Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE 2021 MEETING

June 3, 2021, 2:00 p.m. – 3:30 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Arien Malec	**Change Healthcare**	**Co-Chair**
David McCallie	**Individual**	**Co-Chair**
Ricky Bloomfield	Apple	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Jim Jirjis	HCA Healthcare	Member
Edward Juhn	Inland Empire Health Plan	Member
Ken Kawamoto	University of Utah Health	Member
Victor Lee	Clinical Architecture	Member
Leslie Lenert	Medical University of South Carolina	Member
Clem McDonald	National Library of Medicine	Member
Ming Jack Po	Ansible Health	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Wanda Govan-Jenkins	Office of the National Coordinator for Health Information Technology	Staff Lead
Denise Joseph	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
Great. Thank you very much and hello, everyone. I'm Mike Berry with ONC. And I'd like to welcome you back to the interoperability standards priorities task force. Today is our last meeting believe it or not in preparation of our presentation to the HITAC next week. So, I'd really like to thank Arien and David, our co-chairs, and all the task force members for their hard work over these past few months getting us to this point. So, I really appreciate it. I'm going to open up today's meeting with roll call and I'll start with our co-chairs. Arien Malec.

Arien Malec
Good morning and/or afternoon.

Michael Berry
David McCallie.

David McCallie
Present. Hello.

Michael Berry
Ricky Bloomfield.

Ricky Bloomfield
I'm here. Thanks.

Michael Berry
Cynthia Fisher. Valerie Grey. Jim Jirjis. Edward Juhn. Ken Kawamoto. Victor Lee.

Victor Lee
Present.

Michael Berry
Leslie Lenert. Clem McDonald. Jack Po. Raj Ratwani. Ram Sriram. Sasha TerMaat. And Andy Truscott.

Ram Sriram
Sorry. Ram Sriram was present.

Michael Berry
Great. Thank you. And I know some members are joining us now and I'll keep track of that for our attendance. And I'd like to turn it over to our co-chairs, Arien and David. Thank you.

Report Overview (00:01:50)

Arien Malec

So, Mike, as you said, we have made a tremendous amount of progress. When I think back to the beginning of the work group, we put together a set of prioritization input, put together a prioritization framework, prioritized our focus areas in a time of vast disruption to what our priorities normally would have been based on the work that we've done in the last task force meeting. We heard from no fewer than four different topic areas for testimony and no fewer than four different topic areas. We got to a succinct set of recommendations and formatting them in a recommendations transmittal that at least has the appearance of being coherent and useful. And, hopefully, actually, it is useful to Micky and the rest of the ONC. I keep thinking Micky and the ONC should be a pretty cool band. So, our task today is to go through the Power Point deck that we're going to put in front of the full advisory committee. It's mostly lifted straight out, it is lifted straight out, of the transmittal. So, it also gives us another chance to review the transmittal letter feedback.

And then, I trust that everybody has gotten the transmittal and has been able to do a review of it. But if we have extra time, we can go back through the transmittal and do a last editing past, last call there. We do need to wrap everything up. Mike, I think we need to send over the material on Monday or Tuesday over to the full advisory committee.

Michael Berry

Earlier is better because there is a vote. And the more they have time to review it, the more they will vote to approve.

Arien Malec

Yeah. So, it would be nice to clean this whole thing out by tomorrow so that we can send a transmittal over for the meeting on the 6th, I believe. Sorry. The meeting is on the 9th. So, it would be nice if we could send it our Monday morning or Friday afternoon for the meeting on the 9th. So, let's try to make sure that we're consistent with the goal of getting these high quality recommendations without egregious typos if possible. Let's make sure that we optimize for getting the advisory committee the final transmittal by no later than the weekend so we can send it out Monday morning and, ideally, by Friday so we can send it out Friday afternoon. With that, let's go through the recommendations. So, we go through, as we saw last time, our charge, membership, background. That includes the prioritization process that we used, the folks that we heard testimony from, and our high level recommendations. Then, we go into our full level of recommendations and then, go into future considerations, which is the step that we punted. Can we go onto the next slide?

So, we skip over this. it's our charge, how we met. Next is just who we are. I think we all know this.

David McCallie

Go back one. Oh, no. There is Clem. Okay.

Arien Malec

We do acknowledge that addition of Clem. I think everybody is in the right job.

David McCallie

Everybody double check and make sure we've got your name and your job right because there are several versions of this floating around that had dropped people as the membership waxed and waned. Looks good to me but you're responsible for your own name.

Clem McDonald

I'm okay, too. Thank you.

Draft Recommendations Review and Discussion (00:06:02)

Arien Malec

Yeah. Thanks, Clem. We do acknowledge that you exist and you have a job so that's a useful thing. Let's go onto the next slide. We did our prioritization process. We heard a bunch of testimony. Let's go to the next one. So, here we get into the meat of it. Most of the edits that we did were primarily just cleanup, making sure our high level recommendations track with our detailed recommendations, a little reordering of our high level recommendations. We were a little more nuanced in some of our topics. So, as we get to some of the areas that we had some changes on, we'll do a little voice over on what cleanup we did. So, if we go onto the next slide.

David McCallie

Arien, I want to point out and thank Wanda for doing the renumbering and putting these in the right format for the committee.

Arien Malec

Both Wanda and Cassandra have been putting a ton of work into getting to the stage that we're at here. So, we're definitely appreciative of both of them. Nothing changed here since we got all of the FHIR attributes right. So, we'll just pause there and see if there is any feedback for this item. With that, let's go onto the next. Here, we alighted the broadly disseminated research model for instances just for sake of not causing confusion. That was the main thing that we addressed. If we go onto the next slide, this is on terminology. And, again, I don't think anything has changed here. Oh, what changed here was transition the nation towards terminology meeting the policy premiums, including but not limited to licensing, working with health terminology terminators to align development policy or transition to alternate terminology standards. So, not trying to be directive about what means are appropriate but to list multiple means that could be achieved to address the policy outcomes.

So, that was the main change that we made here.

David McCallie

And we reorganized a tiny bit, I think, maybe from earlier versions of the documents in that as close to the source of the data as possible got folded into this broad topic. I think we had it as a separate numbered it in a previous draft that's up here.

Arien Malec

That's right. And we also mentioned LOINC and UCUM. Cynthia?

Cynthia Fisher

Hi, Arien. Thank you. I just have a question. And I'm not a data tech person but as we look at all of these standards and one of the things that is near and dear to my heart, it kind of comes along with my name, is price transparency in healthcare. And as we look to all of this sharing of data, the laboratory data and all across the system, I've corrected input from many tech parsers, people that are parsing the data, to show pricing from the hospitals. And we just did a study of 500 hospitals on looking at their pricing data. And from a patient perspective, in addition to all of the data that gets shared across healthcare, researchers, developers, etc., as we move to price transparency, what's been really clear is there is no standard right now on how the pricing data is being transitioned. So, as we look at imaging and the coming onboard of laboratory data, coding, and standards, what I got from pulling together a task force separately of tech innovator that are coming up with mobile apps to be able to provide great shopping applications at hospitals, and this will also then be lapsed, is they are looking for a standard trial format.

And even an example like CSB, just something that's very simple that can be implemented by 2022 when the OPPS rule is updated for the hospital price transparency. But we could see where my question is to you all on this task force. Where are we covering just a really easily implementable standard that can go across anywhere in healthcare that the machine readable pricing files in we disclosed in one standard file format. And we pick such as CSV. And the reason why we recommended CSV for the hospitals was that it is more defined in the insurance or the transparency coverage rule. So, it would be consistent so that we could rapidly get to a place where all of us could shop on our mobile phones for care anywhere and get this data. So, where do we see this in this task force and us bringing this forward that could be so easily implementable by January 1, 2022?

Arien Malec
That's a really important comment and thank you for it. I do think the terminology recommendations that we're making additionally help price transparency. And I think some of the issue historically have been cross licensing of the procedural terminology to allow for, for example, consumer use. I think we should include in our future considerations this topic. Cynthia, as you might know, I, actually, have development teams that are helping hospitals provide price transparency. And you're correct that it's catch as catch can. And there is a little bit of either people just making it up or doing shenanigans like hiding the data or making it hard to parse or removing it from the **[inaudible] [00:12:57]** fields from search and indexing. So, I don't think we have enough time to go through the deliberation here. But Cynthia, what I'd recommend is that we include that in our future item section. And then, I would note that our terminology standards section does support price transparency and consumer transparency.

Cynthia Fisher
Where does it in the points that you're putting forward for this final full committee say about pricing transparency?

Arien Malec
Sure.

Cynthia Fisher
And I applaud you for whatever efforts you are doing to help the hospitals. And what we have found, we just studied 500 hospitals, and we found that only 20 percent are compliant with the rule putting the data up doesn't mean that it's up simply. And then, the other 70 percent are providing incomplete fields in office

gating. And then, 10 percent are doing nothing of the 500 that we looked at. And so, what we see is we, actually, worked really hard and we're going to put forth standard recommendations that are easily implementable that we connected with many, many different tech companies that are trying to parse this information now. And we, basically, have 10 simple points of what can be easily feasibly put in place by January 1, 2022, in the updated rule. And my concern is if we just put it for future consideration, the thing is that this can be done and released to the marketplace along with the insurance compliance of their rule starting January 2022. So, once we have all of that information, we could have true transparency.

And for us to delay that when this could be simply presented and formatted, I think, would be really great. And it's just easy things that could be done like defining the standards chemo for disclosures with all names and data types, which comes from a directory. So, there are existing CMS directories. So, why not just have it be all written out. So, these are easily implementable standards. But I'd really like to recommend that if our committee could look at putting easily implementable standards in place timely that would be so cool.

Arien Malec
Yeah. Thank you for that. And I, actually, have zero objection to including commentary here that ONC should evaluate standards for this. My only concern is that we're, literally, at the eleventh hour. I think we're, literally, a week out from the HITAC presentation and we haven't had any deliberation on this topic.

Cynthia Fisher
Yeah. I think that's kind of curious, don't you? The rules started in January and I've gone to Micky. I've come into the HHS and I find it very curious that there is all of this obfuscation going on and I haven't heard anybody really asking for this to be implemented. *The Wall Street Journal* has reported on the obfuscation that's been intentional. So, this is so easy to, actually, get done. So, I think it's kind of curious that our committee hasn't come up with anything.

Arien Malec
Again, I would note that we went through a prioritization process and collected topic items. And I don't believe this topic came up, which I do think shame on us as a group for not considering it and contemplating it. But it, literally, didn't get into the input so it didn't get through the prioritization process.

David McCallie
We had numerous meetings where we revisited our list of prioritization items. And this, unfortunately, didn't get raised by anyone. I think it would have easily gotten traction had it been raised.

Arien Malec
I agree, yeah. Clem, I want to go to you. Your hand is raised.

Clem McDonald
Yeah. I was just going to comment on Cynthia. I, usually, agree 99 percent with her and I don't disagree. But CSV, it will be a mess just like a PDF, unless you've got some other specs that can lock it down.

Arien Malec

So, Cynthia, here is my proposal to you, which is just given the consideration that we're late in the process, if you could format a recommendation for consideration by the task force and if we can get email based approval of that recommendation today and tomorrow because we want to close out the report by Friday so we can get it out to the full committee and get email based role call on it, I have no objection to going through that process.

Cynthia Fisher

Yeah. Well, I'm happy to do that. I think it would be intriguing to say, "Look, if we could change the world of healthcare, especially in this time of crisis, the one place we could do it is lower costs and by giving the empowerment to the patients to be able to shop." And right now, it's not shoppable because of the pricing files are not in a standard format. And the plan names are being obfuscated. There are all sorts of things. But we have a 10 point way of what can be done. And quite frankly, CSV or JSON but to be consistent so that as parsers are able to pull up from the insurance rule and the hospital rule that we can, actually, get it done. I think that's the big thing. And the other thing is just to require disclosure of full payer and plan names. Just to stop gaming it and just put the actual names in place. So, these are easily doable things. And what we're finding is a lot of the data fields also are not being filled. So, there is not applicable or they just leave them empty.

And so, they're not, actually, complying with the rule. So, one is just posting the actual prices and allowing it to all be in a file. And CSV, Clem, was really because, at a minimum, anybody could put that in a common file or standard file format and just decide on one. And any tech parser can pull it up either from CSV or JSON file or whatever. But we thought CSV because then, the consumer could also look at it as well and log in and see those differences and how to be downloadable. So, I don't want to take up too much time here. But I just thank you all. And I find that this is something that we could implement very fast that would be in line with the insurance compliance.

Arien Malec

Definitely thank you for that. And as I said, my proposal to you is if you can do like on the order of the other recommendations, we can do something where we recommend that ONC create a standard for price transparency. And then, we can submit to the full task force for consideration. Let's move on to the next one. So, any other comments on what's here on the slides now? All right. Let's go on to the next one. So, more terminology standards. So, we soft pedaled, not soft pedaled, but we pointed back to our policy statement on procedural coding standards. And so, I think, again, going back to the policy recommendations that we have, there is a wide range of options that ONC in coordination with CMS could take. I don't believe we made any other changes in these recommendations. Let's go onto the next one. Go ahead, Clem.

Clem McDonald

I just worry a little bit. ONC can ensure that they're harmonized. That's going to take two-way collaborations. And they have already fallen out. But that's a strong statement that it may not be in their power or encourage or something a little softer.

Arien Malec

That's why we say there is a direct role for ONC with regard to USCDI and EHR certification and then, a coordinating role, which is coordination with CMS. I think that clearly holds the lion's share of the policy levers in this area.

Clem McDonald

No, no, I understand that. But how can those two organizations or even LNM ensure that the two things end up with a single source? They're at odds.

Arien Malec

Which one are you talking about? Are you talking about 3D, 3E, or 3F?

David McCallie

It's 3E.

Arien Malec

Yeah.

Clem McDonald

They were working together for a couple of years and then, there was a big breakout because of really strong disagreements. And one is an international organization but both of them are not in the US.

Arien Malec

I hear you.

Clem McDonald

I just think "ensure" is too strong to encourage or something like that might be a better word.

Arien Malec

Yeah. I tend to believe that we're not Estonia with no disrespect to Estonia. But we're a strong policy actor with regard to **[inaudible] [00:23:16]**, with regard to WHO. And we've got a good chunk of the world's population and, certainly, more than our fair share of healthcare expenditure. So, maybe ensure is the wrong word. If you've got an edit, I think that's fine. I do think it's useful for us to call for what we want rather than just assume that it's political and it's hard to do.

Clem McDonald

We, actually, are 62 percent of the membership fees for SNOMED. But I can't talk about it here. There are some very complex connections and barriers. Anyway, it's complicated and not easily expressed. So, I just think ensure is putting the burden that it can't be done.

Arien Malec

Maybe continue?

Clem McDonald

To encourage harmonization.

Arien Malec

Or to say continue SNOMED CT and ICD-11 harmonization?

Clem McDonald

There is no harmonization now. No, they broke up.

Arien Malec

Yeah. Okay. So, it sounds like it's a pretty important recommendation. If you've got an alternative word to ensure, I get your discomfort on ensure.

David McCallie

None of what we write is binding in any way. They're just recommendations. And I think that ensure captures the strength of our feelings about this that this should happen. So, I'm not surprised or upset if ensure is not how it's carried out. But I don't know that that means that we have to try to anticipate what is the right political word for how different agencies depend on the FACA input. We're asked to give input and we feel strongly about this.

Arien Malec

I think we're saying it would be dumb of SNOMED CT and ICD-11 were not harmonized under the nation that has adopted both SNOMED CT and ICD and will adopt ICD-11. We have a policy interest in seeing that they're harmonized. Whether they get harmonized at the end of the day is, as you say, a political question and something that requires work and requires like thinking people to work together towards a common interest. So, again, if you've got a good additional word, I don't want to soft pedal the recommendation because I think we are saying it's something we want to see happen.

Clem McDonald

How about to lead to?

Arien Malec

To lead to?

Clem McDonald

Yeah. Harmonization of SNOMED CT.

Arien Malec

Okay. Let's do some wordsmithing maybe offline from the meeting and then, submit it for the full task force consideration.

Clem McDonald

Okay.

Arien Malec

Can we go onto the next slide? Health equity, I don't think we made any changes here. No. I don't think we made any changes here. Can we go onto the next slide? Here, we did make changes. So, alighted all of the common research data models. We kept the rest of it. We're more consistent thanks to David in a common foundational research model. Harmonized to the common research data model. Those are the major changes with just more consistent language and less futile attempts to be exhaustive in enumerating existing research models.

Cynthia Fisher

This is Cynthia. I'm sorry I didn't raise my hand. Where is a standard that's upfront that the patient can opt in or opt out of having their data shared for research and clinical data? That is part of the standard.

Arien Malec

That's right. Thanks, Cynthia. So, that's in consent the first bullet of 5C and then, we also make recommendations for the FHIR based consent model that provides for patient participation and enrollment.

Cynthia Fisher

Okay. But can I raise my hand here because this is a problem?

Arien Malec

Please.

Cynthia Fisher

Part of the problem is that today, EPIC systems, for instance, at the Brigham Partners here in Boston, if you go in to sign in, they just give you a pen and you sign in on a digital form. You don't even ever get to see what you're signing. If you ask to see it, they tell you to go online. It's somewhere. So, the consent form is a hurdle. You get blank signatures today. Now, when you go and get them to print it out and you go through all of that trouble and they're giving you a hard time, it, basically, says that you consent to pay by penalty of law whatever they choose to charge you. And then, you have to give social security, all sorts of identifiable information that should not be required. They ask for credit card information. And then, on top of it, the consent for research is built into the payment on the same line of the signature. So, you can't get services. You're, actually, denied getting care if you refuse to consent on the information being shared. We've had this happen.

We've had it happen among our employees but we've also tried this with other patients that have come to us. And so, unless you just say yes, you can't go forward. And that same form is the same signature in the EPIC system, at least with the big hospitals here in Boston and down in Florida. We've looked at some down in Florida as well. So, I'm sure EPIC has this built in. So, I think when you say we've got consent that consent is automatic, yes, or else you can be denied care. I kid you not. We've had people sent away because they didn't sign that form because it's linked with your insurance information and your agreement to pay for everything.

Arien Malec

That's right. First of all, I definitely acknowledge the point that you're raising. Other places where this becomes an issue is where you've got one long master set of authorizations and contracts that, for example, obligate you to sign up for out of network billing and things of that nature. In various incarnations on the policy side, the policy committee back in the day, I don't know if the advisory committee has taken this up more formally, but the policy committee back in the day called for very intentional language around meaningful choice exactly for the reasons that you're articulating. I think it's fair to say that the industry as a whole has not moved to a meaningful choice framework. Our role from a standards perspective is to make recommendations with regard to the enabling standards that enable meaningful choice. And there is a set of policy recommendations, as I said, I think, actually, the National Coordinator already has that call for

meaningful choice with regard to data sharing and information sharing that's sensitive to the kind of sharing that's being done.

So, I absolutely acknowledge and agree with the point that you're making. And I think our role here is to make sure that we've got the places where consent and authorization can be captured in a structured and computable way and there is an accompanying policy piece that, Cynthia, I agree with you. It's probably worth doing another pass at as a full advisory committee. David, I don't know if you have any other comments here.

Cynthia Fisher
I would just throw it up that I do see that the consent is not clear. And you can't get services if you don't allow for it. You cannot be denied. And so, as a standard, I think we should make things very obvious for the patients to be able to opt in and opt out as a choice without being denied care or have it be automatic that it's linked in because this is very serious. They should have the right to opt out or opt in.

Arien Malec
Completely agree with you. And as I said, one of those is used with meaningful choice. So, actually, with meaningful choice, the opt in and opt out can be all or nothing or it can be tailored and meaningful. As I said, I think we, generally, agreed in the meaningful choice standard. Clem, I see your hand is raised.

Clem McDonald
Well, Dave was waving. Why don't you let him because he had his hand up first?

David McCallie
I just agree with what Arien said. I think this is a policy issue. It's got governing law under the common rule and under HIPAA to determine whether what those hospitals are doing is legal or not legal. It's not a standards compliance issue. It's a policy and legal issue. You can't consent away a legal right. If their behaviors need to be challenged, challenge them on the policy front. You can't fix it with a standard.

Cynthia Fisher
Yeah. But it's been built into the EPIC system the way they handle it in the majority. It's how EPIC just has unraveled it.

[Crosstalk]

Arien Malec
Fortunately, this guy named Micky Tripathi was the co-chair of the privacy and security tiger team. So, I think you'll, actually, find a receptive audience for this notion of meaningful choice with regard to how the consent and authorizations are called for. I'm going to go to Clem. And, Cynthia, I'm going to do a link to the privacy and security tiger team's recommendations or, David, if you can find it. There have been so many good tiger team recommendations back in the day. Clem, go ahead.

Clem McDonald
So, just a couple of clarifications. I don't think that if the consent says you can do something with research, it does not allow anything like invasive or randomized trials. So, I'm not sure what it is but it's not the big

deal, invasive studies. But what I wanted to point out though was that there are a couple of things. You should say we should work harmonized to the common research data model. I don't know what you're saying because there is not words in here that say what it is.

Arien Malec
Yeah. So, this is an accompanying recommendation to 5A, evaluate, develop, and harmonize to a common foundational research model, not the USCDI. And then, 5B, harmonized –

Clem McDonald
Okay. I missed that. And then, the second thing is the separation of research into clinical data. I don't know what that means. But currently, it's oil and water. They're different systems. There is a research system and I'm not sure what you're trying to get through there. The third one is the terminology for preapproved new **[inaudible] [00:36:18]**. These are drugs that haven't been approved. I thought that was already happening.

Arien Malec
Clem, the intent here and we're just pulling the recommendations out but there is accompanying text in the transmittal letter. Our intent here is not to focus on sponsored clinical research for NCE's or for Phase 4 trials for approved entities. This is for real world evidence recovery like trials and comparative effectiveness or what Les called pragmatic clinical trials that are primarily conducted using clinical data captured in EHR's but in a prospective and retrospective approach as opposed to something captured in EC systems.

Clem McDonald
You need to clarify which of these things don't have terminology. I think they all do. The FDA has a device thing that you've got to get identified. Chemical entities are located in a couple of places, including the FDA has chemicals. So, I don't think we're missing terminology. Maybe we are.

Arien Malec
So, the issue on terminology for preapproval of new chemical entities is the point that if I use RX Norm as my coding system or if I use one of the commercial medication databases as my coding system for documenting medications, I don't have a way to document in the chart exposure to a preapproval NCE.

David McCallie
Again, I think we're calling for solutions to these problems, not trying to define the specific solution. And in some cases, if it's essentially solved then, that's great. If it needs a lot of work, at least people are aware that it's part of what has to be solved in order to enable this pragmatic research.

Clem McDonald
Why don't we say we're missing, we're lacking, or we're absent?

David McCallie
Well, I think that just goes without saying. You should breathe as long as you can. I don't know.

Arien Malec

Yeah. If you read the recommendations here, we're not saying that there are gaps in each of these areas. We're saying that we recommend that ONC creates sections in the ISA and works with stakeholders to develop text and promulgate standards and implementation guidance for representation and implementation of pragmatic research studies within EHR's. And priority areas of opportunity include the following. So, this may be, Clem, to your point, as simple as here is the sections in RX Norm where NCE's are captured and where the standards for those NCE's are maintained and cross linked in the RX Norm and the NOM and the UMLS. Or it could be we got this FDA database over here and we've got RX Norm and here is the work that's going to reconcile the two of them. And we're intentionally being policy oriented as opposed to driving down to that level of detail.

Clem McDonald
I still think it's misleading. You're not going to get everything with RX Norm. Devices aren't part of it, for example.

Arien Malec
Right. Which is why we also –

Clem McDonald
There is a device code system.

Arien Malec
Using for biologics and devices. I'm going to suggest that, Clem, if you've got some wording suggestions, I think we're happy to hear it.

Clem McDonald
I think I would say where they're lacking because I think it's misleading now.

Arien Malec
What we're calling for is for this to be in the ISA.

Clem McDonald
No, I understand. But the other thing, chemical entities, in general, are not approved. And there are 50 million of them or something like that. But they're coded in a couple.

Arien Malec
Yeah. NCE is just a term of art for, as you know, preapproval of small compounds. But, again, I don't think we're saying there's a gap. I think we're saying that it's a priority area for listing. And if it's not a gap, as David mentioned, it's just an easy call out to here is how to do it, which is one of the major points of the ISA is that it's a convenient compendium of here is how to go do X.

Clem McDonald
Yeah. But why doesn't that say we're lacking or we're absent because it makes us look –

Arien Malec

Well, I don't think we want to say that it should be in the ISA that we're absent. I think we want to say it should be the ISA. The ISA is the place to go for things that are being worked on but it's also the place to go to get the current reference for what to do. Right?

Clem McDonald

Well, it makes us look ignorant.

Arien Malec

Why don't we move on? And, Clem, I don't think we want to say we're absent because, again, I think the goal of the ISA is to list we're present or absent. And, again, if you've got, for example, a point or two the cross links between FDA registration and new chemical entities and RX Norm that would be useful content to go along with this so that it's easier for –

Clem McDonald

Well, RX Norm has no pretense of going beyond drugs.

Arien Malec

Again, that's an example of the kind of challenge that we're pointing to is that if I want to document in my EHR a patient who is on a preapproval medication, I need a way to do that with that harmonized terminology. The same thing for devices. I need to make sure that the device registration and device ordering catalog that I have is inclusive both of preapproval and approved devices. Why don't we move on? Let's go on to the next slide. I do not believe we made any changes here. Let's go on to the next slide. I do not believe we made any changes here. So, I think that's it. It might be worthwhile if we have the technical means to do so to go to the transmittal level and cover the high level recommendations because, in many cases, much of the work that we did was to go over those high level recommendations and make sure they're consistent with the cross linked information. Perfect. Thank you.

So, if we go down to the bottom here, we made consistent this section to make sure that we're calling out the right FHIR standards and resources. We can go on to the next slide or next page. Same thing for B and C here. Recommendation mapping of USCDI and FHIR to this really should be a common research model instead of the common research model because we have yet to talk about the common research model. So, maybe a note for 02.
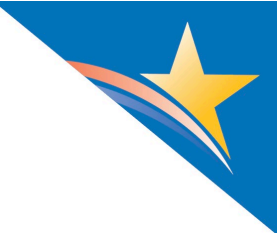
Clem McDonald

Let's slow down a little bit. I'm not sure that any of the vocabulary standards are consistent with ERB. I'm not sure exactly how it's defined. Some of the technical consensus standards have very, very meticulous checks on every step of the way. And when you get 20,000 new terms coming out in a year or 10,000 or whatever that hasn't happened in any of the vocabulary standards where everybody votes on every additional term. I'm just a little worried. I don't know for sure what's in the circular. I know it says it encourages them. I don't know how tightly it defines voluntary consensus standards.

Arien Malec

Maybe we can, actually, go pull up the circular and the language on voluntary consent.

David McCallie

But it is what it is. It's issued. It's whatever string the circular has.

Clem McDonald
I thought it mostly said that we should be supportive of consensus standards, in general. I don't recall it mentioning vocabulary standards, specifically.

[Crosstalk]

Arien Malec
We're just calling for use of voluntary consensus standards. For the language, this is an OMB Circular A119 as revised, Subsection I, "Voluntary consensus standards are standards developed or used by voluntary consensus standard bodies, both domestic and international, which are made available on a matter, which includes provisions requiring onerous irrelevant IP, have agreed to make that IP available." And in J, "Domestic or international organizations, which plan, develop, establish, or coordinate voluntary standards using agreed upon procedures. This may include nonprofit organizations, industry organizations, private standard development, professional…" "A voluntary consensus standard body observes principles such as openness, balance of interest, and due process, operates by consensus, which is characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interest." "Consensus regards that all views and objections be considered in an effort being made towards the resolution."

So, to be clear, it's not calling for a vote on every piece of terminology. It's calling for a method for dispute resolution and –

Clem McDonald
I know it well, HL7. ANSI has a really tight definition. And it's very important, in general. I think it's okay. But I'm not sure that any of the terminology activities could, literally, **[inaudible] [00:47:29]** because follow that to spec.

Arien Malec
That's right. You'd have to put your policies and procedures that are relevant for the terminology that you're working on.

Clem McDonald
Yeah. That's got motherhood. I can't be against that.

Arien Malec
It just turns out that we mostly follow it but not always and not consistently. And there is some vocabulary right now that I'm not sure I could point to the policies and procedures and balance of interest. Okay. Let's go on. We just need that section consistent. I can scroll. I've got the power. That's fantastic. We didn't make any change to 04. So, 05 and 06, we streamlined. I don't remember, David, that we did place 05 up.

David McCallie
You reordered this and I was puzzled by it. So, it's possible that it's misordered. It was a late thing between you and me and you changed the location of 04 and 06.

Arien Malec
That's right. I was trying to place 05 closer to 02.

Wanda Govan-Jenkins
This is Wanda. I, actually, reordered it based upon the ordering of the recommendations that we have at the bottom from 1 through 7.

Arien Malec
Got you. I hear you. Thank you for that. We just confusingly in this set of recommendations call for common research model. And maybe I'll sort of cross reference the recommendation 04. Thank you for that explanation. So, most of what we did here is just make this consistent with the detailed recommendations. Nothing there and nothing there. So, these are 06, 07, high level recommendations that map to the detailed recommendations. I'm going to pause. Are there any other comments? So, let me just capture the notes that I've got for what we're going to do. I think Cynthia is going to propose a streamlined recommendation relating to data files for price transparency and standards for those existing data files for organizations that are mapping to the CMS regulations. Clem is going to contemplate essential changes to the word ensure and also to see if we can better characterize what we're calling for relative to NCE and device standards. Again, just the point being that we need consistent terminology and mapping so that I can document the use of research medications in the EHR.

And then, high level recommendations, we're going to cross reference –

Clem McDonald
[Inaudible] [00:51:31] because research medications is a different thing than preapproved.

Arien Malec
Thank you for that. I do mean preapproved. I mean things that are not listed in the approved drug list, which is, usually, where the major drug vocabulary systems pull their lists from. And, again, maybe this is already solved and we've already got it and so, we're calling for something –

Clem McDonald
Well, I just want to emphasize it would be helpful to identify research medications. They may be the placebo or the drug. That's a tougher problem because they aren't anybody's. They're just local whatever. I guess they probably have internal drug company codes.

Arien Malec
They, usually, have internal drug company codes but there are some IND registration of that that allows them to be used in human research subjects.

Clem McDonald
And they're blinded so you don't know who has got it.

Arien Malec

You sometimes don't know and sometimes, you've got blinded issues. Again, all we're going for here is let's figure out some ways so that we can have standardized documentation in the EHR. So, again, cross referencing Recommendation 2 to Recommendation 4 and in the high level recommendations. I think that's it in terms of edits for these recommendations. I'll pause a few beats to see if anybody has anything burning. And then, as I said, from a procedure and work perspective, I would like to close the recommendations out by Friday so that we can disseminate them to the full HITAC for pre-read relative to the approval on Thursday. So, that would be the goal. Push comes to shove, we will absolutely get them out on Monday morning. So, if there is a reason that we're in the last minute editing and need to do it over the weekend, we will. But I prefer to get it out by Friday evening in order to give ONC the appropriate amount of time to disseminate them for the full HITAC.

And with that, I think, Cassandra, we're going to turn it over to you for public comment.

Public Comment (00:54:12)

Cassandra
Sure. Can you bring up the public comment slides, Katie? Operator, can you open the line please?

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

Arien Malec
Okay. Thank you very much. So, again, I think we've got a pretty well defined set of work items. We'd like to get this closed out by tomorrow. I want to thank the task force for a tremendous amount of work in a very, very short amount of time to put together what at least reads to me as a well done set of recommendations that should be maximally useful by ONC. And with that, I'd like to give everybody back a half an hour.

Clem McDonald
Could I get one minute more?

Arien Malec
Sure, Clem.

Clem McDonald
I think it would be useful to read over where NCVHS stands on it. They have some of the same points, I think. But I haven't seen it recently. It would be more powerful if we kind of aligned with them a little better. I don't know if we don't align with them.

Arien Malec
Yeah. The ICAD task force, even though it was done under the auspices of the HITAC, had about half the membership that was from NCVHS. And that report was read back out to NCVHS. My personal view is that ONC and HHS should start moving NCVHS and the HITAC closer together because we do make

recommendations in very similar areas. And we're the two most notable advisory committees that make advice on standards certification and vocabulary standards. But that level of coordination alignment has been done. And, Clem, I think I'd also do the call away point to read this report back out to NCVHS. I think that would be a useful coordination point. We are going to coordinate with the USCDI task force as well because I think there are a number of recommendations that we made that have some cross linkage to USCDI. But, Clem, I think that's a great call out.

Clem McDonald

Yeah. I think we are probably pretty close. I just haven't read it most recently.

Arien Malec

Cool. All right. With that, let us give ourselves officially an extra half hour. Thanks, all.

Adjourn (00:57:39)