HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) U.S. CORE DATA FOR INTEROPERABILITY TASK FORCE MEETING

April 20, 2021, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Leslie Kelly Hall	**Engaging Patient Strategy**	**Co-Chair**
Steven Lane	**Sutter Health**	**Co-Chair**
Ricky Bloomfield	Apple	Member
Hans Buitendijk	Cerner	Member
Grace Cordovano	Enlightening Results	Member
Jim Jirjis	HCA Healthcare	Member
Ken Kawamoto	University of Utah Health	Member
John Kilbourne	Department of Veterans Health Affairs	Member
Leslie Lenert	Medical University of South Carolina	Member
Clement McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Mark Savage	University of California, San Francisco's Center for Digital Health Innovation	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Daniel Vreeman	RTI International	Member
Denise Webb	Indiana Hemophilia and Thrombosis Center	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	Staff Lead

Call to Order/Roll Call (00:00:00)

Operator
All lines are now bridged.

Michael Berry
Good morning, everybody. Welcome to the USCDI Task Force. I'm Mike Berry, I am with ONC, and we are starting Phase 2 of the Task Force today. On behalf of ONC, I want to thank Leslie, and Steven, and all the Task Force members, especially Al Taylor from ONC, for all their hard work in getting us through Phase 1. It's greatly appreciated. As everybody knows, HITAC voted unanimously to accept the recommendations from the Task Force, which are currently being transmitted to National Coordinator. Steven and Leslie will talk about that more in a minute. Let's open up the meeting, and I'll call the roll, starting with our co-chairs. Steven Lane?

Steven Lane
I'm here. Good morning.

Michael Berry
Leslie Kelly Hall?

Leslie Kelly Hall
I am here. Hi.

Michael Berry
Ricky Bloomfield?

Ricky Bloomfield
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Grace Cordovano?

Grace Cordovano
Good morning.

Michael Berry
Jim Jirjis? Ken Kawamoto? John Kilbourne?

John Kilbourne
Good morning.

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Michael Berry
Les Lenert? Clement McDonald? Aaron Miri? Brett Oliver?

Brett Oliver
Good morning.

Michael Berry
Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber from CMS has a conflict, so she won't be with us today. Abby Sears? Sasha TerMaat?

Sasha TerMaat
Good morning.

Michael Berry
Andy Truscott? Sheryl Turney? Dan Vreeman?

Dan Vreeman
Good morning.

Michael Berry
Good morning. And Denise Webb?

Denise Webb
Good morning.

Michael Berry
Good morning to all. I will turn it over to our co-chairs, Steven and Leslie. Take it away.

Steven Lane
Thank you so much, Mike. I heard from Andy that he had a conflict as well, and Denise told us before we went public that she needs to take up the middle half hour to do something else. I wanted to make sure we got that down. Also, if or when Abby Sears joins us, we will give her a chance to introduce herself. Abby is the CEO and is a member of the HITAC, a fairly recent addition. She had a number of comments to share when we presented our recommendations the other day. She popped right up and said she would love to join the Task Force for the next phase of our work, so she will be joining us. We are excited about that. I understand Ken Kawamoto has joined us, which is awesome.

Thank you again, Mike and the ONC team, for your help in getting us to this point. I want to remind everyone so we don't forget that the April 15 date when we made our recommendations to HITAC was also the date that the public comment period for Draft Version 2 closed. So, all of the comments that came in over the

past few months both from the public and from the HITAC will be considered by ONC as they put together the final Version 2. Al, do you want to say a bit about that process so we understand how that will go forward?

Al Taylor

Sure. Thanks, Steven. As Steven mentioned, all of the public comments including the HITAC recommendations are in, and the public comment period is closed now. ONC is working on evaluating all of the recommendations and comments that have come in, breaking them down by the different data classes and how they identify different priorities according to the submissions. These comments include supplemental information from the submitters as well as public comments on other submissions. We will take those all as a whole, look at the weights and the value of each of the comments, and see how those are going to inform our final decisions on what is going to go into USCDI Version 2.

Although the comment period for the Version 2 draft is closed, the comment and submission system continues to be open, and we will continue to accept submissions and comments. All of those that are contributed as of last Thursday will be considered for the next cycle of USCDI Version 3. The end of the submission period for Version 3 will be sometime in September of this year. Anything that comes in between now and then will be considered for Version 3.

We also plan on publishing the final Version 2 in July. At the same time, we will be publishing what ONC is setting as its priorities for selecting among the Level 2 data elements that will be considered for Version 3, just like we considered a list of Level 2 data elements for Version 3 as well. We will publish around the same time. We would like to try to make it close to the same date. We will publish what we consider to be any updates to the evaluation criteria and any updates to the prioritization criteria that we use to select from those Level 2 data elements. I think that is what I needed to cover, Steven.

Steven Lane

Great. Thank you. I see that Abby is here and has joined us. Abby, are you on audio?

Abby Sears

Yes, I am.

Steven Lane

Wonderful. I did give you a formal introduction at the front end of the meeting, but I promised that you might like to say a few words about your interest in the Task Force. Perhaps if there was anything that you wanted to share as a HITAC member regarding comments on the recommendations that we brought forward on the 15th, this might be a good time to do that.

Abby Sears

Okay, I would be happy to do that. First of all, I am particularly interested in this committee for a couple of reasons. We work with some of the most at-risk patients in the country, and we move a lot of data. We are lucky enough to get to pilot a lot of different interactions and exchanges of data, whether it is referrals or electronic case reporting nationally. So, we have a unique perspective related to our patient population, 1.) from an equity standpoint, and 2.) what some of the challenges are of moving their data and understanding their data.

I think we have a plethora of social determinants of health data and have longitudinally had that data for many years, so we have a lot of experience related to what we are finding to be most useful related to that data. We are also in 40 states, I think. Because a lot of our patients are covered by Medicaid or some sort of public insurance, every state is designing and doing their own version of trying to capture information, all for really good reasons around understanding how best to use the money they are investing in Medicaid. But without having stronger standards, it is very expensive and very challenging to change the way we are capturing data in all of those different states. So, one of the things we really want to relay on this committee and this task force is to talk about that data.

The second thing is to talk about the movement of our data related to labs, especially because 60 percent of our patient population has chronic diseases, and another 50 percent has severe mental issues. We have significant diagnostic information that needs to move. We are a big advocate in alcohol and drug treatment, moving alcohol and drug treatment data to HIPAA because we had three examples of deaths related to that data not being available in emergency rooms.

So, I have a lot. I am trying to distill it really fast and share it as quickly as I can. I'm picking out the high points, but there is a lot that we want to share, and help communicate, and help from a process standpoint to make sure these patients are brought forward just like the commercial population. Thanks, Steven.

Past Meeting Notes (00:10:05)

Steven Lane

Thank you so much, Abby, for making the time. I see that a number of the members of the public have joined us. Welcome to all of you. Clement McDonald has joined, thank you so much. We did jump over regarding past meeting notes, and there are a couple of sets of notes that are actually on my plate to finish reviewing and get posted. We are a little behind on those, but hopefully, we will have those up there soon.

I also wanted to say that we asked a number of questions of Al and the ONC team about the general scope and purpose of the USCDI as we move into future phases, as the focus of information blocking is going to be moving forward over time, this whole question of what is Core and where things are going. I think that we were waiting sometime after Micky Tripathi took his new role at ONC for the team to be able to get together with him and talk about USCDI. My understanding, Al, is that that happened last week. Is that right?

Al Taylor

We had our first briefing with Micky last week, yes. That's right.

Phase 2 Kickoff Discussion (00:11:29)

Steven Lane

Perfect. And I have reached out to the ONC team and said that the Task Force is interested in getting a broad view of what the intentions are. I think as we move into our Phase 2 work it is important for us to know, what are the guardrails? I believe our role should be to do the bidding of HITAC and ONC, and bring forward the input they are looking for. If we spend a lot of time working on things that they are not interested in, we are just spending a lot of time to less value. We are scheduling a meeting with Micky, Al, Steve, and the teams there, I hope for later this week. I don't think it's on the calendar yet, but we'll have a chance to

discuss a lot of these questions about the intended direction and the desired input there. We will be looking forward to that.

I also wanted to share that one of the things Leslie specifically included in our presentation to the HITAC was a question to that group as to whether they were prepared to weigh in in terms of stakeholder prioritization. Were there specific stakeholder categories that they felt should be prioritized, or that there might be a need for specific outreach? And there really wasn't a strong feeling that I got from the HITAC. Denise, you might be able to weigh in as well on this. I think that the HITAC felt that we were going in a good direction, we have a lot of good stakeholder representation here, and that the various stakeholder categories have been well-defined in the draft. Leslie, did you want to comment at all on that issue of stakeholder outreach or prioritization?

Leslie Kelly Hall

We did not get clear direction, although I would like to thank Abby for many of her comments about supporting these patients and SDOH. We heard her loud and clear, and love to have her participation in this committee. I do think that we had a great conversation, and it was wonderful to have a unanimous vote. I see that Denise has a comment, as does Mark. Denise?

Denise Webb

Hi, this is Denise. I was just going to agree with you, Leslie, and also with Steve's sentiments. I think when you posed the question to the committee, it is possible that folks didn't take the time to absorb it and really think about it. Some folks were probably ready to express what they thought, but not the majority. I didn't see any real opposition to what we are doing on the Task Force in terms of stakeholder groups, but I would have to agree with you, Leslie, that the question was not really directly addressed by the committee members.

Leslie Kelly Hall

I think that as we go through the suggestions in process, when we do go back to HITAC with that, it is worthwhile to offer our opinion and seek feedback from there as well. Is there a comment from Mark? Thank you, Denise.

Mark Savage

Leslie, my comment goes back to something else. I'm not sure if this is the appropriate time, but if it is, I am happy to jump in with it.

Leslie Kelly Hall

Go ahead.

Mark Savage

Okay. I may have misunderstood, but I thought I heard Al say that in July when ONC published the USCDI Version 2, they were also publishing the prioritization criteria for V3. I may not be connecting the dots well, but I thought we were actually trying to come up with some recommendations in September around prioritization. I am just checking about the alignment of those, whether we are supposed to be doing something earlier. Maybe I just misunderstood.

Steven Lane

Perhaps we can go to Slide 5, which describes our Phase 2 work. Just to be clear, Mark, our Phase 1 was focused on Task 1, and now we are just looking at Tasks 2 and 3. I think what we have discussed here is that there is an opportunity for the Task Force to provide input on the prioritization process used by ONC that they will use for the V3 cycle, so this slide is getting a little out of date as we need to refine our thinking. Al, correct me if I'm wrong, but I think that what we've learned is that we do have an opportunity to provide input on prioritization in time for it to be included in the prioritization document that will be republished in July along with Level 2. Al, can you either challenge or verify that?

Al Taylor
No, that's right, Steven. Directly to Mark's question, we were considering moving it up just so that particular recommendation for prioritization is not delivered until September, and it may be too late to affect giving guidance to those who might submit over the summer.

Steven Lane
As part of that, Al and the team at ONC are working to develop a document that we've asked them for which does a better job clarifying the role of USCDI in the ecosystem and in ONC's work because that has been such a persistent question that we have had here, as well as others. Al is working on that. My understanding, Al, is that you really are not far enough along to say what the details of that are. But again, that document about the intended role and scope of the USCDI as well as the document regarding the prioritization criteria that will be used for evaluating these three submissions are both anticipated in July.

Al Taylor
That's right. More than likely, we will publish that in a new version of our Standards Bulletin, which is a periodical that we put out on various standards initiatives at ONC. We expect that will be the vehicle for delivering those things around the same time as we publish the Version 2 final.

Steven Lane
That is going to set our schedule now as we enter into our Phase 2 work. My thought – and any of you are welcome to provide others – is that we should start thinking about the prioritization process that's used to select from amongst the submitted data classes that are ready for elevation into a future version once we have that done, packaged up, and ready for us to present to HITAC, probably in the June timeframe so that HITAC can comment on it. That can get back from HITAC to the ONC team in time to inform their July publication date once we finish 2C, then focusing back on 2A, 2B, and finally Item 3, which is going back to our initial submission.

You will recall there are a number of items that people brought forward that we said we needed to hold onto because those will be V3 suggestions. I think for September we will be able to provide the HITAC with input more on 2A and 3. 2B is in between; in a sense, 2B and 2C are related as to what the criteria are for selecting a level and how prioritization is done. I don't see a bright line between 2B and 2C, and I anticipate our discussion here today and going forward will cover both of them. Is that all good with you, Al?

Al Taylor
That sounds great.

Steven Lane
Okay. Mark, did that answer the question?

Mark Savage

Yes, we should see that September date there. That helps me very much. Thank you.

Al Taylor

That was the due date that we set because it is close to the time for the cutoff for submissions for Version 3. It doesn't mean that the Task Force and the HITAC can't deliver it sooner.

Steven Lane

I think it is important that we get clear about when exactly we need to have our recommendations in. I am trying to see when. There is a HITAC meeting on June 9, and there is a HITAC meeting on July 14 that I will not be able to make. And since you're talking about publishing in July, Al, it seems like this June 9 HITAC meeting is when we really need to bring forward our Task 2C recommendations. Does that make sense?

Al Taylor

It does, and I think that timeframe would allow those recommendations to have the greatest impact.

Steven Lane

This really means we have a fairly short timeframe for this. All right, what I would like to do then is remind everyone what the current prioritization criteria are, the ones that ONC published and has used for prioritizing the V2 submissions. You all got that with your homework, so I will just voiceover here. Specifically, it included only Level 2 data elements. We have had to come back and forth here in a discussion of Clem's favorite elements of ocular tonometry. It is not for us to move things between levels, but we do have an opportunity to weigh in on the criteria that are used to assign levels. I'm sure we will do that.

That was a Level 2 data element, but it was identified as having been a significant gap in the prior version, which anyone could weigh in on. This is needed and supported by ONC certification. What is supported by this could be a little fuzzy. Whether that means it's required by certification or it's consistent with certification, I am not sure, but it was supported by modest technical standards development. We certainly spent a lot of time talking about that, and implementation guides that are in process but not finalized, and modest aggregate lists for vendors to develop and for users to implement in the context of the pandemic.

So, those are the current, existing prioritization criteria. That is what we are going to spend at least the next couple of weeks evaluating and seeing if we want to make some changes or suggestions in those for the next cycle. All right, great. Grace, your hand is up?

Grace Cordovano

Yes. As I'm going through and listening to this, I wanted to ask if it would make sense to ask where we are in today's world where some of the population is post-vaccination, some of the population has recovered from COVID, some of the population is struggling with long-term compilations from COVID, and eventually, we hope to be in a post-pandemic phase. As we think about prioritization criteria, should we be thinking about looking through that lens of this world that we're in and what data is going to be most important for patients and for the rest of the ecosystem to get us through this public health crisis?

Steven Lane

Yes, I think that goes without saying. These criteria exist at a moment in time, and the criteria that were established for evaluating the V2 submissions are likely to be somewhat different than the criteria used to evaluate V3, and I imagine that the criteria used to evaluate V4 will be different yet again. I see this as a dynamic process, and I think that our focus when we're looking at the criteria should be on right now. What should be the criteria right now? I don't assume that whatever we recommend now will necessarily be appropriate a year from now, when I hope that at least some of us will be here again having the same conversation. This will be a dynamic process.

Grace Cordovano
Steven?

Al Taylor
I think there is definitely room for adjustment in these priorities over time, so I agree. And I hope a lot of you will be around in two years.

Steven Lane
Sorry, Grace.

Leslie Kelly Hall
Grace, I think that it is incumbent upon us, as Steven just said, to do the here and the now in the conditions we have today as part of our due diligence and part of our reference. As we go through the day, Mark will talk to us about what we did and present some of the ideas that I think will get to your point.

Grace Cordovano
My question was, how do you balance data points that may be essential, or data class and elements that may be essential, that don't have standards? I feel that that seems to be a limiting factor, and the pushback is that while there are standards in place, this is a crucial component. There are some comments on that.

Steven Lane
Grace, to be clear, the criteria was modest technical standards development. It does not say that there must be standards. It doesn't say there must be implementation guides. I think we have discussed at some length data classes and elements that are not supported by robust standards or implementation guides. I think there were some we felt require those and that it will be a prerequisite for moving them into the next version, hence the anticipated discussion with HL7 and ONC that Andy is helping us to coordinate. Al, correct me if I am wrong, but I think there is nothing here that says there must be strict technical or implementation standards to support bringing an element forward.

Al Taylor
I don't think that is 100 percent right, because we do set the standards for determining something to be Level 2, and that is being represented by at least a terminology standard or an implementation guide. Having it be in an implementation guide doesn't mean it's represented by one of the terminologies, but at least it gives a good idea for users and developers about how to implement one of these developments. So, it needs to be usable through the use of standards or implementation guides.

Grace Cordovano

I would offer that when SDOH was put in V1, we didn't have the standards developed. That work has been largely done in the Gravity Project, and UCSF's work has driven standards to be ready for that use. So, there is that kind of yin and yang that has to happen, but we do have precedents that show we have presented data elements and then developed the standards. I understand there is tension here, and I just think it is worth discussing as we make recommendations for change in prioritization and such if that's possible. I see Clem has a comment, too.

Clement McDonald

I'd just like to say a couple of things. First, there is a lot of acceptance of narrative content that opens the door if one can say what it is. The challenge with no standards whatsoever is it can be gibberish. It's babble, and nobody can use it. That's where the tension comes in. If you don't agree on how to do it and say it, who can do anything with it electronically? The narrative has been fairly wide open to various kinds of reports, so that's the escape hatch, I think. But still, there would have to be somewhere to ship it, and there is a way to ship a lot of narrative reports already.

Steven Lane

Right. Clem, you have made the point in the past that there is data being exchanged today that could be considered for addition, and I wanted to emphasize what Al said about the Submission of Evaluation Criteria slide that you've all received. For an item to make it to Level 2, it says it "<u>Must</u> be represented using a terminology standard <u>or</u> an element of an SDO-balloted technical spec." That is the criterion that we are meeting.

And Grace, your point is that there might be things out there that would be valuable, but I guess the feeling is that it is not going to make it over the line to the Core or be included in the USCDI unless it's exchangeable based on that level of technical maturity.

Clement McDonald

If I could add just a comment, the other dimension is that there is a whole pile of opportunities that we have, and we can't do them all at once. So, the stuff that is trying to get out the door should probably get a little priority over the stuff that still has to be figured out. But this should also motivate people to get important content into a format that can be shared and reused by others.

Steven Lane

Yes, and that is exactly the work that Gravity and others have been advocating, moving these technical specs and implementation guides forward. And as we saw, a number of SDOH-related data elements made it to Level 2, and we can include them in our recommendations. Many more are in the hopper back at Level 1 at the comment level.

At this point, we want to ask Mark to share some information that he prepared which really looks at stepping back and looking at the large view of USCDI, and where it is and could be going. Then he will talk a bit about the experience he had working on an earlier workgroup under ONC that tackled a different challenge but came up with a prioritization schema that we thought might be helpful to inform our process going forward.

Mark Savage

Great. Thank you so much, Steve and Leslie. Next slide. In addition to the criteria that we've seen from ONC and the different points of view that members of this Task Force have brought forward, we at UCSF have also thought about other ways to look at USCDI. This is a slide that I developed a while ago to illustrate how any particular data element serves a lot of national needs, just to remind myself and ourselves about how important these things can be for different use cases.

Especially from a USCF perspective, care might be the thing that goes into research. We know from Michelle Schreiber it goes into digital quality measures. These could be the elements that help us develop health equity and disparity. I am thinking of, for example, the sexual orientation and gender identity data elements that we recommended. Those are for care, but they are also for identifying disparities. Shared care planning and the recommendations we have made about care team members are the kind of thing that enables a huge use case, as well as bringing patients value-based care delivery because you start to shift the curve to earlier points in the care delivery cycle.

No one of these is the answer, but just a reminder about how important USCDI is to all of the use cases we are facing now. This also illustrates Grace's point about COVID-19. That is one of the things that we are seeing clearly, that COVID-19 is amplifying our appreciation of that need. Next slide, please?

From a UCSF perspective, in the first round of comments trying to think about what should go into Version 2, we looked at some strategic priorities that might apply for us, as well as apply nationally. I am repeating that slide here. Again, I think we came more from a perspective of, what's the need within the healthcare system? There is a need for some elements to deliver better care, elements for referrals, elements around care coordination having great importance, also elements that help on the patient and family caregiver side. Some of those are demographic data sets to help understand and meet the patient where she is. Some of them are about the care planning and coordination process.

And then, for all of them together as a shared decision-making team, we recognize the importance of bringing in data from patients and care team members, elements that might have a bidirectional component to them such as patient-reported outcomes, social determinants of health, etc. This illustrates thinking about this, not just from a maturity of standards perspective, but from a criticality of need approach. We understood that it's important to think about those needs from other perspectives, too, such as payers, public health researchers, and other core stakeholders. This isn't meant to be an exclusive list. This is meant to illustrate a way that we looked at and thought about making recommendations on USCDI.

Steven, do you want me to pause here, or do you want me to go into the framework that we used back in 2015?

Steven Lane
Why don't we pause for any questions and to acknowledge what is going on in the chat here? Specifically, Hans raised the question – and this goes to task 2B, just to be clear – as to whether elevating something into USCDI or to Level 2 so that it can be selected for inclusion in USCDI should require both the terminology standard and technical specification or implementation guides, pushing it more in the direction of standards than less so. I don't know, Hans, whether you wanted to add color to that comment, and maybe we'll give Al a chance to respond.

Hans Buitendijk

Yes. As Leslie indicated, it is a little bit of a yin and yang push-and-pull that we are trying to achieve. What goes in that has a reasonable chance to make it in the USCDI version next, in this case, V3? Therefore, I would agree that for everything, having a full set of implementation guides at the time it starts to move into Level 2 might not be necessary, but there needs to be a reasonable understanding that there will be once it gets to the USCDI V3 definition. The rationale behind that is that USCDI is being used for certification and other topics as well. We talked about this before. It is used for that.

Therefore, in order to be certified, one accepts a variety of means by which things are being interoperated, if that is okay. Unless the intent is to get consistent about that; then you must have a standard by that time to be able to be certified for real-world testing or otherwise against that. So, that is the rationale. I am not saying at the time that we are suggesting or proposing that to go into Level 2 everything must be there, but we need to have a reasonable idea and intent that by putting it there, it can get over the hump to get there, we can get it done, and it has a reasonable chance by USCDI V3 to be defined.

Steven Lane
Thank you. And then, Clem had a counter-comment in the chat that sometimes asking too much in terms of implementation guides is just that, and it creates more work than is necessary. Again, there is a balance and a sweet spot between requiring more and fewer specifications on these.

Clement McDonald
Could I just elaborate? The current structures cover an awful lot of what people want. There is a tendency to over-model sometimes. One could make a special specification for Complete Blood Count, but we don't. It all fits into the general lab structure, as do most clinical observations. I think we have to be careful about over-modeling. It creates more work on the development side, and it creates more work on the user side.

Steven Lane
Great. Abby, your hand is up?

Abby Sears
Yes. On the first bullet, I'm just wondering if there is a way to make the wording meet the intent. It doesn't have the gravity it could – excuse the pun. The physicians of specialty care, and continuity of care, and care coordination, it would be great to see the importance of the mental health referrals, the mental health components, and the community. I know that is part of what's meant by continuity of care, but to have specialty care called out like that reinforces that specialty care. And, in all honesty, it needs to be equally mental health and community partners as well as specialty care. So, I think with the wording there, I would love to see more specifics related to what I just said.

Steven Lane
Just to be clear, Abby, this is Mark's wording, UCSF's wording regarding how they interpret this. For us as a Task Force, we need to think about how we translate this into recommendations to HITAC. Again, those recommendations are going to be on the leveling process and the prioritization process. I guess as we think about this, think about how these observations will turn into specific recommendations.

Abby Sears
Yes, you are right. Thanks. Mark, I guess I will just offer it for you to consider then.

Mark Savage

Thank you. For our purposes, this was meant to just illustrate a perspective. I agree that the Task Force's work needs to be inclusive, and it wouldn't just focus on the way this particular slide looks.

Steven Lane

Mark, maybe you can go ahead and share with us how your prior workgroup worked on this and modeled a prioritization schema. In that case, you were looking at specific use cases as opposed to data elements or data classes, but I think the prioritization approach is helpful.

Mark Savage

Thanks, Steven. Next slide, please? When the draft Interoperability Roadmap came out early in 2015, there were 50 use cases attached to it. The advanced health models and meaningful use workgroup was tasked by the HIT Policy Committee to develop some priorities among those 50 use cases. So, I am sharing what that framework was for back then, but it illustrates perhaps a creative approach that we could use here with some tweaking. I will also add that I am describing what we did back then. It's meant to be illustrative. This Task Force can tweak it and change some of the criteria as well. It is not being presented as something in concrete.

In trying to figure out how to prioritize those use cases, we looked at four broad dimensions or domains. What was the potential impact of the use case? We were looking at the triple aim: how much did it meet national programmatic needs, for example, the national quality strategy; what was the operational readiness of the use case; and what was the impact across the range of beneficiaries, not just one beneficiary group but the range of stakeholders? It was a pretty complicated spreadsheet, which I am happy to spare you. But each workgroup member then rated across those, gave their ratings, and those ratings were aggregated. When you looked at the aggregation across the different workgroup members, you saw some very interesting insights about the use cases.

In talking with Steven and Leslie, one idea is that a similar framework could be used to evaluate Level 2 data elements for inclusion in a version, say Version 3. It could also be used to identify Level 1 data elements that are getting a lot of love from Task Force members and, because of the ratings, might suggest they deserve some additional consideration, even though they have been preliminarily categorized as Level 1. A few of the details are included in the next slide.

For impact, we looked at healthcare and cost or value. I changed the words "use case" to "data element" just to make it a little more relevant for us. But for example, on care, does the data element make the healthcare more patient-centered, reliable, accessible, and safe? Does it reduce cost? Does it improve value? We were taking the national indications of critical impact and applying them here to the data elements, but that is not the only factor. It is not the only dimension. To the next slide?

Another important dimension is meeting national programmatic needs. At the time we used two areas. We used the national quality strategy and the six domains within the national quality strategy. We also used the Nationwide Interoperability Roadmap. It has three phases. There was a 2015 to 2017 phase about just helping the basic exchange, sending, finding, receiving, and using; a second phase about exchanging and care coordination; and a third phase about learning the health system. I didn't add all of that in here. This just illustrates ways in which you could take each of these domains and think about a data element or a

use case. It might be important to one thing and not so important to another, so you get the whole of understanding about how the data element fits into the national ecosystem. Next slide, please?

Operational readiness is also a very important dimension. We broke it down into four areas: the business and cultural readiness for an element; the technical environment, which is the area we have had a lot of discussion about already on this Task Force; the stakeholder effort, what it takes to get it up and ready; and the policy environment. Is it fitting a particular policy need that has already been articulated? Is it something that has not been discussed much? Again, we were looking at operational readiness as a dimension and different subdomains of operational readiness to consider. The last slide, please?

I remind those workgroup members to think about the different stakeholders in there. We may have more to add here, but look at the impact across the range. It's not just the impact for the health professional, but also the impact for the individual, the impact for the public, the impact for payers. So, just consider all of these. And again, the data element or use case might have a great impact for one, and less for another. Take it all into consideration in evaluating for the nation as a whole, what to recommend as a priority, and perhaps what not to recommend as a priority.

Again, this is what we used back then. It is presented here just for illustrative purposes, about a way to factor in a broader range of considerations than I think I've heard on these Task Force phone calls, and to allow us all to rate and consider them. Have I left anything out, Steven or Leslie?

Steven Lane
No, that is great, Mark. I really appreciate your sharing this with us and bringing forward the hard work of a prior Task Force to inform our discussion. Sorry, Leslie.

Leslie Kelly Hall
It was very helpful when we did this in the Policy Committee to guide discussions. Even though we did some ratings, the discussions about the beneficiary net impact were very, very meaningful, and each stakeholder group had a chance to talk it through. We were able to see where the congruence was. There were three groups impacted positively, or all five were. It really did help us to set prioritization and to drive discussions. So, thank you, Mark.

Steven Lane
One thing that I'll observe about this, Mark, is you guys put together a complex and detailed rating system. But then, it was also supported by a weighting system, both within and between the various dimensions that were considered. I would just have to ask you and perhaps the folks from ONC, how much was that actually utilized? You were looking at 50+ use cases and prioritization for which ones would get more love, as you say, from ONC. We are looking at potentially hundreds of submitted data elements. How helpful was this framework, and how much was it actually put to use?

Mark Savage
Is that a question for ONC or for me, Steven?

Steven Lane
Well, if anyone knows.

Mark Savage

I'll say for the workgroup's perspective – and Leslie, you may have comments on that as well – it was very helpful. I have spared you on this call, but there was a presentation by the workgroup to the Policy Committee. It was very useful for their deliberations. We did not present on everything. The process within the workgroup allowed us to sort the wheat from the chaff. Where it was especially useful was in spotting the priorities and having a discussion around that subset that was closer to the top in trying to figure out where to say yes and where to say no. That was definitely useful to the workgroup. My recollection is that it was very useful to the Policy Committee. Al may be able to say more about the ONC's perspective on that.

Leslie Kelly Hall

I think it was also useful when people submitted an idea or a use case. Having a common framework allowed for some due diligence so we were all speaking about the same content items. More than laboriously looking at every single data element every single time, it was a due diligence process that we benefited from more than anything.

Al Taylor

I'll just add that we discussed this a little bit in the past of couple days at ONC, and I am not aware of an analysis of the long-term impact of this framework over the last six years. So, I would have to talk to some more folks at ONC to really say. I think that fact alone is indicative of a little bit of what impact it may or may not have had. I just haven't seen any follow-up analysis of the impact of this.

Steven Lane

I think what I would observe, Al, is that the underlying principles here of technical readiness, operational readiness, evaluating the impact on stakeholders of various stripes are reflected in the submission evaluation criteria that ONC has implemented to evaluate submissions to USCDI, as Mark said, this engendered discussion, shared appreciation of these various dimensions. Practically speaking, the detailed level of analysis on an item-by-item basis is really laborious. It is a lot of work.

As we go from whatever the number was, 130 submissions that you guys got in V2 to whatever we will end up seeing in V3, there is going to be so much need identified. You guys really do need to have a workable process for leveling and prioritizing what's to be brought forward. I think this is great work, but even if it wasn't exactly translated into the process at ONC, you can clearly see how it has informed that process. Abby, your hand's up?

Abby Sears

Yes. I'm just going to say that I understand the importance and the practicality of what we are talking about. I also would just like to make the case and state the obvious, that what the ONC puts forward will set the tone for the rest of the country. Some of the things that we are advocating for are probably not as well developed as some of the more medical-related data and the standards around that. And I understand the perspective related to the practicality of putting forward things that are more developed and more mature, but we will set the tone.

We need to set a tone that says that there must be equity related to healthcare. The mental health, behavioral health, and social factors related to some of our most at-risk patients are not as well developed. They can't be left behind another 10 years just because they are not as far along on the continuum related

to standards. I implore us to find a balance and to consider that, if we set the tone, it will dramatically change and drive the agenda nationally related to standardization of data in those areas. Because if we don't do it, I don't know who else will.

Steven Lane

Well put. Thank you. Again, the purpose of inviting Mark to share this and discuss it here was to help orient us and to invite input from other Task Force members and the public. Those of you from the public, we would love to hear from you when we go to public comments as to how we want to suggest to ONC that they evolve the prioritization criteria, remembering that the established criteria are the elements in Level 2, that there is a significant gap identified in the prior version of USCDI, and that the data is supported by certification. It involves modest technical standards development. This could be on both the implementation side and the terminology, and it's a modest aggregate lift.

All of this seems to me, at least as an individual, perfectly valid. I think one of those criteria that we have been dancing around for some time now is the question of Level 2. Are we as a Task Force, as ONC, committed to prioritizing simply amongst Level 2 elements? And if so, do we have the right criteria for bringing things into Level 2, or is there a practical role for data elements that fit the Level 1 definition to be pulled forward, perhaps even "prematurely," into USCDI?

Andy is not here, so I will just channel him a little bit. He keeps coming back to the word "core." Is an element really core to Nationwide Interoperability if its technical or operational maturity falls below the requirements for Level 2? I think we got a little sideways around the whole tonometry issue where we have people saying, "No, no, it's a Level 1." It's also at a comment level, certainly at both Level 1 and comment level, when you look at "on deck." And yet, Clem has repeatedly made the very cogent argument that it's being exchanged, it's ready for exchange, it should be included. I will note that Clem did share that perspective at HITAC, and HITAC did not propose that as an amendment to our recommendations, so it's still sitting out there for future consideration.

Al, you made a comment a week or two ago that ONC might consider Level 1 data elements for inclusion in USCDI. I am hoping we can clarify this and put it to rest one way or the other. I think what you said was if interaction with the submitter and/or public commentary made it clear that it had been misleveled, that it got published as a Level 1 but it ends up with additional input that meets the criteria for Level 2, and that the reason it would be brought forward is not all the way from a Level 1 but it was actually a Level 2 all along, we miscategorized it, and therefore we're bringing it to Level 2 in the next version. Do I have that right, or is there some subtlety where you believe that a true Level 1 element might be brought forward into the next version?

Al Taylor

Actually, I think you got that exactly right, Steven. There is that and one more thing, but there's a timeframe for the reconsideration of a Level 1 data element, and that timeframe is before the drafting of the version, not two months or six months later. But that is exactly right. We may have missed a detail, or maybe a detail hadn't been provided in the original submission. That's the other part of it. It could have been added, or when somebody sees the data element submission, they may have additional information unrelated to the original use case that would demonstrate more maturity, more readiness of that data element.

They can do that to the comment process or from direct collaboration with the submitter to improve the quality, if you will, of the submission. At that point, presumably, it happens before we've drafted the next version. In that situation, something originally determined to be a Level 1 becomes a Level 2, and at that point is in the mix for consideration.

Leslie Kelly Hall
Al, as things evolve in standards and evolve over the years, is part of our process then to first validate in this version as we consider Level 1 and Level 2, make sure that they are defined correctly given the evolution? Is that part of our role, or is that process separate?

Al Taylor
Yes, I think just checking, evaluating, and getting recommendations from HITAC and the Task Force about what we consider a Level 2. Hans brought up a point about clarification of a standards development organization balloted implementation guide, and that may not be the right language for the evaluation criteria for Level 2. It may be early balloted, but it's not really ready for primetime yet. That may not be a Level 2 data element if it has a more immature early ballot as opposed to something that's published. If it's published, then maybe that is more mature more appropriate for Level 2. So, some of the criteria for the level decisions are definitely something we're looking for feedback on.

Leslie Kelly Hall
Okay. We have comments from Grace and Daniel. Grace?

Grace Cordovano
As I'm listening along, I'm struggling with advanced directives and end-of-life care, which pertain to everyone, healthy, chronically ill, providers, anyone in the ecosystem because no next moment is guaranteed. It is still at Level 1. My understanding is that there just aren't enough standards in place to move that forward, though there is progress. Is that really how we view end-of-life care?

Al Taylor
To use your word, that could be what the holdup is. It could be a lack of consensus about which standards to use. That certainly happens sometimes. We went through that when we dialed back the requirements for smoking status because nobody could agree on the right questions to ask to determine smoking status. There just wasn't consensus about exactly what should be determined. It could be the lack of standardization, it could be lack of consensus around standardization, it could be the lack of broad applicability, or it could be lack of overall standards development. It could be any of those things.

Grace Cordovano
What I am hearing is we are going to look and see if definitions of Level 1 and Level 2 are still accurate, and if the Task Force has comments to that, it would be welcome as part of our process for review. And to Grace's point, in the comments around advanced directives, the comments were very specific about the standards in place today to do that. I think it is worthwhile for us to review that, correct?

Al Taylor
That would certainly be an area to discuss. It could be a disagreement, or as Steven called it, "mislabeled." I am okay with that representation. It could be that we missed it by not recognizing what was stated as a standard. That's certainly a possibility, and that is during the initial evaluation portion, not after we publish

V2. We want public input before we publish the draft. We want public input as soon as it's published on the on deck system.

In some cases, we'd gotten some significant feedback from not only the submitter but also other stakeholders on other submissions. And in some cases, that changed the level and changed the considerations for Version 2. But certainly, looking at it, you want to try to get as many people involved as early as possible in the process. If that sort of consideration was looked at in October or November of last year after the submissions were put in, it could've had an impact.

Grace Cordovano
But going forward for the next version, we have that included in our process, correct?

Al Taylor
Yes, for sure. But it's on the stakeholder, the submitter, to try and get other people to weigh in on it and to possibly get it reevaluated – possibly, but maybe not. All of that is fair game as far as recommendations go.

Steven Lane
I think your point, Al, is that the leveling must be done, and our consideration is based on the leveling that is done prior to the publication of the draft.

Al Taylor
Yes, that's right.

Leslie Kelly Hall
Daniel has a comment.

Steven Lane
That's really helpful.

Daniel Vreeman
Yes. Piggybacking on Grace and Al's comments, I think it's important to note that we're early in the process of this evaluation, meaning it's not 100 percent precise. And while ONC is doing its best to establish the framework, it's not as if it is entirely scientific, right? So, I think these are great comments for shaping that process. What we've set up is the idea that effectively anyone can propose a data class or data element. We want that barrier to be quite low. But as Al pointed out, there is a significant responsibility as far as the data gathering, the marshaling of community support, understanding the significance, and characterizing it appropriately. In some cases, the proposer might not be fully in the best position to do that. Therefore, a larger community effort is needed to appropriately or more accurately level something.

I think what this discussion is illustrating is that there are cases where the initial leveling was done with the best information available at hand, and still, we as a Task Force come in later and say, "Hey, but wait…" That's the whole process, trying to figure out how to move that upstream so that it can happen more rapidly and be appropriately considered when it's necessary at the time the publishing is urgent. So, I think we have the challenge to use the criteria, but also gather as much of the supporting information as possible without forcing each submitter to have to take on that entire responsibility for the lifetime of that data element so it officially makes it to the USCDI.

Steven Lane

Dan, thank you for that. You were almost precisely channeling the input of the prior USCDI Task Force. Again, we want a very low barrier to entry. We want to get things on the table. Grace and Leslie, for example, are advocating for disability data, which hasn't been brought forward yet. We want to encourage the community to bring items forward. It will be more than the submitter that will need to be involved to get things all the way to Level 2, to get them to where they are ready to be added. They need to be quite mature. Like it or not, it doesn't do anyone any good to throw things into the sink if they are not ready to be truly used. It would actually lower the value of USCDI as a whole were we to bring things forward based on advocacy that are not truly prepared for access exchange and use.

We got this slide up from the homework. I believe that our next task as a Task Force is to look at these five bullets and to see the next versions, so V1 instead of V2. What would be any changes that we feel would be indicated to these prioritization criteria? Supplements, more bullets, change in wording, change in focus? That is what I had hoped we would start to get on the table today. We have about 10 minutes or so until public comment, so have at it. Hands up, please.

While the hands are coming up, I will just say we are part of a bigger process. We have an opportunity to impact that process, and it's meant to be a repeated process. It's not like any given annual cycle is the last chance for any data element or class. The things that are not brought forward in V2 will have another opportunity to make it into V3, etc. Grace?

Grace Cordovano

As I am looking at these bullet points, I keep going back to the COVID-19 framework. We didn't anticipate having successful vaccines, for example. How did the pandemic shape the prioritization? I am not sure it is emphasized enough, and it may impact one or two things that might be closely tied with other data classes or elements under consideration.

Steven Lane

Abby, do you want to put a voice to your comment in the chat?

Abby Sears

Yes. I feel torn because typically, I would be responding in the exact same way as these priorities are. But I think what I have been learning for the last couple of years, especially the last year, is that we have not been in the practice nor have we emphasized some of the elements related to public health, related to mental health, and related to equity issues. As a country, we have been predominantly managed by more of a traditional medical approach to the moving of data, so those parts of our industry are the farthest behind. That is what we encountered during COVID.

I don't know how to rectify in my head the pragmatic and practicality of moving forward with things that are more well-developed and the fact that we are suffering under the challenge that the things we need the most are the least well-developed. I don't know how to rectify that when I look at these prioritization criteria, which on the surface seem completely reasonable. But if we do this, we will be perpetuating the issues that we have been suffering under for the last two years, and we are consistently creating data for our commercial population because it is easier and more well-developed. It is actually not the commercial population, except for end-of-life issues. It's not the commercial population that is actually some of the most

at-risk and some of the most expensive care we have as a country. So, I don't know how to rectify that in my head.

Leslie Kelly Hall
This comes up significantly because when you look at the data underserved, then none of these elements would make the data underserved people more served.

Abby Sears
Exactly.

Leslie Kelly Hall
There is tension there because there is no one organization that shepherds the needs of the data underserved through standards bodies, so it's a perpetual cycle that makes those underserved actually get a wider gap and not a gap that's reduced. We have talked about this offline wondering, how do we rectify it? Is it that the need exists and has been highlighted by the USCDI process and others? But where is it appropriate to take this idea or this underserved gap that we have? Where do we take it to resolve it?

To Steven's point, you look at these priorities, and they seem very well thought out. And yes, if we are looking at data elements, they have to be defined, as Clem just said, or we have gibberish. The fact of the matter is if no one is sponsoring the underserved gibberish then it continues. So, I would love to get some guidance on this, what we had hoped to get when we asked HITAC for its guidance on prioritization of stakeholders. If the data underserved stakeholder were elevated in interest, that would somewhat weight the lack of standards to be not as important as stressing the data underserved.

I see Mark has his hand up, and I would love to get Steven and Al's comments about this as well.

Clem McDonald
I've been disconnected by the network. I lost connection.

Mark Savage
Go ahead, Clem.

Clem McDonald
Well, there are a couple of things. One is about the end-of-life and death. We do now have DNR as an order to be picked up, but it's a tough problem because there is no single, reliable holder of it. There have been proposals on where people would put it so you could find it. That's a big, complicated problem. Regarding the underserved, the problem is that no one said what you really want. Say something specific that we can deal with. Just saying there's a problem and wringing your hands doesn't get us anywhere. Be specific.

Steven Lane
Thank you. Mark?

Mark Savage
What continues to strike me about these criteria is that they build on the status quo. They look at where we are and say, "We'll make incremental change." I am speaking a little overbroad here, apologies. But one of the questions we are talking about right now and one of the questions I have been asking for years is,

where do we need to be? We have examples of that. The HITEC Act in 2009 says we cannot continue with a paper-based record system. Where do we need to be? And we figured out a way to move forward. I will think about a way to articulate that. I don't have it right now, but I think we need to add to these criteria about where the national ecosystem needs to be.

Al Taylor

This has been stuck in my craw a little bit as this discussion has gone on. There is a difference between these prioritization criteria, which were designed to help ONC select from the data elements for addition to USCDI Version 2. Some of the concerns that were raised by Grace and Abby and Leslie are about what data elements should be submitted to on deck. I don't disagree that some things are not well represented, and there is not an advocate. The advocate is the one who is going to do the work to develop the standards around these data elements, then do the submission to the on deck system. That's a different gap than what we are talking about when we talk about the prioritization criteria that ONC uses to put something into the next version of USCDI.

Steven Lane

That's a really good point, Al. Again, we and the USCDI as a whole cannot fix all of the ills of healthcare and healthcare data. It's just not going to happen. What I am hearing as I listen to this is really what Mark and Leslie's Task Force got at earlier, the importance of recognizing national programmatic needs as it was characterized there, but really priorities, underrepresented data, underserved stakeholders. How does ONC, working within the national ecosystem with CDC, and CMS, and everybody else, institute some sort of affirmative action, for want of a better term, that would allow us to bring things forward?

I think we got at that in our conversations. We identified areas that were not all the way there that we felt realistically needed some more work by HL7. Now that discussion has begun with HL7 and their team. How can we do that? It's that notion of advocating for and pulling things up by the bootstraps, and I wonder if there is another bullet that could be added to this list of prioritization criteria that would get at that. We'll have our chance to weigh in on the leveling criteria, but let's just take as gospel that something needs to be Level 2 to be brought forward. Then we can work on what allows something to be Level 2.

Clearly, a significant gap in the prior version goes without saying. We will respond to gaps. We need to understand what "supported by" means in the certification process, and understand where that process is evolving so that we can stay in concert with that. If there needs to be development, there needs to be development. But it sounds like somewhere in there we want to have advocacy, identification, and we have mentioned public health, mental health, equity, data underserved, pandemic response. Those are all appropriate categories, and that may change from year to year, the hot topics that need to be addressed. But I am interested to hear how people think we might approach the advocacy question, and how we could phrase that as prioritization criteria, and whether that changes this from a list of "ands" to an "or," because I think they all need to be Level 2. They represent a gap.

We're going to go to public comments now. I do hope we have some public comments, then we'll come back to think about how we're going to move forward.

Public Comment (01:23:18)

Michael Berry

Great. Operator, can we open up the lines for public comments?

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

There are no questions at this time.

Steven Lane
Thank you so much. Again, we continue to invite the public to contribute to this venue and look forward to comments when they are available. In the last few minutes, I think we've had a pretty broad-ranging discussion. Mark has presented a lot of deep work that we've done by an earlier Task Force facing a similar problem, and I think we have certain parameters within which we need to function. One of our tasks is to provide recommendations regarding the prioritization process. As Al said, that is one step. The first step is the submission system, how to encourage, support, and even advocate for submissions. The next is the leveling process, and how we make sure that we get that right. How, if at all, should the leveling process be tweaked? How can it support advocacy for underrepresented data and stakeholders? And the third is the prioritization process itself.

I think that our homework for next week is to lose some sleep on this, really think deeply about how we can manifest the kind of advocacy and affirmative action that we have all agreed is appropriate. Does it go into on deck? Does it go into the leveling process, and/or does it belong in the prioritization process? I hope that all of you can come forward with ideas as to how we can do that. Please, please share them with the co-chairs at your earliest opportunity, because I am frankly at the crossroads, personally. How do we move this forward within the opportunity that we have? I am very interested in your thinking. Please put a voice to it between now and our next meeting. Leslie, do you have any other thoughts?

Leslie Kelly Hall
No, I agree. I think we are at a crossroads. I do love your suggestion that there are some "ands" and some "ors" on the prioritization. If it's a matter of scope, for instance, where we select something that meets the data underserved as an "or," but it is a minimal amount, the industry has a chance to catch up, to make the standards for that. But I think that your suggestion that there is an "and" and an "or," and how do we prioritize within that "or," is a really good way to look at this. Otherwise, the gaps just get bigger.

Steven Lane
I'll also add that we do hope – and Al, I hope it can be accomplished this week – to have a meeting with Micky and Steve, and perhaps Elise and the team, to get the input from ONC. I think that we have brought ourselves and our thinking to a good level to engage in that discussion. The co-chairs will have that discussion and come back here. I am not sure if that is appropriate for a full Task Force dialogue, but who knows? Maybe it will be.

With that, we are at time. We don't have hands up. I really want to thank everyone for your thoughtful engagement. Again, go think about these things and bring us your suggestions in anticipation of our ongoing discussion next week. Thank you.

Leslie Kelly Hall
Thank you, everyone.

Al Taylor
Thank you.

Grace Cordovano
Thanks, everyone.

Adjourn (01:28:32)