry about that, guys. I don't know what – okay. Good. We've got more time. Mark, I see your hand up. Mark, we can't hear you if you're talking.

Mark Roche – Centers for Medicare and Medicaid Services (CMS) – Member

Hello?

Christina Caraballo – Audacious Inquiry – Co-Chair

Mark, is that you?

Mark Roche – Centers for Medicare and Medicaid Services (CMS) – Member

Hello?

Christina Caraballo – Audacious Inquiry – Co-Chair

Yes, we can hear you.

Mark Roche – Centers for Medicare and Medicaid Services (CMS) – Member

Okay. Perfect. So, I had a question on once you have the proposed data elements defined, how will you title data elements to the tactical standards such as Fyre, and how will you wave them into health information exchange? What's the link between the Fyre and those data elements? Or do you intend to separately define and say here are the data elements and, by the way, here are the code systems and value sets that you need to use to define them?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Yeah. So, it's a great question, Mark. I'm glad you brought it up because it's kind of a both/and here. So, as we've approached the USCDI and as we've discussed before, and this is a point that I didn't mention earlier so you'll have to forgive me, everyone, for doing a one minute monologue here on this. The USCDI really, as we approach it, is about data policy. So, as you just brought up, Mark, it's about identifying here are the priority data elements that are important for nationwide exchange. We have, as I noted earlier, attributed as applicable the value sets, code systems, vocabulary, bindings that may be appropriate to that particular data. And then, after that, the community knows this is the data element. Here may be the particular constraints on that data element that is relevant for interoperability. But then, the syntax, the content exchange standard that that data could go, could be variable based on the types of use cases that may be present.

So, we have two right now that we have experience with, which is the consolidated CDA and

Fyre. And so, as we look just solely at if we are myopic to ONC's regulatory space, we have referenced the USCDI as part of the certification criteria that includes the consolidated CDA as a content exchange standard as well as the new API certification criterion that references Fyre as the base content standard. So, in both of those cases, the USCDI would need to be properly included or embedded within those two content standards. If there is another content exchange standard like a V2 message or something else that may be CDA based, those would all still be applicable or available for industry stakeholders. And that could be what they test out as part of their Level 1 and Level 2 progression. I know you've worked on some of the cancer reporting and other things like that. So, there could be other implementation guides that use certain USCDI data.

But the point being for us from a USCDI perspective is that it's, effectively, content standard or syntax agnostic at this point. And then, leaving it up to the industry to determine what the best ways are to transact with that information if they know this is a data element and here are the semantic kind of associated bindings with it.

Mark Roche – Centers for Medicare and Medicaid Services (CMS) – Member

Thank you.

Christina Caraballo – Audacious Inquiry – Co-Chair

Terry?

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

Yes. Thanks, Christina. So, Steve, my question, I guess, goes back to the step diagram and how you funneled down the number of comments that get to Level 1 and Level 1 that gets to Level 2 and finally gets to USCDI. It seems my impression is that's a really tight funnel given the amount of data elements or data classes that are going to want to be in the cue. What are your thoughts on this? I'm a little concerned that it's very slow but recognize that industry has got a long lead time and is taking on a lot of the burden.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Yeah. The premise of each of the levels is that there should be a body of evidence associated with the data element related to its readiness to be promoted to the next level. And so, I could say it in this way. First, it would be a great problem for us to have that we would have, and I'm going to be hyperbolic here, many hundreds of data elements that have had work done with them semantically, that have had work done at various STOs to include them in content standards, and that they've been tested across many different independent systems. I guess you all can chime in otherwise, the practical reality of that happening, at least in the near future, is probably limited by the amount of resources, priorities, etc., that everyone has to do. And I think what we're looking to have is an achievable set of characteristics for each level in the USCDI promotion process that can get things up to Level 2, especially.

And then, there's going to be this dynamic where the HITAC would have an opportunity to weigh in as well as ONC to consider what are the implications of, again, this is going to be a hyperbolic, hypothetical example, including two or three dozen data elements in the next

version of the USCDI if they are ready and mature and have gone through that entire process of building the evidence and doing the testing and being fully specked out in the appropriate content exchange standard to be used. That's a good problem to have. I guess I would love to be in that position in the future. So, I don't know. Does that help answer your question a bit?

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

Yeah. Obviously, and I can see there are constraints in the system and, in a sense, we're relying on the natural constraints that are built into the system. I guess the question would be do we have an estimate or an idea of what industry could absorb and do we have to think about whether all of the elements in the USCDI or all of the data classes apply to everyone or whether someone could get more in if they only applied to a few of the sectors of healthcare?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

No, you raise two really good points that I'd like to comment on as well that we've given some thought to. So, the first one being the dynamic of – I'm trying to remember. I know the point that I want to make but I can't remember how to restate your first question.

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

I can't remember. That's terrible. I guess it sort of jumped to the second question. That was maybe a certification issue that it's sort of who does the USCDI apply to? Does it apply to everyone equally or is it segmented?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Maybe I'll start there and then, it will help job your memory on the first one. Sorry. So, for the dynamic of the USCDI, we have to consider that from a certification perspective and that's something that we expect to get as part of public comment. There is a broader applicability of the USCDI as a whole. And our expectation is that separate from the policy parameters in which it may be applicable from a regulatory perspective, it does send an important signal to the market at large about here are the data elements that have been through a rigorous process of sorts weighed in by the HITAC, etc., and have made it to nationwide exchange prominence and it may be that only two or three of the particular either data classes, data elements that are in the USCDI are relevant to a particular use case. But that's what we'd like, ultimately, industry stakeholders to look to first.

So, a lot of it is what kind of guidance to the industry as a whole can the USCDI as a community driven process signal and serve as a resource. And so, if you were going to tackle a particular type of use case that only needed some subset of the USCDI then, we'd want stakeholders to be consistent with that subset that they're using and use what's derived from the USCDI. Does that make sense? It's not an all data all of the time kind of construct.

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

Yeah. That's okay. And, again, this process is really good. And I think I remembered my first question, which was how many data elements or data classes do you think could be through

the pipeline?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Thank you. So, this is a really important point for you all to discuss as well and think about toward the end of the process when we've defined what we think is the most impactful role for HITAC would be weighing in on the Level 2 and kind of consideration of the cumulative effect. And this is why I got off track. My immediate thought on the answer to your question is it kind of depends. And there is probably a lot of data, and if Sasha is still on, she can probably comment that there is a lot of data that they capture today that could potentially already be at Level 2 because they're exchanging it with other partners, etc. But no one has ever brought it up to the broader public engagement. And then, there could be new data elements that are really novel in terms of their specification, overall consideration, clinical priority.

And it seems to me like you'll have to kind of take that context into consideration if there are vital signs, for instance, that are routinely collected today but they're not currently in the USCDI. There could be a bunch of those that wouldn't be too much of a burden to include as part of the USCDI next version. But there may be other data elements like a new social determinant of health where there will be a long tail perhaps with some of them where health IT developers need to build in ways to collect that data. You need to go to the SDO and figure out what are the content exchange standards that are most likely going to be used to exchange this type of data, etc. All of that would happen up front before something would be considered included in the USCDI. So, that's where my depends fits in. And it's hard to say. But it seems like we won't necessarily have a hard quantity assessment.

It will be more on the cumulative evaluation of a few of these data elements seem like they've been in existence forever but now, they've bubbled up to the top. All there is are new. The nationwide experience with these is not yet fully robust or comprehensive and so, you need to kind of factor that into consideration.

Clem McDonald – National Library of Medicine - Member

Steve, if I could just interject. You said vitals. I thought vitals are already part of at least our requirements because they've been collected and required for meaningful use for the last cycle. Am I wrong about that?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

You're right. And there's a bunch of data that are attributed to vital signs. I'm sure there are other vital signs that all of you could come up with that aren't in that list. And that was kind of what I was getting at.

Clem McDonald – National Library of Medicine - Member

Okay. Thank you.

Sasha TerMaat– Epic - Member

Just as an example, I don't think body temperature has been in the vital signs list in the past but that might be one that would fall into Steve's category of probably widely collected, even though it's not been on that list to my knowledge.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

Thanks, Sasha. That was my phone a friend right there.

Christina Caraballo – Audacious Inquiry – Co-Chair

I don't see any more questions for Steve. Does anyone else have any questions?

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology

And, certainly, as you all dig in, I'm sure you'll have other thoughts. You're welcome, as I mentioned, to ping Al or Adam or myself as that comes up or work it through Terry and Christina, your infinitely capable chairs.

Christina Caraballo – Audacious Inquiry – Co-Chair

Okay. Terry, did we want to get started or let people have some extra time? We didn't earlier discuss what we would do if we ended a little early. I'm sure we can open it to initial reactions.

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

Yeah. Let's do that. I think we're going to run into public comment pretty soon. But why don't we open it up to anyone who has got anything they want to say?

Steven Lane – Sutter Health - Member

Terry and Christina, maybe as co-chairs, do you want to talk about your vision of how we're going to work through our specific charge here?

Christina Caraballo – Audacious Inquiry – Co-Chair

That's the call we're on next.

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

But we could give a preview without any planning. It will be all ad hoc. And I think my initial sense of that timeline that was given, it's a pretty fluid timeline. I wouldn't read it in the way that says this is what we're going to do this week and this is what we're going to do the next week. It's probably going to be a series of discussions focused perhaps on that issue but iterating on what was talked about before and grabbing what we're about to talk about when and if we have the chance. So, it's going to be sort of a rolling process, I suspect.

Christina Caraballo – Audacious Inquiry – Co-Chair

Yeah. And to that, we've got a nice consolidated, four page document. So, I think one of the things I'd like to request of the task force is to go in on your own and read through it and do the redline, as Steve mentioned a couple of times, redlining that. So, I think we can take an

approach of working in the actual four page document recommendations and also additional recommendations through slides. But we need to tighten that up a little bit and look at whether that's going to go into a Google document in the formatting. But I would definitely say, if you haven't, read the four pages.

Steven Lane – Sutter Health - Member
Can we get that document in Word so we actually can redline?

Christina Caraballo – Audacious Inquiry – Co-Chair
Lauren?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. That's not a problem. We can get that.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
And Steve, I like what you and Ken did in the ISP task force where you really kicked it off in the sense of redlining but then, writing down the comments. So, going through with what you think are the most significant issues with this whole process, let's begin to flag them and write them down so we can keep them at top of mind as we go through. So, that might be part of the first exercise we do in preparation for the next call. And really, each of us just think about what are the issues that you really think are going to be the critical ones for us to tackle. And the answer, all of the things that are listed here is not the right answer. So, we need a little bit of prioritization. But I would offer that up as part of the first patch of homework. It sounds like everyone has quit the task force. They're all gone.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
We're not all gone.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
All right. Lauren, why don't we do public comment and if there is time at the end go back and sort of keep up our own comments. And if we don't have any, we'll break early.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. Operator, can we open the line?

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 cue. You may press star 2 if you would like to remove your comment from the cue. 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
And do we have any comments in the cue?

Operator
No comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Terry, I'll hand it back to you but I think it sounds like we may just wrap up for the day.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
I think that's an excellent idea unless someone has a parting comment.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
I second that motion.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
And thanks, again, to Steve for launching this mighty vessel.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology
You all have to row the ore. So, I'll thank you, too.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
The overview was really good today of the next charge so thank you for that.

Steve Posnack – Office of the National Coordinator for Health Information Technology – Executive Director, Office of Technology
Much appreciated.

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