Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) U.S. CORE DATA FOR INTEROPERABILITY TASK FORCE 2021 MEETING

June 15, 2021, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL
# Speakers

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

Operator
All lines are now bridged.

Mike Berry
Great. Good morning, everybody, and welcome back to the USCDI Task Force. I am Mike Berry with ONC, and we really appreciate you joining us today, and on behalf of ONC, I want to thank the co-chairs and the entire task force for last week’s presentation to the HITAC and the unanimous vote to adopt those Phase 2 recommendations. We know it is a lot of hard work, and we really appreciate it. I am going to open up today’s meeting with roll call, and I will start with our co-chairs. Steven Lane?

Steven Lane
I am here.

Michael Berry
Leslie Kelly Hall?

Leslie Kelly Hall
I am here as well.

Michael Berry
Ricky Bloomfield? Hans Buitendijk? Grace Cordovano?

I am here.

Michael Berry
Jim Jirjis? Ken Kawamoto? John Kilbourne?

John Kilbourne
Here.

Michael Berry

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Abby Sears is away this week. Sasha TerMaat?

**Sasha TerMaat**
Good morning.

**Michael Berry**
Andrew Truscott? Sheryl Turney is joining us in a little bit. Dan Vreeman?

**Daniel Vreeman**
Good morning.

**Michael Berry**
And, Denise Webb? Okay, thank you, everybody, and I will turn it over to our co-chairs, Steven and Leslie.

**Recap of June 9, 2021, HITAC Presentation (00:01:39)**

**Steven Lane**
Thank you so much, Mike, and welcome, everybody, after you all had a bit of a break. As you know, we were successful. Am I muted? Can you guys hear me okay?

**Michael Berry**
Yes.

**Steven Lane**
Okay, sorry. I thought I heard a comment. So, while you were all on break for the last couple of weeks, we put together the final version of our Phase 2 recommendations and the transmittal documents. We successfully presented those at HITAC last week. They were unanimously embraced by the HITAC, and I believe they have now been transmitted to the national coordinator. Is that right, Mike?

**Michael Berry**
Yes, they were transmitted yesterday.

**Steven Lane**
Perfect, and thank you, Mike, for all the work that you have done to pull those together. So, that went very well. There was not a lot of discussion or, certainly, criticism that we heard at HITAC. We have a number of HITAC members here, so if there was something that stood out to you, I would be very interested for you to share that with the task force members who are here today, but I really think it is a testament to the hard work that all of you have done to help us formulate and clarify the recommendations to date. So, for this meeting today… Actually, I will just pause there. Was there anyone at HITAC…? Arien, maybe you have a unique perspective because you are not usually with us on this call. Any sense about that discussion and anything that we should share with the task force?

**Arien Malec**
No, I think the sense of it was…as you said, met with approval and agreement. This discussion that the USCDI Task Force hit on has been a discussion that has been a theme all the way from the standards committee days, which is if you organize around the floor of interoperability for the country, you do not have
a great mechanism for raising the ceiling, and so, I think a lot of the comment...a lot of the framework that you all put together was a very thoughtful framework for how you pull things in and mature them in advance of becoming the floor, which, as I said, has been a long-term area of policy coordination, and is something I do not think that we have historically done right as a nation. And so, I think the framework and recommendation he put together solves a critical need for the country.

**Steven Lane**
That is great. Coming from you, that means a lot, Arien. Thanks. Others?

**Leslie Kelly Hall**
It does, Arien. Thank you.

**Steven Lane**
Sasha, I know you were there. I do not know who else. David, I guess you were there, certainly as a presenter. Any observations from various other people?

**Michelle Schreiber**
Steven, this is Michelle Schreiber. I was also there. First of all, you did a terrific job, and I think we should recognize that as a committee. Thank you for that.

**Unknown Speaker**
Amen!

**Michelle Schreiber**
I thought the discussion was really very good, and it was supportive of taking it further in the future and, at the same time, balancing what is available to people now. But, Steven, really, thank you.

**David McCallie**
Steven?

**Steven Lane**
Leslie was the perfect partner on that. Yes, David?

**David McCallie**
This is David. I will just... Since you mentioned that I was there, I will just add a comment to Arien's comment, and this is coming from an outsider's point of view, not normally listening to your presentations at HITAC. I agree that the ONDEC presentation made a lot of sense, and as Arien described, it lays out a well-thought-out pathway. But, from an outsider's point of view, it struck me that there might be a little bit of a catch-22 that you guys are going to have to watch for as it gets implemented, which is that, as I remember, in order to advance to Stage 2 or Level 2, whatever it was called, you have to be deployed in four different EHR systems. That is a pretty high barrier to achieve for something that is not required by anybody, so I just would caution you that you could have made it too hard to get the ceiling raised.

**Steven Lane**
That is a really good point, David, and thank you for raising it. We did not specifically discuss lowering that bar. That was set by ONC early on. Actually, Al, can you comment? Is it really four systems? I thought it was three or more. I do not have it in front of me.

**Al Taylor**
I think it was four, but I do not know that that is… It was four or more. And, there was… I think that is what we set, and although we have not…we did not really get…we have not really gotten that kind of feedback, that that is a particularly high bar, but we understand that in some cases, it might be.

**David McCallie**
This is David again. If I remember, I might have been wrong, but the way I read it was that it was four different vendors, not just four instances of EHRs.

**Steven Lane**
Yes, it was.

**David McCallie**
Four vendors doing something hard, as we all know, is not easily achieved. There has to be some strong drive to make that happen, either regulatory pressure or some market opportunity, and it just struck me as if we might not get a lot of things advanced to Level 2 once the easy stuff is done.

**Steven Lane**
Yeah, I think you make a really important point, David, especially given our focus on minority use cases. Minority use cases might be supported by a smaller number of vendors, and I think that particular requirement really came to be when the vision was that this was really something that all EHRs should be able to do to meet majority use cases. I think it is a great point, and perhaps something that we might squeeze into our Task 3 work. We will see if that fits in as we proceed. Any other thoughts from others who were there about the discussion or the contents?

**Leslie Kelly Hall**
I would just add that the group was very complimentary and there were very few questions, so, good work, everyone. I think we covered our bases well and made sure that our recommendations were thoughtful, so I appreciate all the due diligence of each one of you.

**Denise Webb**
Steven, this is Denise.

**Steven Lane**
Getting back… Sorry, Denise. Go ahead.

**Denise Webb**
Hi, I am just on the phone right now, and I am not back to the house yet to my computer. Of course, I was there too, but I wanted to let you know that I did not really have anything to add, and I appreciate David bringing up that point about the minimum of four systems. I guess that was a nuance I did not quite notice.
Past Meeting Notes (00:09:56)

Steven Lane
All right. I do want to remind people that our past meeting notes are posted on the web. You can go to the HITAC calendar to find those there, and we did catch up from the last meeting that we had. The ONC team has been doing a really great job turning those around quickly, and Leslie and I are trying to support this work. Okay, so, talking a little bit about the work that is before us, our Phase 3/Task 3, really focusing on recommendations related to USCDI Version 3, so all the threes align here, and… Do we have the tasks on the next slide? I do not have the slide deck. What is on the next slide here? Ah, okay, we did that. All right, that is fine. We can go back to where we were. Sorry about that.

So, our Task 3 does have to do with ONC priorities for USCDI in the Version 3 cycle that we will be starting up soon. Al, I think the kickoff of this cycle really begins in earnest, even though the site has been open and I think you have said people can submit new items now, that not much has been coming in over the course of the springtime and the winter before it, but that with the publication of Version 2 anticipated next month, there will also be a publication of guidance and the framework for the Version 3 submission cycle, hopefully well informed by this last draft of recommendations that we sent forward. Do you have anything to say about that process or how you anticipate that going? Have there been any changes in ONC’s approach for the publication of V.2 and initiation of the V.3 submission cycle?

Al Taylor
Not really anything significant. We plan on publishing on July 8, which is going to include updates to a new standards document as well as the website that will show all the changes, and we hope to also simultaneously publish either an update or a confirmation of the evaluation criteria and the prioritization criteria, along with some other language about where ONC feels like things ought to be headed for the Version 3 cycle and beyond. So, basically, all those are still in place.

Steven Lane
Great. And, I know that we have offered a lot of input on all three of those things, the evaluation, prioritization, and clarification of the future of USCDI, and certainly, the sense I get is that you have heard us loud and clear and that you are taking all that into consideration, but if questions arise as you guys are hammering out the final language, obviously, you are welcome to reach out to us as the co-chairs, and we can certainly reach out to the task force as a whole if there is any further clarification needed.

Al Taylor
Sure.

Steven Lane
Wonderful, okay. So, what we as the co-chairs and the ONC team have put together for planning for Phase 3 is a process of hearing from stakeholders focused in the areas that we have identified as high priority. So, the first presentation we are going to have today by Arien and David is really coming from the Interoperability Standards Priorities Task Force. The ISP Task Force is in its second iteration under the HITAC presently, and they are really looking forward to the standards as they evolve and helping to make recommendations about them, and of course, USCDI is integrally dependent on the development of those
standards. So, I think that while we are focused on what is ready to go and what are the aspirational goals at the data level, the ISP Task Force is looking at the standards and where they are going.

So, in the couple of presentations that this ISP Task Force has made to the HITAC, there have been specific comments in recommendations about USCDI, so we felt that it was valuable to have Arien and David come and cover that material for the task force for those of you who did not hear it at the HITAC because I think it provides some really nice guidance for us. After today, we have planned for next week a meeting focused on public health. As you all know, we have identified public health use cases as critically important for supporting, and there are folks at CDC and folks who are involved in the Public Health Interoperability Work Group that is sponsored by CDC, and there is also a public health task force under HITAC presently, co-chaired by Carolyn Petersen and Janet Hamilton.

All of these folks are going to be coming to join us next week to have a deep-dive discussion about public health use cases, and specifically, in the end, what are the opportunities for USCDI, so we can use that to inform our Phase 3 recommendations. We are also looking at having a meeting focused on equity and disparities. Obviously, there was an executive order, and all of the groups within HHS have responded to that executive order with how they are going to be approaching equity and disparities, and we are going to see if we can tease out any USCDI-focused needs related to all of that work, and then, we have also planned a presentation for July focused on social determinants of health, which, again, is an area that we have highlighted as critically important going forward, and we are going to bring the folks from the Gravity Project. Mark is helping to orchestrate that so we can focus on where they are going.

At Al's suggestion, we decided to hold that one until after Version 2 is published because we feel that how Version 2 incorporates our earlier recommendations on the SDOH data elements is going to inform that discussion as to what will be required in terms of Version 3. And then, also, Leslie has reached out to our friends at PCORI, looking at patient-centered outcomes and the research angle on this to, again, determine whether there are particular needs related to the future of USCDI and Version 3 in particular that relate to research. So, what we are doing is thinking about going through these key areas, speaking with the real deep subject matter experts to help to identify USCDI priorities that come out of it. So, I will pause there and see if Leslie has anything to add to that or if anyone has any questions or comments about that approach.

Leslie Kelly Hall
I think we would also be open to suggestions where we see there are gaps for subject matter experts, so please keep that in mind.

Steven Lane
So, how many meetings we have between now and the end of August will really depend on how those presentations go and our discussion goes. We also are committed to going back through both our spreadsheet and our document of prior task force recommendations. We have a number of items that we deferred to our Task 3, and we will be reviewing those as well, and that will likely end up being separate from these SME presentations. All right. Any questions about that? I do not see any hands up. Denise? Anyone on the phone? Great.

Denise Webb
Sounds good.

**Steven Lane**
Good, thank you. Thanks for that affirmation. So, with that introduction, we are going to turn it over to David and Arien. Maybe you guys can also just introduce yourselves briefly for those who do not already know you, and we are going to hear about the work of the Interoperability Standards Priorities Task Force for 2021 and how those recommendations relate to the work of our group.

**ISP TF Recommendations on Phase 3 (00:19:40)**

**Arien Malec**
Go ahead, David.

**David McCallie**
Thanks, Steven. I think I know most everybody on the call from previous task forces and other context. My name is David McCallie. I retired a couple of years ago after close to 30 years at Cerner, where I was senior vice president for medical informatics. I was also on the HIT standards committee that helped launch all of these processes that we are still now wrangling into productive use.

**Arien Malec**
And then, you can think of me as a junior David McCallie. Arien Malec, SVP of R&D for Change Healthcare, and have mostly followed in my interoperability career picking up stray ideas that David has and running them forward a little bit.

**David McCallie**
No comment.

**Arien Malec**
So, we think about the USCDI and the ISP as two task forces that are joined at the hip. We think about USCDI as defining that “what” for interoperability, defining the information that is exchanged in interoperability, and we think about the ISP as putting together the policy framework for advancing the “how” for interoperability, and in particular, the standards and implementation guidance associated with vocabulary, transport, and content standards that are the mechanisms by which data in the USCDI moves from Point A to Point B.

And so, the thought process was that since we are so closely coupled and because we made specific callouts to USCDI, it would be a good thing for us to share some of the content and context of our recommendations to the HITAC to this group so that we could make sure that we have the proper alignment. We have all of the recommendations, with the exception of our Section 3 on vocabulary, as approved recommendations. There is a little bit of controversy over the vocabulary recommendations that perhaps we can talk about when we get there, but I do not believe that materially affects some of the work that we are doing with USCDI coordination.

So, we will skip over a bunch of slides here and get into the meat of the recommendations. Let’s just try skipping slides until it looks like we are caught up and we get to the first recommendation slide, please. One more. One more. There we go. So, for context, when we were thinking about prioritization for the ISP,
since the P is for “prioritization,” we contemplated a set of priorities that included health equity, future pandemic preparedness, or the lessons of our shared experience with SARS-CoV-2 and COVID-19, which were previous ONC priorities and previous task force items that the previous incarnations of the ISP Task Force, led by the esteemed Dr. Lane, had recommended that we take on.

At the end of that prioritization process, we came up with a framework that addressed three recommendations in general foundational areas, which is to say, standards implementation guidance that we as a task force believed brought the nation forward in a set of areas that were foundational in nature and cross-cutting. And then, four areas of recommendation…three areas of recommendation? We will get there…associated with research, so, really, the lessons of COVID…

One of the few positive lessons of our shared experience is that we demonstrated that we can actually implement a learning health system on top of a set of deployed EHRs, and so, we make recommendations regarding the learning health system and deploying the EHR community for real-world and pragmatic research. We make recommendations associated with advancing efficiency and reducing physician burden, particularly on the overlap between clinical and administrative areas, and we make recommendations relative to situational awareness and recommendations associated with health equity. We deferred the recommendations on public health data systems to the Public Health Data Systems Task Force, so that ordinarily would have been an important area for our discussion.

So, we are first going to go over the foundational areas. Most of these are non-overlap relative to USCDI. In particular, we call for better maturity, production, adoption, and eventual incorporation for HL7 FHIR standards to address workflow flexibility, starting with FHIR CDS Hooks, Clinical Decision Support Hooks, which is this crazy idea that a certain David McCallie came up with and Josh Mendel took and ran with, that allows for clinical decision support to be plugged into EHRs, and it solves a problem for EHR vendors in that they are always trying to plug in a variety of CDS systems, and it solves problems for CDS systems vendors who are trying to get their content plugged into EHRs, and it clearly solves problems for clinicians and health systems who value additional decision support without doing a ton of custom and bespoke integration and configuration.

It turns out those same workflow hooks can be used for things like decision support for data capture, for pregnancy status and travel status in a Zika situation, or travel status in a COVID-19 pandemic, or, some of the same foundational standards are actually used for interoperability related to electronic prior authorization. We also believe that FHIR subscriptions provide some of the same general workflow characteristics, and this is akin to some of the work that the Argonaut Project did to open up FHIR-based APIs and make the EHR more of an API platform. These two foundational standards help drive flexible workflow that is integrated into EHRs. David, since you have got so much history and are really the inspiration for some of this work, I wonder if you have any comment here.

David McCallie
No, I think you covered it pretty well. I might flip the order between Josh Mendel and others. I think I was integral in identifying the problem, and Josh proposed the solution with CDS Hooks.

Arien Malec
As we all do. That is the way of the world in interoperability.
David McCallie
Right. Josh was phenomenally productive during that era of many of these things. I think the main point here that I am pretty sure everyone is already aware of is that these things have to be implemented with specific guidance, tested, and refined. None of them are just plug and play right off the shelf, so I think our call here is to continue to focus on these particular techniques and make them work well enough to actually deliver on their promise.

Arien Malec
Exactly. And then, the same things for FHIR questionnaire, which, again, is about plugging into EHRs to collect additional data that is not traditionally collected in the EHR. This is a core part of the Gravity specifications, but we believe it also has applicability for pragmatic research. And then, the same thing for FHIR consent comes up again in the Gravity Project relative to SDOH, but it also comes up pretty obviously in a situation for research. So, again, we believe these FHIR standards are foundational. Let’s go to the next slide.

Sorry, just one piece on FHIR. We do make some commentary relative to USCDI in the actual transmittal text that we presume that as USCDI adds data or data classes into USCDI, there will be corresponding work to make sure those data classes are incorporated into implementation guidance associated with interoperability. Otherwise, there is an implication that we are all dressed up with nowhere to go with respect to the data that is collected in USCDI, so we believe that that level of alignment with ONC is an important consideration that ONC is shepherding the implicit alignment between new data capture or new data interoperability relative to USCDI and the associated standards and implementation guidance that are the mechanisms by which that flows.

So, as a trivial example, if we are collecting additional data on sexual orientation, or gender identity, or some of the other data elements that the USCDI Task Force has contemplated, right now, there is no way for that data to flow in a standardized way via interoperability. There are pretty obvious consent mechanisms that need to be contemplated for those workflows, so our perspective is the USCDI work is the first stage in a broader standards evolution to address interoperability for USCDI data elements.

The second set of recommendations relates to common data models, and again, here is the obvious alignment with USCDI. So, USCDI really calls for data classes and some level of constraint and specification on the types of data that are interchanged. There is a model component that is associated with that data. In particular, there’s a FHIR representation of that data that exists in a treelike structure rooted at patient, and then, a variety of attribute about patient, some of those attributes having sub-attributes. And then, there is an implied relational model that is used for analytics, particularly for research, and we believe that lining all of those up is an important activity by ONC that, if done correctly and well, helps downstream actors in particular in the learning health system world better take advantage of the data that is collected clinically in order to drive research and also administrative uses.

We make pains in the recommendations to note that we are not really calling for research to be driving data capture in the EHR. What we are calling for instead is that as USCDI expands data classes, that we do the lining-up work to make sure that the data that is routinely collected in EHRs is maximally applicable to research and administrative efficiency. So, in particular, we call for ONC to continue to map USCDI at HL7
FHIR and older foundational standards, build a clear and rapid roadmap to expand USCDI, and in particular, we call out here that we contemplate that as USCDI expands, there are areas of maximal leverage for research needs and there are areas of maximal leverage for administrative needs that are win-wins for clinicians in particular relative to driving administrative activity that is currently an administrative burden. Likewise, here is our comment that we want to clarify that expanding USCDI data definitions applies both to FHIR and other ways that data flows.

And then, we also call for work with industry stakeholders to map USCDI, and I think we did not get the language updated for this version, but to a common research data model and to HL7. So, again, we think this work of alignment for research, alignment for FHIR between USCDI is a critically important activity that ONC can promulgate. I am going to pause here. David, any additional comments here? I think this is an area where the USCDI Task Force might have some comments. Steven, how do you want to handle commentary? Should we just go through it all and then open for questions at the end, or do you want to go through questions incrementally?

Steven Lane
Let’s forge ahead. We are watching for raised hands, so if anybody on the task force wants to jump in… Oh, there is a hand. There is Hans. So, we will do that now. Thanks, Hans.

Hans Buitendijk
Good morning, Arien and David. I just wanted to underscore 2A1 here. I think it is an important notion and recommendation you are making that that mapping is important. I am not sure whether that includes not only A sub V.2, but NCPDP and other standards because we ultimately need to make sure that if we agree on USCDI, that no matter how the data flows, whether it starts with V.2 and NCPDP or whatever, that it is consistently represented across the board. It is a long task and not easy, but that is ultimately where we need to keep in mind and constantly work to make it happen.

Arien Malec
That is exactly right, Hans, and we make the same recommendations in our administrative section, we make the same recommendations with regard to terminology for e-prescribing, so we are sort of deliberate as such, but it is a useful comment that we probably should be mentioning. We do mention X12 and NCPDP in the administrative section, and we mention RxNorm with respect to e-prescribing. It is a clear, obvious callout that NCPDP is a clinical interoperability mechanism with regard to e-prescribing, so, thanks for that comment.

Let’s go on to the next slide. So, spoiler alert, this is the most controversial section of our recommendations. In particular, I believe the set of controversy here is related to international cross-mapped to international standards, and particularly to procedural terminology, where representatives from the AMA have additional commentary they would like to share with us relative to how CPT is currently being used internationally. We have made recommendations as a task force that are aligned with corresponding recommendations from NCVHS. They make a set of very detailed recommendations relating to administrative terminology, we make a set of high-level policy frameworks that we recommend that ONC work with federal stakeholders to establish policy that moves terminology standards that are developed in accordance with…
And, again, there is a whole lot of regulatory and government policy geeky language here, but basically, there is a consensus process for managing terminology standards in accordance with broad recommendations that these federal advisory committees have made to the U.S. federal government that the licenses are associated with open use, the language that NCVHS used is “free or very low cost,” and are designed to address multiple needs so that we can use one and the same terminology standard across multiple contexts and that are international or cross-mapped to international standards to allow for a multiregional pool of research, again, in a context where, for example, we have emergent drug use in use of already approved compounds to treat a novel condition.

It would be useful to pool the research that is being done in the U.K. with the research that is being done in the U.S. to create a larger data set. And again, when we talk about research, we are talking about this more in the context of a learning health system than we are talking about the context of a pharma-sponsored research, for which there are already well-defined mechanisms that sort of sit outside of clinical data, so we are really contemplating the use of the EHR as a platform for emergent real-world clinical research to address a continuous learning approach, in particular, looking at approved compounds and approved therapies and seeking to optimize their use for clinical outcomes.

And then, we have a whole set of very geeky terminology recommendations. No. 1, just working with federal stakeholders to align existing terminology to terminology meeting the policy. This is consistent with a broad set of recommendations that have had that lab interoperability is being impeded because at least some labs are not using LOINC, UCUM, and SNOMED CT, so we make recommendations for alignment there. If we go to the next slide, our quite controversial point on procedural terminology, harmonization on 3D, 3E relative to aligning of SNOMED CD and ICD-11. When we finally do a transition to ICD-11, it would be nice if we did not have warring and competing terminologies.

And then, Hans, this is where we make the comment relative to RxNorm and NDC, where anybody who has done prescribing knows the pain of NDC cross-mapping to RxNorm, where you have to use something like a representative NDC code that is not actually what you are saying, but because you have to throw an NDC code on to make all the machinery work, you end up throwing some random NDC code, and it is just not ideal from an interoperability perspective. And, much of the issue here is a coordination issue between ONC and FDA relative to terminology associated with drugs. So, again, super geeky, but very important to make USCDI work, and we contemplate this, actually, as lined up with USCDI recommendations for vocabulary. Steven, I am just going to let you be the MC if we have questions.

Steven Lane
Yeah, we have a couple of hands up. Clem?

Clement McDonald
On the side of the databases or the data models, I think mostly, these were referring to research data models, not clinical data models, because FHIR kind of does the job with that, but it also accommodates research. But, in that context, I think we have to remember that only some of the models support USCDI-like vocabulary standards, and without them, it is hopeless. You cannot do the job. You have to get the vocabulary standardized in the model. So, when we think about converging on a model, we should really focus on those that are already converged on USCDI.
Secondly, there is already some nice working going on between two of the big models, OMOP and FHIR, and PCORnet is very close, and I think what we really need is money to help them move their users across to whatever becomes the new one, so that is one thing. On the vocabulary side, NCVHS did not take a specific position as is in your proposal. What they said was that they want to eliminate the difficulty on the boundary between research, clinical care, and administration, and kept it a little more open, and there are a variety of ideas behind that that were not explicitly stated. So, those were the two major things I wanted to say. Thanks.

**Arien Malec**

Thank you, and again, I think there is some misunderstanding about our procedural recommendations. All we are looking for is actually just a re-emphasis on CB, which is maybe transitioning the nation towards terminology making the policy. We are certainly not calling for one terminology system over another. None of us have the... We did not assemble the experts that are associated with calling for one terminology system over the other. We are just looking at a policy framework and suggesting that ONC work with stakeholders to apply the policy framework, which, as I noted, I think, is broadly in alignment with the NCVHS recommendations. But, we are going to hear more at the meeting this week.

**Clement McDonald**

I do not think we should focus exclusively on one country as the international source of data because in OMOP, I think there are 50 million database people from Korea, plus…

**Arien Malec**

So, Clem, I think we are saying the same thing, which is that island national standards are not that useful if we are thinking about pooled analyses, and it is useful to get to a set of standards that are international.

**Clement McDonald**

Okay, never mind. Thank you.

**Arien Malec**

Cool, thank you.

**Steven Lane**

Dan Vreeman, you have your hand up.

**Daniel Vreeman**

Yeah. Thanks for this. This was really wonderful. I had a question. In the NCVHS deliberation around the terminology vocabulary step, one of the themes was this general idea that it is nice to have one vocabulary per content area/domain/data class, if you will, rather than this eternal work of maintaining mappings and harmonizing, et cetera. I wondered if your task force had any conversation around pulling up the high-level recommendations to that effect. It comes out in some of these more specific things, but something on a higher level… I wonder if you have some comments on that.

**Arien Malec**

Thank you. That is an important comment, and this is something that Clem was really helpful on when we thought about research model work. What we were explicitly calling for was not the creation of meta-models
to cross-map between models, and lo and behold, a model for doing research, and as Clem notes, a model that is cross-mapped to USCDI. Likewise, for terminology, we are sort of at pains to talk about areas where we believe that there is already alignment toward conversions to a terminology system. There are two areas, I think, when we are talking about this that are sort of thorny, ICD-10/ICD-11 and SNOMED CT, and SNOMED CT, ICD, and CPT, which are the thorniest of these areas.

I agree with you that it would be a good idea if we aligned on a terminology. I don’t know that we have done the work to make the recommendation that we should move the nation towards a terminology. I think this sort of comes out in the cross-mapped international standards to allow multiregional tools research that our intent is to drive that direction to the extent possible. So, it is an important comment. I am certainly in alignment with the notion. Just as you know, the WHO [inaudible] AMA mega-alignment that would need to happen there may pull the earth tides out of alignment and cause massive flooding, so I think we generally agree… As Clem notes, I think we are trying to make pains to talk about a policy recommendation and make suggested gestures towards an end stage.

David McCallie
Just to comment on that, I think some of these things are long-range, idealistic goals, but there is some very pragmatic stuff that is a real-world problem today, or at least it was when I was last working on EHRs. For example, the distinction between a billing diagnosis and a problem list, and physicians being forced to pick different terminologies to describe what happened in a visit, and ONC setting rules about what can and cannot be in a problem list. It ends up really being a burden on physicians, and it generates lost information because it is too much work to recode things twice. So, those problems have been around for a long time. We ought to try to solve them.

Arien Malec
Yeah, completely agreed, and this is also some of the feedback that the research community gave, which is that at the end of the day, what gets documented in the EHR is administratively driven, and we would be able to do a better learning health system if we had clinically driven documentation for which administrative billing needs flowed out as opposed to the other way around, and as I think anybody who has been close to clinical care knows, there is what physicians need to appropriately diagnose, treat, and plan care for patients, and then there is what is needed to document in the encounter, and at the end of the day, it is useful to be able to get paid for the care you deliver, and so, the documentation needs to get driven by billing requirements. Unless there are other questions, let’s go on to the next section.

Steven Lane
I think Leslie had a comment.

Arien Malec
Fantastic.

Leslie Kelly Hall
Thanks. Hi, guys. So, one controversy that is happening related to all of this is the licensing issues around this coding of vocabularies do not require that when the data is passed, it is human readable. This becomes a problem for any consumer-based app that might be connected. How do we then see what those codes mean? So, the code might be passed on to that consumer-based app, no one can see what it means, so
they are going to call the provider, they are going to call the payer, and they will wonder what that means. This is irresponsible. So, was this addressed in your group? How can we promote this lack?

Arien Malec
Thank you for that. Again, as a little bit of meta-commentary here, that is a side effect of some of the licensing rules that we have for terminology. In the way that we license IP, you cannot put IP around copyright or data, but you can around text. And so, it is the pieces of text that are the explanatory comment or content that are the pieces that you can put IP licensing restrictions around. I think our recommendations relative to open terminologies are consistent, Leslie, with this call to make sure that everybody in the ecosystem can get access to good, human-readable content. I think we all understand that developing such content requires money. We need an appropriate sustainability framework for being able to do that, but that framework should be licensed in such a way that it is not onerous for a PHR, a patient app...I think “PHR” is so old-school that I have completely dated myself...a patient app, patient-controlled data...that that licensing is not so onerous as to effectively tax the adoption of those uses and allow for the obscure piece of letters and numbers to be translated into human-readable text.

Leslie Kelly Hall
Yeah, it is a really big deal.

David McCallie
I was just going to say it is particularly true when the vocabulary is required. You do not have the option of substituting something else. It should not be a barrier to use a required vocabulary by a consumer.

Leslie Kelly Hall
And also, if we believe that the patient access is the access to their record and the way that the record is coded, then it is a requirement of access, and it should be human-readable, and it is a justice issue that needs to be considered, and I believe a form of information blocking if we consider stakeholders need to be made ignorant by deliberate design. So, there you go. But, I appreciate your help.

Arien Malec
Thank you very much. I appreciate that. So, let's go on to health equity. We are all agreeing, and I think at this point, we just need to make sure that this alignment flows through into the full advisory committee. With respect to health equity, we re-endorse the USCDI recommendations relating to HL7 Gravity Project nomenclature and value set standards. We recommend that the ISA track interoperability priorities identified by the Gravity Project, and we note capture of SDOH and capture of individual consent. I am sure Mark Savage is on to violently disagree with these recommendations.

Mark Savage
Hear, hear.

Arien Malec
We make recommendations to make sure... So, this is a super-geeky item that somebody glossed 4C. When we discovered the issues that we had with identifying disproportionate impact of COVID-19, lack of testing, lack of vaccination, et cetera, among specific communities, when we thought about how to better address contact tracing, one of the major obstacles was that demographic information, address information,
et cetera was being captured in the EHR, but it was not flowing through to the lab, and so, there was a secondary cleanup at the lab in order to flow it through to public health, and when you look at the root cause of that issue, it ends up being that, as in many things in healthcare, we have done our lab-ordering interfaces in ways that address the administrative needs of lab ordering, but not necessarily the clinical needs of lab ordering, so the order flows through with the minimum information that is required to address the test results and the analytes, but not the information that is required to give context to those test results and analytes, and in particular, for example, age, race and ethnicity, gender, and address information.

All the information that was necessary to flow through to public health was missing, and so, these recommendations are about making sure that the deployed interoperability addresses capture and exchange of demographic and contact data for multiple purposes, including public health. Likewise, there was work that ONC had worked on with USPS on better capturing address information, and we believe that work is important for geolocation of information to address, for example, geolocated outbreaks. Here in the Bay Area, we discovered that certain ZIP codes and census tracts had a disproportionately high COVID impact, but we did not have that awareness in time to muster the appropriate public health response to those areas that are disproportionately impacted, and that is just one of these areas where better geolocation data would help us track in real time social disparities. Let’s go on to the next slide.

All right. Now we get to EHR data use for research. We support the catalog of common research data models and support existing work by stakeholders to evaluate, map, and harmonize to a common foundational research model, map to the USCDI, and cross-map to FHIR. So, as Clem notes, our callout is to create…align…support the work that stakeholders are doing to align to a common research model, but that research model is cross-mapped and aligned with USCDI and FHIR, we have common concepts, and then we note that we are not looking for a meta-model, we are looking for supporting the community in aligning towards a research model. And again, just to take pains to… When we talk about a research model in this context, we are not talking about industry-sponsored clinical research, we are talking about a learning health system, pragmatic research, recovery type, comparative effectiveness research.

Because there are a number of federal actors who are involved in such research models and the research is done in federal healthcare provider settings, we believe that the U.S. federal government can be an important arm in helping this alignment. We believe that ONC should create sections in ISA and track both the models and standards and implementation guides for better supporting the use of EHRs as a platform for pragmatic research, particularly in consent, which we have already addressed, prospective randomization enrollment and de-enrollment… So, one of my comments…one of the things we learned out of the U.K. work in recovery was that they were using the EHR as a platform and they supplemented that with a randomization framework, and it would be useful for physician organizations who wished to participate to be able to have the option of triggering randomization and enrollment events within the EHR. We believe, again, those foundational standards we already called for can be a helpful, supportive element there.

Separation of research and clinical data, terminology for pre-approval of new chemical entities and biological devices… So, in a pre-approval status, I get some opaque identifier from the investigational sponsor. My patient may be exposed to the compound or to placebo. I do not have any clean way of documenting that work in the EHR in ways that are aligned with the terminology that we already use. And
then, ONC should work with stakeholders to address other EHR opportunities relative to research. David, anything from you or any questions from the task force here before we move on?

**David McCallie**
Just a little bit of a real-world comment on the mapping question about mapping to a common research data model. As Clem mentioned earlier, we heard really interesting testimony from three different research groups that are in the process of trying to figure out how to take data out of a FHIR message and put it into their data models, and on the surface, it may sound like a simple problem, but the feedback we got from the experts was that it is anything but trivial to figure out how to properly extract data out of FHIR and put it into a more relational-like model. So, I think the lead effort in that space right now is between OMOP and FHIR, and in particular, George Hripcsak, who runs the OHDSI database work, was very positive about that process, and so, we are basically saying this is not automatic, it needs to be funded and managed to completion so that everyone can benefit from it.

**Arien Malec**
Let’s move on two more slides, I believe. All right. Second-to-lastly and not second-to-leastly, we recommend that ONC add sections to the ISA to track relevant interoperability priorities relative to the harmonization of clinical and administrative data and track items being addressed by, et cetera… So, here, again, we are looking for maximal use of captured clinical data to improve the downstream administrative processes of the U.S. healthcare system and reduce physician and patient burden related to the administrative processes of care. As I have noted to a number of people, when we think about the U.S. healthcare system, we have this dichotomy of incredibly kind, caring, highly professional, and knowledgeable clinicians and support staff who provide amazing care and an almost 180-degree view on the administrative side: A cold, uncaring, somewhat heartless, and not well-designed set of systems related to the administrative side of the U.S. healthcare system.

We believe that aligning more towards the clinical care model and using that clinical care model to drive administrative processes is the right end stage for the U.S. healthcare system. And then, we request that ONC harmonize the implied administrative data model expressed in X12 and NCPDP to USCDI, so here is another USCDI call-out, and again, we make pains to note that we are not calling for the opposite. We are not calling for the EHR and USCDI to be driven by administrative needs. In fact, what we are calling for is for the clinical needs expressed in the USCDI to be maximally useful to drive administrative burden reduction.

And then, the last one, which is definitely not least, is situational awareness. We heard from the SANER group out of HL7, which is working on standards for situational awareness. This may be a USCDI alignment issue. The data that is used in situational awareness often is not EHR data, it is HRIS data, it is supply chain management data, it is hospital bed status, ICU status, ER bed status. Oftentimes, these data are collected in systems that are not the EHR, but are still part of the machinery of providing clinical care, and so, we recommend that ONC list situational awareness interoperability priorities in the ISA.

We heard from the SANER group that the way that, for example, HHS and states align on situational awareness policy is often, as so many things in healthcare are, a little stovepipe. So, I have one thing that is associated with pandemic preparedness, another thing associated with emergency preparedness, a third thing associated with requirements under EMTALA, but they are actually foundationally exactly the same
thing, providing a higher-level dashboard that allows for situational awareness of resource limitations in a geography, and aligning on policy and aligning on funding requirements would help address activity in this area. So, we have thrown a lot at you. I am sure you all have additional comments. This was a pretty meaty set of recommendations that took a fair amount of deliberation to get to.

**Steven Lane**

Thank you so much, Arien and David, for boiling this down and presenting it to the task force. Again, as I pointed out in our public chat, I think our goal as a task force is to take these recommendations to understand that they are being transmitted directly to the ONC and to the national coordinator, so we need not reiterate those that do not apply directly to USCDI, but really to identify within this whether there are specific recommendations that would be appropriate for us to add as part of our Task 3 that relate directly to USCDI and future direction. So, as I noted in the chat, I did capture one of these and put it into our Google doc for our future consideration. I think Mark Savage may have another one that he is going to draft, but I think that if there is anything that jumps out to task force members as specific additions to what we should be including in our recommendations, we would love to hear about it, either now or, as you have had time to think about this, adding that as comments in our Google doc would be wonderful.

I will just say that certainly, what I heard in these presentations is that there may be an opportunity for us to consider recommending whole new data classes. Situational awareness is certainly one that would move USCDI in a substantially different direction. It has really been focused on core clinical data as opposed to situational awareness data, which arguably falls outside of the definition of EPHI, but that does not necessarily mean that it needs to be outside the definition of USCDI. I think also administrative data... Much work has been done on administrative data and the harmonization of that with clinical data, but is there a need for an administrative data class within USCDI? I think that is a question we should consider.

And then, also, research, obviously. There has been a lot of discussion here about research, supporting research, the interoperability of the data to support research... Are there data elements that perhaps belong within a research data class, perhaps, about enrollment or consent? There are some key issues that are needed to support research data or data interoperability to support research that may warrant inclusion. So, as the task force considers this information, think about whether there is a need for new classes, new directions, and/or new elements specific here. So, David, go right ahead.

**David McCallie**

I totally agree with that, but there may be even easier areas where it is not necessarily a new class, but it is expanding the depth of an existing class. So, for example, one of the issues that we heard when we surveyed the research community was that, particularly in the case of COVID research, ventilator settings were often not included in the data extracted from the EHR. I do not know that that is necessarily a new data class, but if that content is missing, it is an inhibition to the research.

**Steven Lane**

That is a really good point, and David, you have missed a lot of our discussions. Certainly, we as a task force encourage stakeholders to identify new classes and data elements and to submit those through the ONDEC process, and of course, as a task force, we also have that opportunity, especially here in our Phase 3 work, so, good point about ventilator settings. Is that something worth adding? If any of the task force
members want to take a stab at that, that would be a good one to add to our shared spreadsheet, which we will be considering at a future meeting.

Arien Malec
Yeah, and I would note there that it device interoperability is sort of a sub-class, where there are data that are being collected about a patient that could well be normalized to existing USCDI data classes, but are often collected in bespoke device systems and are not unified in a patient-centered way, and so, I think what David is noting is that there may well be USCDI data classes, for example, on results that are perfectly situated to collect vent settings or other results that are captured by medical devices, but where there is not the interoperability and aggregation available to drive interoperability for those elements. David, was that a helpful gloss on what you were just saying?

David McCallie
Yes.

Clement McDonald
Can I comment on that? This is Clem.

Steven Lane
Go ahead, Clem.

Clement McDonald
So, there is a whole variety of structured variables in intensive care that are also valuable, and we were pushing for this, but I do not think it was achieved, that we would get other class and structured data that is already in machines. So, that includes things like dialysis settings, ECMAL settings, and pump-assist settings, and those all would be valuable, and I think they could easily be picked off of machines. There are a lot of ICU systems. Anyway, that is enough, I guess.

Arien Malec
Absolutely, Clem. I completely agree.

David McCallie
Yeah.

Arien Malec
And, it is the same thing for wearables. Increasingly, we have patient-centered wearables; we have medical devices like CGMs that are medical devices that are collecting important contextual information about patients and patient care that, again, should have the same level of alignment and collection.

Steven Lane
Any other thoughts from the task force?

Mark Savage
Steven, it is Mark. Could I ask a broader question? I really appreciated one of the broader themes here, which was looking at other federal agencies, so I dropped some comments in the box about the FDA's
software pre-cert program and device data and... Something for us to be looking at. In two years, there is going to be a lot more happening, so do we do work now in order to be ready for that? I also appreciated the weaving in of what I will call different use cases, different ways in which the same USCDI data gets used for different purposes, like administrative, or clinical care, or research, and I just wanted to ask an open-ended question to David and Arien if there are any other what I will call use cases that you think are priorities for this task force to be considering.

I will give an example for myself. I continue to think that shared care planning and what is required to do that is important now, but even more important to try to [inaudible] [01:12:07] that in going forward. So, that is an example. It is not meant to seed your response, but that is why I am asking. Are there priority use cases in your mind that we should be thinking about?

Arien Malec
I think if we just go up one slide... So, first of all, Mark just related to maximal reuse. We make specific comment on analyte machines being maximally deployed to support, for example, resulting in ways that are standard. I think Clem rightly notes that in some cases, the way that LOINC works, you actually have to have the specimen plus the analyte machine that leads to the LOINC code, but at least, the analyte machine should be maximally situated to make that easy as opposed to completely different terminology that comes out as FDA that then is just disconnected with clinical care, so I think that is in alignment with our recommendations.

The future... The really important work that we did not get to just because we were heavily occupied with the top two priorities, which were health equity and the significant learnings out of COVID-19, are indeed chronic management plans, care plans, and chronic disease management, in addition to portal data aggregation across multiple portals, occupation, and line of work. Again, there is a little miss here on these slides, but also price transparency and data sharing between federal and commercial entities in particular, driving multiple use cases that are associated with care of veterans, care of military servicemembers, people under the care of the HIS, et cetera.

Leslie Kelly Hall
Arien, this is Leslie. I want to just follow up with that question. When you looked at future considerations, did you ever look at disease groups, particularly cancer patients, where the completeness of the record might not include the particular equipment such as diagnostic equipment and treatment equipment devices, which yet are critical in terms of care coordination? So, whether it is cancer or other disease-centric states, have you looked at that?

Arien Malec
We did not. That is definitely a really helpful comment. I think we would put that under our first priority relative to care plans and chronic disease management, and I guess cancers are one of these quasi/acute-quasi chronic disease management, but hopefully, over time, more and more cancers will become a chronic disease condition, and certainly are associated with shared decision-making and shared care planning.

Leslie Kelly Hall
And significant coordination, too.
Arien Malec
Indeed.

David McCallie
A thought that came to mind when listening to Leslie: In theory, homecare would use the same nomenclatures as more traditional locations of care, but given that in the future, homecare may be mediated through non-EHR mechanisms, homecare might be a specific area track.

Leslie Kelly Hall
Thanks, David.

Arien Malec
Yup. So, we have more than enough standards priorities to contemplate. There is always more work to be done to make the U.S. healthcare system a more patient-friendly and more interoperable, higher-quality, lower-cost system.

Leslie Kelly Hall
And, you guys are the two to help. Thank you.

Arien Malec
I appreciate it, Leslie.

Steven Lane
All right. Seeing no hands up, I will again thank Arien and David for taking the time to prepare and present this material. It is really appreciated. I trust this slide deck is or will soon be posted in the HITAC calendar for today’s meeting, and we can reference that, and again, I invite task force members to identify either a particular data class's elements or a general concept to come out of this that you think should be included in our Phase 3 work. As noted, I have tried to capture some of this myself. I actually added a row in our spreadsheet to capture this location of work, which I do not think is in there already, but if there are other items that people want to capture, that would be great.

Arien Malec
And, thank you for this alignment and for the opportunity to present.

Phase 3 Recommendations & TF Schedule/Next Meeting (01:17:12)

Steven Lane
Good. All right. We are supposed to go to public comment in about five more minutes, which we will do. We would also like to discuss with the task force, perhaps before we go there, our calendar for Phase 3. As I mentioned earlier, this meeting with the ISP Task Force is going to be followed next week with a meeting focused on public health use cases and stakeholders, so, for any of you who know of other members of the public who should be joining us for that, that would be great. There is a note here: “Early start.” So, we are going to start a bit earlier next week. Hopefully, people can accommodate that change.

We are then planning to meet…this is June… So, this lists July 20 and 27, which should already be on your calendars, but in looking at the work ahead, I think we need to continue to push ahead with a review of the
data elements on our spreadsheet as well as the general recommendations in the table that we have left for Task 3, so we are proposing adding a meeting on June 29th where we will begin that work, then taking off the first two weeks of July, so there will be no meeting the week of July 4th, which would have been on July 6th, or the following week on the 13th, then coming back together for the last two weeks of July, the 20th and 27th. On the 20th, if we can schedule either an equity-and-disparities-focused discussion or a research-focused discussion, we will do that on the 20th. Otherwise, we will plan to use that time to continue to work through our leftover Task 3 priorities.

Then, again, social determinants of health will be on the 27th of July. Remember, we really need to have our recommendations together for transmittal by the end of August, so I think the August schedule will remain open. August 10th is in the middle of HIMSS, so we probably would not meet that day, but I think it will depend on how we are doing as to whether we end up meeting the other Tuesdays in August, getting ready to move ourselves towards the HITAC presentation on September 9th. So, I think we really do need to have our Task 3 recommendations pretty well finalized by the end of August. So, we are taking off the first half of July, August remains an open question, and we will otherwise be meeting on Tuesdays. Mark, you have your hand up.

**Mark Savage**
Yes, thanks. I wondered if there had been any decision from ONC about USCDI submission date for V.3. There had been some discussion that that might move up to September from October, and thinking about whether that influences the timing of any of our work. I agree, it sounds like we have got… I am glad we are working forward and not wasting time, but just keeping that as an endpoint in mind.

**Steven Lane**
Al, any comment on that?

**Leslie Kelly Hall**
And also…

**Al Taylor**
I am here.

**Steven Lane**
So, the question was the final submission date for USCDI V.3. We had previously said as soon as that… if that date is going to be moved forward, making that clear to the community as soon as possible. Have you guys made a decision on that?

**Al Taylor**
Not the exact date yet, but we are looking at some time during the last two weeks of September.

**Steven Lane**
Okay. And, presumably, you will be sending that out with USCDI V.2 on July 8th, or do you think there is some chance we could get that out sooner?

**Al Taylor**
At the latest, it will be on the issue of V.2.

**Steven Lane**
Okay, great.

**Leslie Kelly Hall**
And then, I think, Al, you pointed out that on the 20th of July, we will see the final V.2 presentation.

**Steven Lane**
That is to say that V.2 is going to be published on July 8th. Our subsequent meeting will be the one on July 20th, and Al or others from ONC will have a chance to just give a general review of what was in V.2 and the other materials that will be published with it and respond to questions. So, yes, let’s pull up the public comment slide and go to public comment now.

**Public Comment (01:22:24)**

**Michael Berry**
Operator, can we please open the line for public comment?

**Operator**
Yes. If you would like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing *. We will pause for a brief moment to poll for comments. There are no comments at this time.

**Steven Lane**
Excellent. Thank you so much, and thank you to members of the public who join us on the phone and listen in. We really greatly value your presence and participation and welcome your comments, either in the public chat or verbally at the end there. All right. So, any questions or further thoughts regarding our plans for our Task 3 work? I just realized in looking over my notes that I wanted to capture David McCallie’s earlier comment about the high bar that is set by the Level 2 requirement of exchange between four or more vendors, so I am going to add that in as an item for us to discuss when we get back to reviewing the items in our documents.

All right. Yes, Mark and Leslie, I appreciate your comments in the public chat. Arien and David are really remarkable resources who have worked very hard for many years, and it is great to have them so involved in this work.

**Al Taylor**
Steven, before we start wrapping up, I just wanted to say something I probably should have said earlier. Even though we are shooting for the date for release of V.2, any number of things could come into play that would subject that date to change.

**Steven Lane**
Ah, interesting. So, the July 8th date… Of course, nothing about the future is completely predictable, but we appreciate that that is a goal. Great. Well, let’s go ahead and call it a day. Thank you, everyone, for your
time and attention. As always, we really appreciate the engagement and commentary. I am very excited for the remainder of our Task 3 work. I think we have a good plan, and we will see you next week with focus on public health, use cases, and data needs, so, prepare any thoughts or questions you have in that area, and also, feel free to continue to add items to both the Google doc table and the spreadsheet, as we have them posted. If anybody has lost those links, just let us know. We can send them back to you for the task force members, or maybe ONC would want to include that in the homework for people to look at that.

**Mark Savage**
That would help, thank you.

**Leslie Kelly Hall**
Yeah, that is great. Thank you, everyone.

**Steven Lane**
Have a great day.

**Michael Berry**
Thanks so much. Bye.

**Adjourn (01:26:11)**