U.S. Core Data for Interoperability Task Force

Transcript

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Virtual Meeting

Speakers

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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
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Sasha TerMaat	Epic	Member
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Operator
Thank you. All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Hello, everyone, and happy Friday. Welcome to the USCDI task force. For members so far, we have Christina Caraballo and Terry O'Malley, our co-chairs, with Steven Lane, Sheryl Turney, Clem McDonald, and Sasha TerMaat. Do we have any other members that have joined who are on the phone? Okay, hopefully others will join us here. I will turn it over to Terry and Christina to get us started.

Christina Caraballo – Audacious Inquiry – Co-Chair
Great. Terry, do you want me to get us started, or do you want to?

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

Christina Caraballo – Audacious Inquiry – Co-Chair
Great. Well, thank you, everybody. Here's an update from our Phase 1. We did submit the final recommendations. Carolyn and Robert signed off on them, and I think they went – well, they signed off on them. I'm not sure if they've been submitted to Dr. Rutger yet or not, but we are done with that and moving on to Phase 2. You all saw the Google document. Thank you so much for all the comments that have been put in the Google document for the second phase of our task force, which is going to be looking at the ONC draft for the USCDI data element promotion model.

Today, we're going to go ahead and get started. We wanted to talk in general about the timelines and then head into the sections. As a reminder, we have five sections in the promotion model that we'll be reviewing. Those are the promotion model guidelines, the promotion model lifecycle for submitted data elements, the data element submission information, the data element promotion criteria, and HITAC's role in the promotion process. Today, we're going to focus on the first two of those, which are the guidelines and the promotion model. So, we can go ahead and move to the next slide. Terry, did you want to add anything on that? Okay.

So, this is broken up in two ways. First of all, we were talking about the timeline in general. A lot of comments within the Google document that we started brought up the timeline to include the speed and duration of promotion, and how we identify and push through data elements of critical importance. I think this is addressed in some of the upcoming slides as well, but we did want to pause and get initial reactions so that you guys know what's coming, what we've done with the slides, which went out today. We took the information in the actual draft of the promotion model and incorporated everybody's comments into this deck, so we will be going through it in more detail. But, I think we can go ahead and pause here really quickly for a general discussion on the overall timeline.

I'm wondering if it's best if we just go ahead and move into the comments. I think these two items are covered throughout. Cool, great. So, we've got three slides under the promotion model guidelines. The

first bullet on here is actually one of the recommendations that we gave in our first round, which said that any individual or entity may submit a data element to the USCDI process as well as contribute to a data element promotion. It seems like we gave the thumbs up as a task force in our comments within our Google document, and we didn't have a lot of comments around that.

The second is that stakeholders will submit data elements for consideration as part of the USCDI promotion model, with the sub-bullet under that – and, I'm going to pause really quickly. Anything in blue or black is directly lifted language from the USCDI data element permission model draft from ONC, and anything in red is comments that the task force has brought up to date within our discussions and within the Google document that we're working from.

So, on this data elements for consideration, the first bullet is that a data class with multiple data elements may be submitted, but each constituent data element will be individually evaluated for level placement. We had an addition of level placement and advancement as a recommendation. A data class may have data elements at different classification levels, and a single data element may be a data class in name as well – for example, immunization.

So then, moving into task force discussion to date, we had brought up how many data elements get advanced at one time as something that we wanted to talk about today, and whether there a programming cost that may be difficult to estimate. So, I'm going to go ahead and pause there and open it up for group discussion. Feel free to bring up other topics outside the ones identified here, too. This is just what we've got in our comments so far.

Steven Lane – Sutter Health – Member
Do you want to use hand-raising, or are we just jumping in?

Christina Caraballo – Audacious Inquiry – Co-Chair
Sorry, I forgot about that feature. Go ahead, Steven.

Steven Lane – Sutter Health – Member
So, the issue of how many data elements to advance at a time or in a cycle – I think it really depends. It seems to me our goal is to do this in a way that industry can appropriately engage, analyze, provide feedback, digest, and produce the expansion that's desired. I don't think that the number of data elements is really the issue. It's the complexity, the diversity – if you've got a lot of simple data elements that all hang together, like social determinants, it might be for one or two rounds. If you've got things like we discussed the other day, where you're looking for a date to be added to a diagnosis, a date of onset, dates and diagnoses exist – that's sort of minor programming – but there might be other things that are really significant and require rearchitecting of systems. So, I don't know that we should look at a number limit. I think it's going to depend on the specifics.

Christina Caraballo – Audacious Inquiry – Co-Chair
I agree with that comment.

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

And, I think the other really important part of that was creating a process that is very transparent to industry so that they know what's about to get into USCDI, what's in Level 2, and what's in Level 1, and it gives them a long, advanced timeline, which I think is going to be important. I was thinking if there are other comments on this slide, let's hear them now, but maybe, Christina, if we just go through the slides quickly and give everyone an overview of what came out of the Google doc…

Clem McDonald – National Library of Medicine – Member
This is Clem. I didn't put my hand up, but I think there are some dimensions that should be considered. Firstly, when we're talking about what should be entered, is it stuff that already exists? We talked about this back when we first talked about USCDI. The data exists, it just isn't being captured in a way that's useful, or isn't structured, or something like that. I'll give a couple examples. So, one of them is cardiac ejection fraction. I want to illustrate – I want to walk through this because it illustrates some of the complexities we may have to deal with in these specifications.

So, ejection fraction is really important to the care of heart failure. I think everybody knows that. We don't get it. There's no place anywhere in any of the specs that say you have to report ejection fraction currently, and it's not even on any of the new things coming in the next round. So, how do we ask for that? "Give me ejection fraction," implying someone has to type it in? We recognize the fact that it's produced in at least three studies – cardiac CT, cardiac echo, and MUGA scan.

Then, we get into whether we want the whole report or just to say that – and, there are other structures in there – do we want to say, "Give me at least the ejection fraction from any of these studies, and then, we'll take anything else you have that's structured"? I'd like some discussion of that because I think it's – we're dealing with – I think we're assuming in this thing something brand new that doesn't have anything to do anything, and it's going to be a greenfield, as we talk about it. But, how do we talk about this content that's been flowing for years, but just isn't part of our spec, and it isn't necessarily in a place you can get ahold of it to compute on?

Steven Lane – Sutter Health – Member
Clem, I'll give you my response, and that is that, again, it's going to depend on the item. I totally agree that we owe it to the world to add ejection fraction to the USCDI, but when we do that, it'll be specific to that data, and the process will involve or acknowledge everything that you just said. There are different types of ejection fraction depending on the study that was done… So, I think whether it's a new data element that systems don't routinely collect or an old one, it's still going to go through the same process, and I don't think anyone is assuming that we're talking about new versus old. When we look at what's going to go into USCDI Version 2, or how we're going to rank new items that come in that are proposed, I think we'll just take them each on their own merits.

Clem McDonald – National Library of Medicine – Member
Well, the problem is there's no point in asking for just the ejection fraction because it almost always has some other variables that are with it, so I think we should expose in these documents the fact that this is a common complexity. It's the same with spirometry, maximum expiratory flow, and things that are used for managing asthma. There's a whole bunch of them like that that I think we should characterize it and then decide what we should be asking for because otherwise, you're going to have

people asking for a single variable that is going to sound like you have to type it in, but it's really part of a test. You wouldn't ask for just serum glucose out of the comprehensive metabolic panel, and of course, that's already covered, so we're golden there.

I think we should grapple with this so we give people some – what would we tell them to do? Would we say, "Give us at least the ejection fraction from five tests," the tests that would carry it, whenever it's available, or even pick out a few more – encourage them to pick other ones that are commonly reported? EKGs – there are always 10 coded variables. They're almost all the same. I guess that one is where we ask for all of them. But, I think we should give some guidance to people who are submitting these things to what some of the realities of the world are. I think it would also be good to ask them – at least, on Level 2 – to specify what resource they think they'd be delivering in, because this would push them to understand the context of how the stuff might get sent and what might make sense.

Christina Caraballo – Audacious Inquiry – Co-Chair
Clem, I think these are excellent points, and we can jump ahead, but I think that's more in the data promotion criteria. So, with what you're saying – since we're on the guidelines – are there any overarching guidelines that you would think of to address this? I'm looking at –

Clem McDonald – National Library of Medicine – Member
I think we should give some guidance and then ask them to specify the current content that it would likely be carried in, and we're just really asking for it to be structured and available as a structure within that current count panel. That's going to be a lot of stuff. Now, there's brand new stuff that is more greenfield, and we don't have the current content to deal with it.

Steven Lane – Sutter Health – Member
Clem, I wonder if some of that's going to get worked out just in the proposers who are advancing a particular data element or data class. We'll need to get it specified to a point that they've got a constituency that agrees.

Clem McDonald – National Library of Medicine – Member
I would bet it would be, but why make them guess? Why not lay out some of the realities that we know exist and point them? Why not give them some guidance so they're not just swarming?

Steven Lane – Sutter Health – Member
So, we should add a section around guidance to people who are nominating data elements?

Clem McDonald – National Library of Medicine – Member
Well, at least for content that actually exists. The numbers are reported all over the place for ejection fraction. And, what are we really asking? "Just send me only the ejection fraction"? Or, should they look around a little bit, understand what existing data – how it comes – and then indicate that they want at least that, but that the other content that also comes coded would be welcome? Something like that? I'm not sure how narrow to be, but we're going to have a whole swirl of stuff, and we're going to have really busy people digging through things because we didn't give them any examples of how one might do this for different categories. And then, the number part may go away. We should

always report… EKGs – they're all structured now; we just haven't talked about them. Well, the lead EKGs, anyway.

Steven Lane – Sutter Health – Member
Clem, that reminds me of another discussion we had a year ago on this, and that was about what we do with text or unstructured data that's available in the sense that it needs to be packaged so that it can be interoperable?

Clem McDonald – National Library of Medicine – Member
Well, I think we've done the unstructured data. It's in the spec now.

Steven Lane – Sutter Health – Member
Yeah, we included notes, and we specified what we're talking about.

Clem McDonald – National Library of Medicine – Member
I think we got everything. I think we nailed that pretty well. I just wanted to go through all the specs. The structured things that could come unstructured or not – we would like to have them exposed for – there's probably 100 variables that are important for managing Disease A or Disease B, like eye pressure to make sure they're not getting glaucoma. Those things usually come in bigger packages – that's the thing I'd like to express – and then we'd say if you're asking for it, describe the packages or the report content it might be in, and then volunteer if there are some other attributes that are routinely stored that we should probably grab, too. That's what I'd say about these kinds of things. It makes me think I'm going to send a bunch of them myself.

Steven Lane – Sutter Health – Member
I think the point about how there need to be packages of data. I think you're right. I don't think we're going to be talking about specific individual data elements. In a sense, they're all going to be data classes with several parts underneath the class that would move as one.

Clem McDonald – National Library of Medicine – Member
The data class is a more generic thing, which I think is a good part of our proposal, but these things come in a report with other attributes, and the class might not even be here. Now, I want all cardiology results, but I want to get the ejection fraction, and they should be aware where they're going to get it from, and at least maybe say "at least the ejection fraction" in the structured variables that might be available in the three or four cardiac reports.

The problem with asking for all the cardiac reports is then, you have to go through all kinds of negotiations to figure out every detail about what should be reported, and we won't get very far very fast with that. But, if we said we want this one variable, but we'll take the other ones, then maybe other stuff would emerge. I just had this discussion with ejection fractions with the quality care people, and they're all tied in knots trying to decide whether it should really be a diagnostic report, a procedure, or whatever. They've spent two years on it.

Christina Caraballo – Audacious Inquiry – Co-Chair

Okay. Let's move on to the next slide. I like Terry's idea of going through the promotion model really quickly, and then we'll come back to the comments. So, there are about six or seven bullets under this. The other areas in the promotion model are that the data element information submitted for entry into the USCDI promotion process will determine whether the data element is classified as Level 1 or 2, no data element can proceed directly into USCDI to promote transparency, planning, and predictability, a data element would need to be at Level 2 for at least one process cycle before promotion into USCDI – let's go to the next one, and then we'll come back so everybody can see them.

So, the next item is that the data elements that do not demonstrate advancement will be removed from the promotion process after a specified period of time, and finally, the USCDI promotion process guidelines and criteria will be transparent to the public. I'll give people a minute to digest that, and I guess we can back up and look at our comments. Can we go up one slide again? That was the promotion model. As their reference, if anybody wants to open the Google document, this is also in there if you want to jump back and forth. I'm still seeing Slide 6. Can you go to Slide 5? There we go. So, pausing here under this first bullet, one of the things that we brought up for discussion is one task will be defined – the precise criteria for both initial level and advancement, and both should align.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
We had made a bunch of very specific recommendations last year about how to get through our six stages instead of three. We may be able to repurpose a lot of what we did last year to put those in a reasonable order.

Christina Caraballo – Audacious Inquiry – Co-Chair
Sorry, I've got the Google doc up and am looking at comments to refresh my memory on some of these.

Steven Lane – Sutter Health – Member
I think the comment about engaging STOs early in the process is really well taken, and we should call that out in our recommendations.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
In some side discussion, Steve Posnack suggested that with good coordination and working in parallel, the standard for trial use could probably be ready to go within a year. That was his estimate. So, Steve and I agreed that putting this together as a specific recommendation…

Steven Lane – Sutter Health – Member
It's interesting because when Steve says "within a year," that almost feels too fast for industry for anything other than a trivial change, and it's hard to imagine anything in USCDI being trivial. A lot of the NPRM stuff uses the two-year or the 18-month cycle time, thinking that that's how long it takes to develop, implement, and get out, but when you think about the realities of change management on the ground in a clinical world, two years is really fast. So, I think while we're all enthusiastic to move forward with alacrity, there is a reality of development, and we all see clinical organizations that lag behind in their upgrades, and if you force them to upgrade on a certain timeline, that means they're not going to be doing other things. I think we have to try to find the middle path here.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
That's an interesting comment, and I think Steve Posnack also suggested that by providing industry with a clear list of where elements are, where they're going, and what's coming next, you could separate the aggressive early adopters and allow them to begin to incorporate the future USCDI elements into their current products, and then there will be a group that will ultimately put them in when they finally upgrade five years from now.

Steven Lane – Sutter Health – Member
That's a really good point, Terry, that the beauty of the standards advancement model is that USCDI itself could move along, but that doesn't mean that the requirement to be at any given version moves along apace. The requirement comes with rulemaking, so the USCDI can go to Version 2, to Version 3, to Version 4, but the rules may just – it may take three years for them to say that Version 2 is required. I think the benefit of this is that it allows developers and users to confidently move forward to what will eventually be required, and I appreciate – Didi Davis is on the public chat, and she has a tremendous amount of experience in this, and also suggests that we don't go too fast for industry.

But again, it's going to be up to the ONC and CMS in their rulemaking to say how fast the industry has to move, but USCDI itself could move forward more quickly based on when things are actually ready and have been through the process. I guess we don't have to be afraid of being sure things are slow enough because that's not really up to USCDI, that's really up to the rulemakers.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
That's a good point. We should think about a process that has as few encumbrances as possible so that you can move through levels with some certainty and a fair idea of what the timeline is going to be, and we should just make sure that process works well and is transparent because you're absolutely right. There are going to be some normal rate-limiting steps in this whole process, and Level 2 is going to be a real rate limiter, taking standardized data elements that now have a standard for trial use in place and putting them into production. That's going to be the big barrier. And then, after that, you're right – it's the rulemakers. You now have to sign up on Version 2, 3, 4… So, maybe we focus on the process itself of moving through the levels. What do you have to do to get from one to another without worrying so much about the time?

Steven Lane – Sutter Health – Member
Good question.

Christina Caraballo – Audacious Inquiry – Co-Chair
I like that approach, Terry, because worrying about the time and making it very prescriptive becomes limiting. I think it's more about transparency and where things are, and if we can tag a timeline that we foresee, then it's good. For example, if we can identify data elements that we think are going to be ready for USCDI a year or two in advance, whatever that time is, that's good, but I don't think there should be a timeline for each piece. If I remember, Ken put in a comment that things change and industry readiness to implement a standard changes over time, so why should things be reset, have to leave USCDI, or come back when they change? Level 2 should probably be a little more fluid until

you're just about right to come to Level 3, and then some kind of tag or star gets put on you. Other thoughts?

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Sasha, not to put you on the spot, but I guess I will. How does this sound – the idea of as much transparency as possible with as much lead time as possible, but without a clock on the process?

Sasha TerMaat – Epic – Member
Well, I think I would agree with Steven's point earlier, that it's probably going to be highly contextually dependent on the data class. I agree it would be hard to put a specific clock on, and so, I think a lot of advance notice is maybe a reasonable compromise. There are going to be different categories of things. There will be different sizes in terms of the effort of development to implement. There will be different projects for different groups, depending on their setting. So, if we go back to the earlier example of an ejection fraction, a cardiology system that's putting together a procedural report that needs to capture ejection fraction in a more structured way and transmit it might have a lot of work to do, whereas a system that is used in primary care and is just displaying it and using it for quality reporting might have less work to do because they are not accommodating as much data entry, for example.

And, different systems will be at different starting points with respect to having already made investments in the development of the standards, or in using the standards, and so, there are certainly cases where people would say, "Oh, let's add the concept of an encounter to USCDI," and everyone may already have some concept of encounter and think that that's very reasonable, and there might be things that are completely novel that would be much different… That's probably a long non-answer, Terry, so I don't know if that's helpful to you, but I think that developers do struggle with the same factors that Steven identified in terms of both timelines for development and testing, but also deployment in the field.

They also struggle with forecasting. Sometimes, there's a misconception in these types of task forces that if we say something is coming in the future, people will immediately start developing it. That doesn't necessarily mean that enough guidance is available to even start development, or that prioritization of something that may be a future item is desirable in comparison to other prioritization of items that are definitely wanted now. So, I'm a little hesitant about the idea that if we give enough advance notice, people will be ready. There has to be advance notice with all the sufficient guidance and certainty that it's right to make an investment now in comparison to all the other priorities that are happening.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Well said. It's not a simple process.

Clem McDonald – National Library of Medicine – Member
So, Sasha, you parsed out the user – a cardiology group versus primary group – as different issues. But, if think we think about the source data, it's more common. So, if you're getting an ejection fraction, it's going to be in one of three or four studies, period. That's the only way you can make them. And, if we

focus on that, all the different clinicians want that. But, the question really is how do we get the structured piece out and visible, and which things we want to structure as pieces are visible, a lot of which are already structured, they're just – in V2, for example, they're structured, but I think – so, we don't have to go to the top of the hill and get it all done to get some good stuff done if we let the producers choose how much more they would do in addition to just giving, say, the ejection fraction, because they're already doing some more structured stuff. I don't know if that makes sense. I don't want to put the burden on the developers, but they should leverage what they're doing right now and just carry it a notch further.

Sasha TerMaat – Epic – Member
Yeah, I think sometimes, that might be possible, and sometimes, to leverage what they're doing requires different development, different software features, or even totally different workflows. And so, it will be situationally dependent. In some cases, the data is there, and to start exchanging it might be trivial. In other cases, if the data isn't even captured, if we said that starting in the future, we want to a have a structured representation of shape of ear, hair color, or something that probably isn't routinely captured today, developers do have to think about who would be the right types of users to document shape of ear and hair color, what products they would use to do that, who would be the consumers of such information, and what products they would use.

Sometimes, the documenters, the people who enter the data, and the equipment that enters the data will not be the same as the consumers. Sometimes, I'll enter it and use it myself. All of those will not necessarily factor into USCDI, which is just a listing of data classes, but they would certainly influence development design as developers want to design in a user-centered way and think about their users that way.

Clem McDonald – National Library of Medicine – Member
I agree 1000%. I think a key thing, though, is to distinguish things that are new data capture, which will be a burden on not only the developers, but the users or the offices. So, those things that are flowing and just can't quite be grabbed as a piece of discrete information for one reason or the other – if we could distinguish those two categories, I think we could do with some easier stuff and some harder stuff, but we could categorize what work had to be done for each time.

Sasha TerMaat – Epic – Member
True. Some of those categories might be faster to implement.

Steven Lane – Sutter Health – Member
So, do we have an understanding of how that separation – how that determination would be made in this process?

Clem McDonald – National Library of Medicine – Member
I think it's relatively easy. I think things that are – well, not trivially easy, but anything that's currently coming out of a diagnostic source – if it's now coming out, and it's in that, maybe only as narrative, that already exists. There's no additional labor to capture that. The additional part is to process it in such a way that the piece that is of special interest is discernable by the computer. Now, everything

that's not a report might – there's a lot of other stuff there too, but at least that boundary is pretty sharp.

Sasha TerMaat – Epic – Member
I don't know, Clem. It doesn't seem quite as sharp to me as you make it sound.

Clem McDonald – National Library of Medicine – Member
Well, maybe I said it wrong, but if it's coming out of a reporting service now – I'm not saying every single day, they send an ejection fraction, but if the stuff is being reported by some reporting service such as an external service or diagnostic service, that stuff is fairly available – at least, to the human eye. Getting it across to the computer is the challenge, but there's no additional data capture required. Most of these things are reported as computer reports now – maybe all of them.

Sasha TerMaat – Epic – Member
Or they could be, I guess. The question for USCDI – if we think of something like ejection fraction, there are several different questions, right? One is are their standards ready to recognize the data in a standard report – an HL7 message, or something – but then, that doesn't necessarily make it trivial for everyone to implement such an HL7 message.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Sasha and Clem, I think you're both right, and I'm wondering if a lot of this discussion is actually going to be about the final step of getting into USCDI, because that's only going to happen with a lot of discussion and comment, and I suspect that industry – particularly, parts of it that are potentially disadvantaged by this data element – will make it very clear in that process.

Clem McDonald – National Library of Medicine – Member
Well, this discussion was useful in the second round. What I said earlier was that I thought we totally covered all the narrative reports. We haven't. We only included imaging, so we've left out general cardiology, we've left out neurology studies, and probably a few others that would be easy to deliver narrative, whether we think about adding that – some of the cardiology studies are imaging, but Holter monitors and EKGs are not.

Steven Lane – Sutter Health – Member
I thought that we simply said any narrative result component in our –

Clem McDonald – National Library of Medicine – Member
I did too, and I hoped it was so, but I just looked at one of the slides – which page? – on Page 6, it doesn't say that – the pink stuff. Yeah, that's what I thought, Steve. That's why I was so positive in the first round. We'll get to that.

Christina Caraballo – Audacious Inquiry – Co-Chair
Okay. Clem, I missed that last part. What did you say was missing?

Clem McDonald – National Library of Medicine – Member

Well, earlier in this discussion, I think Terry said we've got to make sure to get the narrative reports, and I said, "Oh, we're done with that. We've covered it all." I was wrong – well, I don't know if I'm wrong. I thought we had done it. Steve hinted that he saw the same thing. But now, it's the last slide, and on Page 6, there's a pink part that talks about "clinical notes – new," and I don't think it covers all of them. It's got consultation, discharge, history and physical imaging, laboratory, pathology, procedure, and…something else.

Christina Caraballo – Audacious Inquiry – Co-Chair
Oh, you're on the recommendations that we just presented.

Clem McDonald – National Library of Medicine – Member
Yeah, I'm getting ahead. I'm just pointing out that I thought – or, Steve thought – that we did say all narrative reports would be included, and this particular slide doesn't suggest that. So, if we get to that, maybe we can say what we want.

Steven Lane – Sutter Health – Member
Yeah, I think that our transmittal letter was focused more on the CCDA document types that we thought were omitted from the initial list, and the CCDA list is not all-inclusive, so I think you're right.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
I think Clem's point is well taken, though.

Sasha TerMaat – Epic – Member
A lot of those narratives would already be in the other types of data classes, too, so they were slightly different.

Clem McDonald – National Library of Medicine – Member
Steve, what were you saying?

Steven Lane – Sutter Health – Member
I just think we should make sure – I don't know if it's too late to get it into this last transmittal letter, but I think your point about narrative results – be they cardiopulmonary, be they radiology, be they neuro – that we want to make sure that as we've added "clinical notes," that it captures all of that, too. As you say, that's data that's sitting in the system that oftentimes is not moving because we haven't specified that it needs to, and I think that needs to move as soon as we can.

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

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
So, let me ask Lauren, who's our rulemaker and judge. Is it too late to add a line to our transmittal letter?

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
I am afraid so. We'd have to run that through both the task force and the full committee again by Monday.

Clem McDonald – National Library of Medicine – Member
Maybe that's –

Sasha TerMaat – Epic – Member
I thought some of these were included. What was the final language? Sorry, I'm still seeing the promotional model guidelines, not the language that people are debating.

Clem McDonald – National Library of Medicine – Member
Well, I'm not positive of what actually went through, but it's diagnostic studies that are not done in the clinic, just reports of what they saw – most of these are things from the discharge summary, that kind of thing – and are not imaging. So, the radiology will be covered pretty well, and the cardiac echoes will be covered, but EKGs, Holter monitors, nerve conduction studies, hearing testing – there are a whole bunch of things that would be fairly easy to deliver as a chunk because they're reported as electronic things – PDFs or Word documents. It would be fairly easy to get them out, and I had the impression that we'd covered them all, but I don't know if we have.

Sasha TerMaat – Epic – Member
Clem, I actually don't know if those are all easy to get out. In my experience, all of those are actually documented and stored in very different data structures, and part of the reason that they're put into PDFs when they're exported is that they vary so much in the native storage.

Clem McDonald – National Library of Medicine – Member
We're only asking for the PDF because we don't get anything else, except in some contexts, and that is easy.

Sasha TerMaat – Epic – Member
I guess I'm confused. The transmittal letter was talking about C-CDA templates, not PDFs, so that wouldn't have been what you're describing.

Clem McDonald – National Library of Medicine – Member
Let me back off. We're talking about text reports back for a year, and Terry started the discussion this afternoon about making sure we've covered it. We did all these narrative reports, which a PDF would count as, and not having to do the work of restructuring and at least get that stuff. Maybe if the CDA reports include that, we're golden, but I don't think they do.

Sasha TerMaat – Epic – Member
So, Recommendation 13 was that the task force recommended the inclusion in USCDI Version 1 of procedure note. Wouldn't that include most of the examples you're talking about?

Clem McDonald – National Library of Medicine – Member
No. Mostly, procedure notes are –

Christina Caraballo – Audacious Inquiry – Co-Chair
Guys, I'm going to cut this off, sorry. I want to get this back on topic. I think this is really important, and Clem, if you want to get on a call right after this and bring up the old recommendations, we can, and then we can see what we can do with Lauren's, but…sorry, I'm going to refocus us. Thank you. So, back to the promotion model guidelines, one of the things that Terry and I discussed with Al and Adam was that we want to go over this, and then we'll come back after we've gone through the whole process. So, we do want to revisit this after going through the rest of the sections. Unless anybody has any final thoughts, I think we should go ahead and move to the next section, which is the lifecycle. Okay, great.

So, we have three slides on the promotion model lifecycle for submitted data elements. I'm going to go through them quickly, and then we can come back to comment. So, the first is that a submission cycle begins when ONC announces a new version of the USCDI, which marks the beginning of a new data element submission period. A submission cycle ends at the end of the calendar year when the data element submission period closes. Submitted data elements exist as comments until they are classified into Level 1 or 2.

Next slide, please – actually, I think I can move it. The next item is that data elements not classified into Levels 1 or 2 have three submission cycles from the ONC final decision period to remain at the comment level before they are removed. The data submission may be updated and resubmitted to be reviewed again. If the submitter updates and resubmits the data element, this three-year cycle restarts. ONC will make the level classification decisions for each new submission.

And then, the final slide on this section: Once classified into Level 1 or 2 by ONC, a data element has up to three submission cycles to be promoted to its next level, from 1 to 2 or 2 to USCDI. ONC retains discretion to keep a data element in Level 2 for longer than three submission cycles. When a data element is removed from the process due to a lack of progress, it will be archived in a separate section of the USCDI webpage. To be reinserted into the promotion process, the data element must be resubmitted. Finally, after a data element level of classification has been published, a submitter may request to be debriefed on the classification decision.

That is the overview. That is directly from the draft, and now, I'm going to go back up to our first slide with discussion points. The first item that was discussed was that this allows anyone to submit a comment, which ONC will advance based on the criteria. I can't – mine is not coming through. It says, "Should we advise about what those criteria should be, and are we going to call these comments?" So, it was brought up that the comment was unclear, and maybe we should change that language to "unclassified proposals," which is more simplified and accurately describes this tier. I'll pause there and open this up for comments. Or, if anybody would like further explanation on any of the comments or discussion, let me know.

Steven Lane – Sutter Health – Member

I think the question about the internal criteria – it would be good to know what, if anything, ONC is already thinking about that. I think it does make sense that those criteria be specified as far as they can be, and be transparent.

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
This is Adam from ONC. The promotion from comment level to Level 1 is within the submission information section that I believe is on tap for either next meeting or the meeting afterwards, and also, part of the entry into Level 1 criteria. So, they're not intended to be internal, non-transparent criteria.

Steven Lane – Sutter Health – Member
Is that the same for Level 1 to 2?

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
Yes. You can find those in the draft promotion model Google document.

Steven Lane – Sutter Health – Member
Okay. So, we'll be going through those, as you say, at a future meeting. In terms of the phraseology used, the comment did seem a little odd. I think "unclassified proposal" is fine. I had some other suggestions, but I just think we should – something that more accurately describes it makes sense.

Christina Caraballo – Audacious Inquiry – Co-Chair
Yeah, I'm looking at the Google doc, and Steven, you had added that "suggestion" or "recommendation" would be better words. Sorry that got pulled over.

Steven Lane – Sutter Health – Member
[Inaudible] [00:51:51]

Christina Caraballo – Audacious Inquiry – Co-Chair
Are there other thoughts on this? Okay, I'm going to move on to the next slide. On this, we brought up the timeline again from initial submission, whether proposals should be resubmitted, and how this adapts to industry readiness and changes, and whether modifications should be requirement or the original submission may be viable due to shifts in the industry. We had an update – I think this was from you, Steven – to add "modified/updated" and not just "updated."

Sasha TerMaat – Epic – Member
So, what starts the three-year timeline? Sorry.

Christina Caraballo – Audacious Inquiry – Co-Chair
I need to look that up. Adam or Al, do you know offhand? I thought it was –

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead
I'm sorry. What was the question?

Christina Caraballo – Audacious Inquiry – Co-Chair
– the end of the calendar year. What starts the three-year time period?

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead
That would be the initial submission of the data element. I think there is a graphic on the USCDI document at the very bottom that the process is intended to be a year-long cycle – July to July. You can see in there that there's a six-month USCDI submission period that then moves into a six-month review and comments period.

Christina Caraballo – Audacious Inquiry – Co-Chair
So, just so I'm following the idea or timeline we're discussing is that if Clem suggested "shape of ear" as a new data class in year one's submission period, and then it was considered in year two's submission period, year three's submission period, and year four's submission period, then in each of years two, three, and four, it were not advanced, then it wouldn't be around any longer in year five without being resubmitted by someone because it just wasn't getting enough traction.

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead
That's the concept, yes.

Christina Caraballo – Audacious Inquiry – Co-Chair
Okay, thank you. Going back to that part on the unclassified, if I remember correctly, we had put in more buckets, and ONC went back to the three, being Level 1, Level 2, and USCDI for this proposed draft. I think it was that originally, we had the bucket as "emerging," and ONC chose to do just the three in order to be streamlined, so I just want to bring that up. I think the comment is for the language's comment, my interpretation is that it's so anyone can say this is what's needed, but it sounds like we as a task force really do think that we should have something that's not common, but a bucket to catch that group of what's been suggested, proposed…what we can put in "unclassified."

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
And again, Christina, last year, there really was a comment – so, anyone could propose any element and just throw it into the pot, but then, to get to "emerging," there had to be enough of a political will behind that data element or data class that would propel it forward. And so, we no longer have that transition zone. They're all mashed together. So, we're looking at elements being put together, ONC curating that group of proposed elements, and then… I'm not clear on what criteria ONC plans to use, or that we should propose to ONC, to move from comment to Level 1. Does anyone have a good sense of how that's going to work?

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead
This is Al. Adam had discussed the proposed criteria for movement from comment, or proposed, or unclassified proposed – whatever it ends up being called, the criteria during the consideration period to move from proposed, to comment, to Level 1, to Level 2 is that the criteria get listed, so during that six-month evaluation period that Adam spoke of, after the six-month submission period, that process would be undertaken for everything that was proposed, applying those criteria to everything that was

proposed, and then making a determination about what was going to be in each of the levels for that version or that year.

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
The main gist that you can identify between these different levels, which includes the comment level, is that to get into Levels 1 and 2, there has basically been enough definition around a data element being proposed for it to be undergoing testing, whether that is at a connect-a-thon or a pilot site, and anything that is in the comment level and has not been classified into a Level 1 or higher is something that has not reached that level of technical definition.

Clem McDonald – National Library of Medicine – Member
This is Clem. I had assumed that between comment and Level 1, the submitters had to do more work. Is that wrong? Is it that they had to flesh out stuff to make it a clearer proposal, or is it just that what they sent flies or doesn't fly?

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
Yeah, I think that's fair to say. If something is proposed and is diverted – is put into the comments level rather than Level 1, then yes, there is more work that the submitter will need to do, and it will have to be resubmitted for reclassification in the next cycle.

Clem McDonald – National Library of Medicine – Member
Will you inform them of that, or will they just figure it out when it doesn't make it up to the next level?

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
Yeah, I think we definitely welcome comments on exactly how ONC should do that, but I personally think it would be less useful for us to classify something into the comments without some sort of explanation of what needs to be done to move forward.

Clem McDonald – National Library of Medicine – Member
Do you have a mechanism for dealing with duplicates or near duplicates?

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support
We did not specify a process about it.

Christina Caraballo – Audacious Inquiry – Co-Chair
So, I'm curious how much you're thinking about mapping the ISA, too. So, if the data elements are in the comment area, are you going to look at them, see what exists in ISA, and then, for those that might not be in Level 1 or don't exist in ISA, maybe it's evaluated to at least get them in there, since it's kind of like an "encyclopedia" standard?

Adam Wong – Office of the National Coordinator for Health Information Technology – Back up/ Support

We are looking at a process and the actual sites where this information is displayed as being incorporated into the ISA. I think that when it comes – we haven't specified the directionality of comparing what has been proposed to what exists in the ISA.

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead

Also, I wouldn't expect the ISA to be a parking lot, if you will, for things that are proposed for the USCDI. The ISA may very well be a source – a thought, an idea for the development. If it's in the ISA, it might be considered to be proposed as a USCDI element, and we are planning on – the ISA will be the site for hosting the information about the USCDI. There will be a designator within elements posted to ISA that they are USCDI elements. Does that help answer the question?

Christina Caraballo – Audacious Inquiry – Co-Chair

Yeah, thanks, Al. That's actually really helpful. All right, crew. What do we think? Should we move along? We're kind of jumping around with this.

Clem McDonald – National Library of Medicine – Member

Let's move.

Christina Caraballo – Audacious Inquiry – Co-Chair

I stopped on this slide and went back up. Are there any other thoughts here? I'm still thinking it through. I think it's going to be really helpful for us to go into the different levels and maybe revisit some of these sections. So, a third area is to look at our discussion point. So, on this first one, we were talking about how related proposals are grouped and/or split, which was just brought up. And then, at the bottom, we were talking about how this should be very transparent, public information. So, right now, if a data element classification has been published, the submitter needs to request to be debriefed, and we're saying that any classification should be made public, and then, we were asking if there should be a process in place where ONC publishes or writes this information on a site, as opposed to needing a submitter to make an individual request. We'll go ahead and open it up for discussion here.

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

I'm wondering whether, in the ONC process of moving from proposed to Level 1, there's a round of public comment at that level. I'm just trying to square how transparency works with the process of grouping similar data classes or data elements. It seems like there are a lot of moving parts in there, and I just don't know how ONC is going to consolidate similar, linked, or related data elements. Is that something we should worry about?

Al Taylor – Office of the National Coordinator for Health Information Technology – Staff Lead

This is Al. I think there is going to be – I wouldn't call it a black box, but it's not been very well defined at this point. There is the internal process. Obviously, ONC doesn't want to create three different versions of a similar proposal, and there is going to have to be some kind of adjudication process as part of that internal evaluation process. We also don't have – as Adam just said, we don't have a well-

defined feedback process. I think it's an excellent recommendation that we have a formal push result of the evaluation process rather than a pull request, as was described in one of the discussions earlier about it. I think that'll be a great recommendation for us to look at when we set this up, whether it be an automatic publication of the results of the evaluation so that we say, "This is moving on, this is in Level 1, there's not enough information there to put it into Level 1, it's going to stay in comment for a while." But, I think the idea is a very good, clear recommendation.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Thanks, Al. We'll have one recommendation out of the task force.

Christina Caraballo – Audacious Inquiry – Co-Chair
I like that – creating a process for how we start to create data classes versus just the individual data elements, because any data element can be introduced, but the USCDI is grouped into data class. So, Al, I agree. Good point. Any other thoughts on this? This is actually our last slide that we had ready to discuss. I think we've got about 20 minutes left. Terry, what do you think? Should we take the opportunity to pull up the Google doc and start looking at the data element promotion criteria with the levels? It seems like that's the direction the conversation keeps heading in, anyway.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
I'm wondering if discussion about the process of the task force – how best do we want to work? This is what we did today by pulling comments out of the Google doc to put into the original slide deck. That was one approach.

Clem McDonald – National Library of Medicine – Member
Could I get clarification? I got a slide deck with six pages, and I think we only got through three of them. I don't know whether that was a mistake or I'm reading it wrong.

Christina Caraballo – Audacious Inquiry – Co-Chair
We have an appendix.

Clem McDonald – National Library of Medicine – Member
That appendix is what led to the discussion about text narrative reports, the very past – Page 6.

Christina Caraballo – Audacious Inquiry – Co-Chair
I don't know what you're referencing, Clem.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Clem, I think it may be two different documents. This was essentially Steve Posnack's slide deck.

Clem McDonald – National Library of Medicine – Member
The second one?

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

The one in the appendix. I don't know what "second one" we're talking about. Then, I think we had – then, we were looking at our transmittal letter at one point around narrative reports.

Clem McDonald – National Library of Medicine – Member
But, it still remains that I don't think that we understand what really gets committed to in narrative reports.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Okay. Well, we'll work on that one. I was just wondering if we wanted – if it was worth reviewing other ways we might work as a task force, and whether… One thought that came to mind would be to work out of the Google doc, tee up questions, and then answer them as a group as we go along, and answer them with proposed text so that we can always come back and refine our proposed text as we think about it more, but have a live process, and at the end, it will be relatively easy for us to create our transmittal letter because we will have thought about, refined, and clarified texts as we've gone around.

Steven Lane – Sutter Health – Member
I think that's a good approach.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
It's still an ISP.

Clem McDonald – National Library of Medicine – Member
Does the Google doc only have content from us?

Christina Caraballo – Audacious Inquiry – Co-Chair
Yes. I like the approach of working in the Google doc, and then, we can just have slides referenced on sections that we're going to discuss – a snapshot to send out to the group prior to meeting.

Clem McDonald – National Library of Medicine – Member
I'll just have to caution that I don't have time to keep seeing what's new. I can't look at it three times a day. So, that's the problem with that mechanism. If there's some intermittent thing that got sent, or we have to pay attention – I'm busy all day.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Right. Christina and I just sit around reading this stuff all day, so we have plenty of time.

Steven Lane – Sutter Health – Member
There is a way to look at new changes. You can display new changes in Google docs. I can't talk you through it, but I know that's a function of Google docs.

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

The other thing is perhaps we just make a pact to review this stuff before the next meeting. You don't have to do it every day, and you can comment when you want to comment. But, everyone can come to the discussion prepared to comment on newly proposed text.

Christina Caraballo – Audacious Inquiry – Co-Chair
And Clem, I think there's going to be a transition. It's kind of like the working process in the Google document so we can continue to add things and see each other's comments, as opposed to pulling it over the slides, but then, as we move through the process, it'll be put into a more formal deck so that we can see exactly what's being recommended, kind of like our worksheet versus our actual recommendations as we're gathering everybody's thoughts.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Any other thoughts on proposed ways to do our work?

Sasha TerMaat – Epic – Member
I like using the Google doc.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Okay. Anyone opposed? The ayes have it.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
It's Sheryl. I agree. Sorry, I haven't wanted to talk a lot because I'm at the airport and it's very loud here, but I agree with this approach. I think this is a good one.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Great. Thank you. Christina, were you proposing what we do with our five or 10 minutes before public comment?

Christina Caraballo – Audacious Inquiry – Co-Chair
Yeah, I'm not sure. We can move over to the Google document and start, but how far are we going to get? Or, we can go to public comment and break early.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Well, I would second the motion to go to public comment and break early.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Operator, can we 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'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing *.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thanks. Do we have any comments at this time?

Operator
No public comments at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Terry and Christina, any closing remarks or action items for the group before we adjourn?

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
I think we'll try to summarize all the comments that were made today, and probably place them within the Google doc, if that's where we all want to work, and see if we can't tee up some specific issues for us to address.

Steven Lane – Sutter Health – Member
If we're going to continue to use the Google doc, may I suggest that comments and suggested edits that we've already addressed be deleted so that we can see the novel content that's been added and is still in play?

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

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
So, we'll edit… Good idea. We want to keep it as clean as possible.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
That's what I was going to suggest too, so thanks for that discussion.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
All right. Christina, any parting words?

Christina Caraballo – Audacious Inquiry – Co-Chair
Nope. Thanks, everyone. Keep contributing to the Google doc. We've got a lot of comments in there, so, thank you so much.

Terrence O'Malley – Massachusetts General Hospital – Co-Chair
Thanks, everyone.

Sasha TerMaat – Epic – Member
Thank you.

Christina Caraballo – Audacious Inquiry – Co-Chair
All right. Bye.