

Transcript

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

May 20, 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	Blue Shield of California	Member
Ken Kawamoto	University of Utah Health	Member
Victor Lee	Clinical Architecture	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Ansible Health	Member
Clem McDonald	National Library of Medicine	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, and good afternoon, everybody, and welcome back to the Interoperability Standards Priorities Task Force. I am Mike Berry, I am with ONC, and we are really happy to have you joining us again today. I am going to open up our meeting and start with roll call, and I will begin with our co-chairs. David McCallie?

David McCallie

Good morning...or afternoon, I guess it is mostly.

Michael Berry

And, Arien Malec will be joining us shortly. Ricky Bloomfield?

Ricky Bloomfield

Good morning, I am here.

Michael Berry

Hello. Cynthia Fisher? Valerie Grey? Jim Jirjis?

Jim Jirjis

Present.

Michael Berry

Edward Juhn is not able to be with us today, but he will be back next week. Ken Kawamoto?

Ken Kawamoto

Good morning or afternoon.

Michael Berry

Victor Lee? Les Lenert? Clem McDonald? Jack Po?

Ming Jack Po

Here.

Michael Berry

Raj Ratwani? Ram Sriram?

Ram Sriram

Present.





Michael Berry

Sasha TerMaat?

Sasha TerMaat

Hello.

Michael Berry

Hello. And, Andy Truscott? All right. Well, thank you, everybody, and I will now turn it over to David to kick us off.

Opening Remarks (00:01:30)

David McCallie

Okay. We are hoping Arien will join us in a couple of minutes. He let us know he is going to be a few minutes late, so we are going to get started without him, but he is really the driver of the production of our transmittal letter. I think everyone will recall our plan over the next couple of meetings is to refine our transmittal letter in document format, and then, in time for the final presentation to the HITAC committee in June, we will produce a set of slides that mirror the content of the transmittal letter. Instead of trying to do both of them at the same time or going from slides to letter, we will go from letter to slides.

And, hopefully, all of you got a copy of the draft that Arien and I put together over the weekend. I would say it was mostly Arien with some editing from me. I believe we got a few comments from several of you between Monday or Tuesday, whenever it went out, and today, but we did not hear from a whole lot of people, so I am assuming that we will get more feedback as we dive in today. So, ONC, Catherine, or whoever is driving this system, I believe you have the ability to show us a PDF of the draft letter. Let's bring that up to full screen. I see Arien's visage.

Arien Malec

Howdy. I am actually on a phone as well. Apologies for that.

David McCallie

We have both visage and voice. So, Arien, we cued it up for you. Do you want to drive us through the first version of our transmittal letter?

Draft High Level Recommendations Review and Discussion (00:03:35)

Arien Malec

Absolutely. So, we have taken the PowerPoint work that we have done to date, we have taken the draft recommendations and all the feedback that we heard from you, and we have tried to pour it into this transmittal. So, the way this works is that we have a standard form for transmittals. For those who have not gone through the process before, the actual output is endorsed by the chairs of the HITAC and goes to Micky Tripathi as the national coordinator, so, structurally, this will end up being a set of recommendations from the HITAC to Micky, so we are trying to format our work in that transmittal form.

So, if we go on to the next page, which is the table of contents, and then the next page after that, we go over the background. The background outlines our charge, the legislative basis for our charge, which comes





out of a 21st Century CURES mandate to annually identify the priority uses of health information technology, identify existing standards and implementations specifications, and publish a report, so that is what we are doing. And then, we list our charge, so this really comes directly from the charges that we got from ONC, and then, I think David did a fantastic job of summarizing the hearings that we conducted. So, if we can scroll down through there, it just gave a list of the hearings and presentation materials or presentations that we received with links to the ISP Task Force calendar where all that information is available. And then, after that, we get into the actual recommendations.

I am just going to pause there and see if folks have questions on information that should be in that up-front section, and then I am going to make an editorial that the ICAD Task Force did something that I thought was really helpful. We tried to format high-level recommendations as an executive summary of the overall report, but we might want to think about formatting an executive summary. If you read only one thing, read this, and then go read the details. I am just going to pause there, and for the up-front front material, if there are any questions, comments, or feedback on how this document is structured.

David McCallie

Arien, I have control over the scroll, and you probably do too, so it may be easier if you scroll to what you want us to look at, if you have that.

Arien Malec

Oh, thank you.

David McCallie

Or tell me what you want me to scroll to, either way, but I think the presenters may have direct control.

Arien Malec

Perfect, okay. So, one thing that we did not cover as I am looking over this is our prioritization process. We probably should cover our Delphi prioritization process and how we went about choosing our priority orders. If I am thinking about somebody reading this who has not read our deliberations, did we just come up with a random set of recommendations? What did we end up doing? That might be useful. As I said, I think we should have a perspective about whether the high-level recommendations should get moved up into an executive summary section, and then we go into detailed recommendations, but other feedback from the task force in terms of things we could do to make this flow easier to read and more understandable by Micky or other ONC staff, by the task force as a group, or by future readers. Cool.

Seeing no hands, I will editorialize that I sometimes go back to standards committee or policy committee or HITAC recommendations, and I am usually really impressed that those recommendations got some things done that were really well done, and it is useful if you can pick the thing up, and pretend that you have not seen this in five years, and pick the thing up, and you can actually tell what it was you were trying to go do.

All right. So, now, we go through the high-level recommendations section, and here, we summarize our detailed recommendations with a set of nine high-level recommendations, and as I said, I think this could go into an executive summary, but understanding that we are going to have a more detailed set of recommendations that are the nuts and bolts, it is useful to be able to pull some of the stuff out at a high





level and make sure that somebody can read one or two pages and really get the gist of what it is that we are looking for.

So, Recommendation No. 1 is to advance standards implementation guiding in these four foundational areas of FHIR-based standards: CDS Hooks, FHIR subscriptions, FHIR questionnaires, and FHIR consent. No. 2, we recommend that ONC work other federal stakeholders to move the nation toward open and/or freely available terminology standards that are designed to address multiple needs: Clinical care, research, and administrative. And, in areas where proprietary code sets are currently required, we recommend that ONC work with NLM and other federal stakeholders to either license codes nationally or transition the nation toward more open terminology.

Our third recommendation is on source normalization, so we recommend that, in conjunction with other federal stakeholders, ONC promulgate policy to ensure that data are captured in a normalized way as early to source as possible and that federal stakeholders converge on common technology standards where there is current divergence. Here is an area where we went into significant levels of detail in the detailed recommendations. We make recommendations on supporting the current work to align toward a common research model, we make recommendations on developing key standards and implementation guidance to enable clinical research using EHRs, and we make recommendations on mapping USCDI and FHIR to the common research model.

So, those are research recommendations. We make recommendations on using the Da Vinci standards, on supporting deployment of published standards implementation guidance that prioritize interoperability, key demographic, and social determinant data, and then, we make recommendations on burden reduction by advancing the recommendations to the ICAD Task Force and advancing next-generation administrative standards via the ISA. So, that is our high-level recommendation. I will pause here to see if you were to read only one page of text, would this be an adequate summary of our overall deliberations? Clearly, I think this is not a question that is 100% answerable in the moment, but it will serve as a little bit of the homework assignment, but that is the question I would like to ask the task force. Let's make sure that we get to a good, adequate, executive-level summary of our recommendations and deliberations. So, Clem has his hand up.

Clement McDonald

Yeah, it regards to your second overall one, and I talked briefly with David about this. I think we should shoot higher and say the vocabulary should be open and not bring in "freely available" because that is ill-defined, first of all. Free for whom? For everybody? And, how? Let's see what we can get to rather than... I think the second word is a little wishy-washy, and it is not well-defined.

Arien Malec

Sorry, the second word of...?

Clement McDonald

The phrase "freely available."

Arien Malec

Oh, "freely available." So, Clem, your vote would be to stick with "open."





Clement McDonald

We are not going to get everything we want anyway, but let's shoot high and get what we can get.

Arien Malec

Fair point. I think the set of... Maybe we reserve the suggestion that NLM work on licensure as a fallback approach, which could go into the detailed recommendations.

Clement McDonald

Yeah. But, I am from NLM, and even with that one, I think it would be better to say "government agency" or something than to target NLM. Firstly, it happens... Anyway, I should not say too much, they are fussing about funding for some things...

Arien Malec

Got it, fair point. So, rather than call out NLM as the agency... I am thinking about how, historically, NLM has done the nation a service [inaudible – crosstalk] [00:14:17].

Clement McDonald

They still might do it, but it would reduce our targets if we focus on them.

Arien Malec

Fair point. So, let me just see if I can summarize your feedback, Clem. No. 1, we should observe that we have historically done the nation a service by adopting open standards for terminology and by building national licensing of those standards, national payment for those standards, or national funding for those standards as a way of addressing the standards vocabulary maintenance sustainability issue. That has been a good working model.

Clement McDonald

I like that. Did you capture what you just said?

Arien Malec

The transcribers did. I have a limited ability sometimes to remember what it is I said out of my mouth at the moment that I said it, but that sounds like it captures the gist of what you are looking for.

Clement McDonald

Yeah, perfect.

David McCallie

Can I ask a question, Clem? This is David. When you say "open," maybe this is a little too detailed, but I just want to make sure I understand what "open" means in your mind. These vocabularies may, in fact, need to have a rigorous control apparatus so that you do not just generate codes willy-nilly, and that someone goes and makes sure that code is, in fact, a new code and makes sense, et cetera. Is that consistent with your view of "open"? Can it be well-controlled and open at the same time?

Clement McDonald





Yeah, it is tricky. There is a group that has agitated for open vocabulary, and I tried to get a document from them that would specify it, and it has not been written yet, you are right, but I think “open” means that people can submit to it freely, but not necessarily get the codes in because you need that control. You have a good point, but people seem to have a feel for what it is, and I will try to still get a real definition out of this group. There are about six or eight people, including NCI and Melissa Handell, who is a big vocabulary person... But, anyway, I did not get one. We do not have it written.

David McCallie

We actually heard from Melissa, but I do not know if you were on that session. She spoke. She is superb.

Clement McDonald

She is intense. She is sort of a force of nature.

David McCallie

Yeah, I got that sense. The concern I have is producing something like SNOMED, for example, which I think would be a good example of a well-managed and highly controlled nomenclature, is expensive in the sense that it takes a lot of somebody’s time, more than a few somebodies, probably a dozen or more, and if we capture the notion of “open,” it seems to me that what “open” means is that it is openly available. No one has to jump through a hurdle to use it, but it does not necessarily mean that it is free.

Clement McDonald

No, it is more than that. It is not just available. It is not controlled that tightly that other parties...

Arien Malec

We should probably fall back on the executive order text of standards organization, which... There is some formal language around this that captures the intent. There are actually two issues that are both necessary for the level of innovation that we are looking for in source terminology normalization that we are looking for. One is the level of open standards, and again, there is terminology in the executive order that is the correct terminology that our ONC folks can help us dig up, which involves the process by which the terminology is maintained. The second is the national licensure that makes use of the terminology freely available by everybody in the U.S.

David McCallie

This may be a place where our executive summary has the high-level notion without a whole level of detail, such as the use of the term “open,” but our detailed recommendations can talk about stepping stones to reduce licensing cost or eliminate licensing cost and things like that. I am not sure we are going to solve the problem in our transmittal letter.

Clement McDonald

Yeah, that is a good point.

Arien Malec

Agreed. Okay, let’s move on. This is an important conversation. Any other feedback in terms of if you read just this one thing, would you get a good sense for what our recommendations were?





Clement McDonald

Well, Arien, I have to say you write pretty well.

Arien Malec

Thank you.

Clement McDonald

I was really impressed by the longer document. I still have a couple quibbles about it, but it was smooth and clear.

Arien Malec

No doubt. One of my dark traits is the ability to nail things down in ways that at least people can actively disagree with, and I definitely appreciate sometimes that I can write in ways that are maybe a little too nuanced, trying to fit too much into a few words, and I really appreciate it when people come and tear the words apart, so I think this conversation has been fantastic.

David McCallie

That is me. I am his copy editor.

Arien Malec

Way more than that.

Clement McDonald

I gave a few comments to David on the phone, and he said, “No, that goes to Arien.”

David McCallie

Yeah, well, it starts with Arien. Arien, we have an observation that No. 6 is poorly worded, and I agree. It looks like we left out a word or two, so make a note of that one.

Arien Malec

Perfect, thank you.

David McCallie

It sounds like the start of the Constitution or something. “We the people, in order to...”

Arien Malec

I tried to highlight the “why” before the “what,” but definitely, there will be areas where there is nuance that is missing. All right, let’s go on to the next section, and I would definitely look A). For volunteers to help us craft the executive summary, and B). To have folks do copy editing, read for clarity, and read for flat-out misunderstanding things or completely garbling things, so I appreciate all the input. All right, let’s go on to the next section, which is lists of specific recommendations.

Clement McDonald





Could I just clarify one more thing? I am sorry, I did not put my hand up. But, on Item 7, I just wanted to be sure. I was not aware that the Gravity standards were strictly Da Vinci. You probably know, Arien, but I thought they came separately from Da Vinci.

David McCallie

That is correct. It is HL7, not Da Vinci.

Arien Malec

That is right. It was incubated through Da Vinci, and it is now graduated to an HL7 group. That is absolutely correct. That is a great callout. Thank you. Okeydoke. Let's go on to the next section, "Foundational standard: FHIR." This mostly replicates the summary. I am not sure there is a lot of additional detail beyond the summary here, just maybe a few more words. Sasha had a good set of feedback here where she pointed out that CDS Hooks is the most mature of these four, and so, we probably should put some color in our recommendations or findings relative to how CDS Hooks has been under development the longest and is the most ready, and the other three require more support for development, testing, production, and use for broader adoption, so that might be a useful comment back to ONC, but again, the sense of the task force is that these four standards are foundational in the sense that getting national adoption here would help us solve a wide range of downstream problems. I will pause there.

Sasha TerMaat

This is Sasha. Arien, great summary of my email. I agree, that would be a helpful way to clarify it for ONC in our feedback. One question that came up internally as I was seeking some additional feedback here: There was some ambiguity as to what FHIR consent work we were referring to. Is there a specific implementation guide that this recommendation is centered around, just to alleviate ambiguity?

Arien Malec

That is a great question, and I am not going to be the expert here. I looked at the FHIR consent directive, or the FHIR consent resource, which includes a privacy consent directive, medical treatment consent directive, research consent directive, and advance care directive, so I was looking at the consent resource, which I think is called "consent."

Sasha TerMaat

I think it is just called "consent." I stuck a link in the chat. Is that what we are both looking at?

Arien Malec

Let me just look at the link in the chat. That is exactly what we are both looking at. So, that is an oopsie on my part, and that really should be "FHIR consent resource" as the thing that we are looking at.

David McCallie

And, if I can add, the place where it got the most airtime in our deliberations was in passing, but nonetheless importantly in passing, with the Gravity discussion and the need to capture permission to share social determinants with institutions in the community that could help someone who maybe needs some assistance. So, I think that is where it got surfaced as an important capability that would support the health equity, so we could maybe tie that link in here.





Arien Malec

That is right. It has an obvious application for pragmatic research in the sense that if you are performing prospective research with randomization, depending on IRB, you also very likely need to capture additive consent, and it would be useful to be able to capture the output of that more formally. Clem has his hand up.

Clement McDonald

Oh, no, sorry, I did not have my hand up. I will take it down.

Arien Malec

Thank you. Sasha, does that demystify your confusion, which was entirely mine?

Sasha TerMaat

Yes, that is helpful. Thank you.

Arien Malec

Perfect, thank you. All right. Let's go... Clem's hand is going up and down.

Clement McDonald

I mean it to be up now. It is on this maturity level. I think it would be worth looking at what they are formally calling maturity levels of these four things before we make a hard decision. I understood the questionnaire might go to normative this summer, but I have heard that before. I do not know how to find Hooks. Is it a resource to find this maturity?

Arien Malec

David, I wonder if you know offhand where CDS Hooks lives in the FHIR hierarchy and where it lives in the Argonaut hierarchy, or Sasha, you may know offhand.

David McCallie

Not currently. I have not looked at it in more than a year, so it could have moved around. It is an implementation guide that pulls in standards other than just FHIR. It is a higher-level construct because it uses OAuth in a variety of non-HL7 capabilities to deliver an overall service. But, it has been balloted through HL7 for sure, so the core ID gets an HL7 process associated with it. At least, that is the way it was...

Arien Malec

This has been demystified in chat. Ken placed the HL7 Hook to CDS Hooks in the chat. It is CDS-Hooks.HL7.org, and Sasha re-endorsed that, so we want to make sure that we are pointing out to that. It is HL7 CDS Hooks, it is a published specification for clinical decision support, and as David notes, it is an implementation guide that operates over multiple HL7 resources.

Sasha TerMaat

In this section, we may want to just footnote each of the standards referenced to alleviate ambiguity.

Arien Malec





Yup, thank you.

Clement McDonald

And, the other thing... Which of them are supported from the consortium of informatic systems that I think you are involved with, Arien, that is going forward and including things that are a subset of FHIR? I am blanking on the name.

David McCallie

Argonaut?

Clement McDonald

Yeah. Which ones are in Argonaut? Because I think that gives it a little more strength.

Arien Malec

Yeah, as Ken notes, the actual HL7 CDS Hooks provides hook maturity. So, there is the hook spec itself, which is STU, and then, there are hook maturity items that are of various levels of hook maturity, so those are the places where you can place a CDS workflow into an EHR.

Clement McDonald

But, is consent an Argonaut...?

Arien Malec

Consent is in HL7 at a Level 2 level of maturity. To Sasha's point, we can make sure that we put in... So, it is trial use, so we will make sure that we put in links to the actual implementation guides or resource guides, as well as making appropriate overall comments on maturity.

David McCallie

Arien, a broader comment: I think the way the ISA works is to categorize interoperability prioritize, and then, underneath a priority to catalogue relevant standards, some of which may be at different maturities. I think we need to make sure that our wording here, which I think is pretty close, identifies the priority that we are trying to address by nominating a particular standard. Does that make sense?

Arien Malec

That makes sense exactly. I think I tried to capture this. We tried to list the price... Oh, you are right, thank you. So, it is in the recommendation text where I got this wrong. Great point, and let's make sure that we address that.

David McCallie

Yeah, and it is just a subtlety, but it allows for the notion that the standard could fail to become adopted, but the priority still exists.

Arien Malec

Right, or in our quantum computing standards, we can take this new priority and address it through superposition of [inaudible] [00:32:38]. Cool.





David McCallie

Supremacy...our supremacy.

Arien Malec

Exactly. We will move on from this section. We got a lot of great feedback here. So, “Foundational standards on common data models.” Again, in these sections, we tried to separate findings from recommendations, so our main findings were that the deployed EHR base in the U.S. was used for retrospective research supporting therapy and treatment planning. There was a lot of work required, and most of that work was based on lossy normalization of technology in extraction of clinical events that often required multiple remappings that were sometimes lossy, and that bulk FHIR, while potentially useful for research extracts, required remappings from the person-centered implied graphs of FHIR to the more relational-style modeling. Those were findings. Clem, I got your hand, so I will get to you as soon as I verbally cover the overview and recommendations.

Our recommendations are to continue to map USCDI to HL7 FHIR, build a roadmap, which I think we will do in conjunction with our USCDI work group colleagues, to expand USCDI and incorporate research and administrative needs. We put in the really important point that Clem brought up last time that by this, we are not asking for clinical capture or administrative data capture to be the primary driver for EHR workflows, but rather to make sure that EHR clinical capture has maximal impact on research and administrative needs. We recommend that ONC work with industry stakeholders to map USCDI to broadly disseminate research data models, and we make more specific recommendations on vocabulary and more specific recommendations on EHR data use and administrative burden reduction. Now, with that summarized, Clem, over to you.

Clement McDonald

I am not sure I really do have a comment. I was responding to the first draft. It is different now in the recommendations. I do not see anything... Let’s see. Yeah, you are just talking about USCDI. Previously, I was worried we were going to end up with a war between common data models and the fifth version.

Arien Malec

Yeah. [Inaudible – crosstalk] [00:35:21] as well... Les was particularly vocal about this as well. You will see the clarification specifically in that area in the research section, and then, we made pains not to overly wave a red flag on OMOP as the surviving standards, just to let the work that is going on right now be better supported, and Clem, we took a lot of your feedback in terms of this work is going on right now; what is needed is funding, so let’s make sure that we resource the alignment the appropriate way.

Clement McDonald

Right. Okay, perfect.

Arien Malec

Any other comments on this section?

David McCallie

Arien, I have a question that runs the risk of opening a rabbit hole that we do not want to go down, but did we have any discussion about the broader EHR export capabilities that go beyond the bulk FHIR, the





required EHR dump? Is there any need to mention the possibilities of working towards making that standards-based, or is that just way out of scope? I do not remember if we talked about it.

Arien Malec

We do not [inaudible – crosstalk] [00:36:46] about it. I think the implied assumption was that bulk FHIR already had a track for certification and requirement that we did not need to wade in. Again, they were dangerous implied assumptions, so I do not know if there is anybody in the task force who believes that we should say something different there.

Clement McDonald

Well, I have been following David's lead. The current specification is really blah, being that you have to go export it, but who knows how? It would not hurt to say it might not be horrible to get that more standardized. I do not know, Dave. You brought it up.

David McCallie

I think that everyone's hope, and, I believe, the intent behind the requirement, is that bulk FHIR would be the way this is accomplished once everybody is required to support it in later 2021 or whatever the date is, but in the meantime, it is raw data dumps from the various vendors and other sources that are actually being used, and either we focus and say the future should make sure that bulk FHIR is sufficient to address the needs of the research community, which may be the way to do it. That admits that right now, it is not.

Clement McDonald

The dump was not intended just for research.

David McCallie

No, it was not, but I think that is essentially what happens today. Every vendor has a different way of doing it, some more organized than other, but it is not bulk FHIR that is being used.

Arien Malec

Right, but we do have a track to normalize to bulk FHIR. I thought I heard Sasha trying to elucidate this topic.

Sasha TerMaat

Yes. So, when we have talked about this in the EHR trade association, EHRA, we have talked about the vision that expansion of USCDI over time would obviously then cover an increasing amount of all-electronic health information and aspirationally eclipse the need for the more generic EHI export because we would have standards we would come to consensus on for all that data. But, David, when you ask if we should suggest standardizing the EHI export, in advance of coming to consensus for FHIR standards for all electronic health information, what would standardizing EHI export look like?

Arien Malec

I think we have answered our question here.

David McCallie





Well, let me just respond to Sasha particularly because once I said something and realized what I said, I now think it through again, and I think what my intent would be is to say that the expansion of USCDI and the expansion of bulk FHIR would address the research community so that there is no need to rely on unformatted or unstandardized EHR dumps. Does that resonate okay with you, Sasha?

Arien Malec

What it sounds like you should say... Go ahead, Sasha.

Sasha TerMaat

I agree. I think that makes sense. We would want to factor in the research community's feedback to the expansion of USCDI to make sure that their needs are considered along with the other stakeholder groups that are feeding into USCDI expansion.

Arien Malec

So, it sounds like it would be a helpful comment in the recommendations or in the finding section to note that we assume that expansion of USCDI is accompanied by corresponding expansion of FHIR export capabilities that will enable broad support of those export capabilities for research purposes. That is a core assumption...

Sasha TerMaat

I think that is built into the way bulk FHIR is in certification today, the way it is sort of [inaudible] [00:41:05] that, so I think that is the current state, but yes.

Arien Malec

Okay, good. Clem?

Clement McDonald

I picture USCDI as specifying code systems, and that does not get us all the way there. In fact, it is specification for three different structures in HL7, so I think it also needs some specification on how the structure is, and of course, bulk FHIR would do it, but I am not trying to pick an approach. I just do not think it is saying USCDI is going to cover it all [inaudible – crosstalk] [00:41:41] codes.

Arien Malec

Yeah. USCDI is typically conceptualized as data classes and accompanying vocabulary standards, which is not quite a model, and certainly is not a representational construct. So, we typically think about USCDI as saying the “what” relative to constraints on interoperability or requirements for interoperability, and then we think about HL7 or CDA implementation guidance as the representational “how.” So, USCDI is more than just the vocabulary standards because it does describe data classes and, in effect, fields in those data classes.

Clement McDonald

Not very well, because we are always fussing about taking one field out of the registration record, and that is USCDI. Anyway, I do not want to pursue it, but I do not think it is enough to say the growth of USCDI will solve the export problem.





Arien Malec

Yeah. I think the statement that we are making is as USCDI expands through more data classes, those data classes will be represented in bulk FHIR export, and at least with respect to that expansion of data classes, that data will be more available for research needs. Again, it does not predispose that you will not need to go back and do some custom work on the side.

David McCallie

It is a good question to bring up with USCDI Task Force. Arien, I know you had talked about having a joint meeting with them at some point to go over our recommendations. I think this question is important enough if we have that meeting.

Arien Malec

Yeah. I do not know if we are going to be able to get a meeting before closing the recommendations, but certainly, it will be one of the takeaways for after. Okay, let's go on to the next section, on terminology, the most fun section. So, I think we have already taken note of being explicit about what we are asking for, making sure that we have a distinction between "open" in terms of process and "freely available" in terms of national licensing as a goal that is across all needs. So, that is recommendation No. 1, and then we go through various recommendations for LOINC coding. I think there was a comment we got through email, which may have come from Clem or Sasha, though my memory is all scrambled right now, on how this issue also applies to radiology and other kinds of imaging reporting.

Sasha TerMaat

That was me, and I retract the comment. We were internally swirling, and I mistook something that was actually about ordering, which I know we are not addressing with this recommendation, and applied it here. So, I retract my comment on LOINC.

Arien Malec

Yeah. I totally acknowledge that point, which is right on, which is that the orderable catalogue needs to accompany both laboratory and radiology orderables. We recommend that ONC, through conjunction and coordination with CMS, harmonize procedural coding standards. This is one that is worth people looking at and making sure that we have worded appropriately for clarity. This is not intended to be an anti-X statement, but a pro-Y statement, if that makes sense. So, we are not trying to say that terminology standard X is bad, we are trying to say that approach Y is good, and it would be desirable policy for current terminology standard X to be compliant with policy Y. That is...

Clement McDonald

Could I ask...?

Arien Malec

Go ahead.

Clement McDonald

[Inaudible – crosstalk] [00:46:22] a little bit. I cannot quite read it, and it is not the same as the draft.

Arien Malec





This is one that we tried to wordsmith appropriately so that we are not saying X is bad, but we are saying Y is good.

Clement McDonald

But, I cannot quite see the text.

Arien Malec

Oh, okay. It is split over. So, we recommend that ONC, directly and through coordination with CMS, harmonize procedural coding standards to open/freely available, which we will replace by our chosen language for what we intend, and again, cross-map to international standards. Again, we will cross-map that with the controlling policy statement. And then, we note that that outcome could be done by licensing existing coding standards for national use and cross-mapping to international standards, or could be done by building a roadmap for transition.

David McCallie

We would probably want to qualify the word “licensing” there to say “broad licensing” or something...

Arien Malec

Yeah. Again, I think what we want to do is make sure our policy statement is really clearly written, and then refer back to our policy statement in this bullet. And again, just for purpose of clarity, we are not saying to blow up CPT-4 as an example, we are saying it would be a good idea if ONC and other federal stakeholders, including CMS, could work with terminology developers to transition terminology standards to follow the policy arms that we have outlined. Clem, go ahead.

Clement McDonald

Well, there are a couple things. The word “licensing...” I do not know if LOINC literally... I guess there is a license, but no one has... Maybe there is licensing. But, there is some other word... There is no mention of the unit standard, which I think was supported in the other committee, because if you do not have something on units, researchers cannot use the numbers very well, and we are looking at a lot of units in two or three different huge systems, and the inventiveness of unit strings is beyond belief.

Arien Malec

You are referring to UCUM standardization, which... I forget the status of UCUM. I think UCUM is already incorporated in LOINC, so it is already included by reference in USCDI.

David McCallie

Well, they are going to incorporate everything, but importantly, it is in all the standards. It is in HL7; it is in FHIR. That is the way it gets incorporated [inaudible] [00:49:26] reference. So, that is one. And, there is another HL7 standard that might be worth mentioning with it which specifies the mappings from instrument codes to LOINC and SNOMED when there is a quotable answer, and that actually is where all the new COVID tests showed up within a couple days during that period. So, I am just mentioning some of those. I would also mention ICD-11, which is certain to become the mortality standard, and there is a lot of support to make it the morbidity standard. People should be aware of it, anyway. ICD-10 has got big problems. ICD-11 has got far fewer problems, and for research, it is going to be adopted almost everywhere.





Arien Malec

Got it. I think we are good on ICD-11 unless there are other things we want to say in this ICD-11 paragraph. What I am hearing you say is that in this source coding issue... I am having some artifacts caused by Adobe, but in the source coding, we want to note not just LOINC, but UCUM.

Clement McDonald

We should probably name names: SNOMED too.

Arien Malec

That is right. SNOMED for microbiology. Got it. Thank you. Okay. And then, the last one is... Let's continue to harmonize NDC to RxNorm, treating RxNorm as a source terminology, and make sure that we use RxNorm as a single source across all these workflows, which I think... As is often the case, the major obstacle here is agencies within HHS lining up their work. All right.

Clement McDonald

Well, could we throw...? FDA is sort of... There are two issues. In terms of focus on international standards, they use the WHO's drug codes, which is an international standard too. I am safe with what you are saying about RxNorm, but I just want to make sure we are not colliding in our thinking about international standards. And then, the other one is whether we could encourage FDA to use RxNorm to allow its use.

Arien Malec

That is what we are saying here. Correct me if I am wrong, Clem, but I think the WHO issue is related to generics, where there is a WHO terminology for standardization of generics and for compounds, and that is where the international alignment comes into place, rather than on the normalization of that to U.S. brands.

Clement McDonald

Well, RxNorm is for generics too. I do not want to make too much of a point of it, but it would be nice to nudge the FDA, which is a U.S. organization...

Arien Malec

That is right. Just to draw that thread out, Clem, FDA already does work to make sure that we name the generic names in accordance with international standards to make sure that we do not have the acetaminophen/paracetamol confusion that we have for legacy stuff, and that naming process is also the right process for aligning on RxNorm. There is also lot numbering, lot tracking, and all that good stuff that happens at the NDC level that we want to map over to RxNorm.

Clement McDonald

Okay.

Arien Malec

Cool. Thank you. All right. That is that section. That is a fun section. It is a section with a lot of detail. Gravity: So, that was the one task force meeting that I missed, so I sort of waved hands on findings on Gravity, so I am looking for volunteers to help out. There is somebody on the Public Health Data Systems Task Force, I think the representative from Washington state, who does not believe that the CDC terminology is





appropriate for race and ethnicity, and I have been trying to capture information on why that person does not believe it. I think I will do some private correspondence with Bryant. But, I think we are stating that the USCDI terminologies for sex, race, ethnicity, and address...

So, I think race/ethnicity was a masterful piece of work that the standards committee did back in the day of saying the minimum is OMB codes mapped to CDC codes as the controlling terminology, so that is a top-level hierarchy that allows for coding at multiple levels. For example, CDC does a nice job of deconstructing those top levels down to the national race and ethnicity roots that allow for, for example, tracking a disease outbreak to people in the Hmong community as opposed to the broad-level "Asian" classification. So, as I said, I think there is somebody out there who thinks that that code set is inadequate, but we are saying that it is adequate. The problem is that the data does not flow through interoperability in the way that it should, and in the meeting this morning, Clem and I were pointing out the issue that in lab ordering, oftentimes, what happens is it is just the analyte information that flows, or in other cases, for commercial labs, it is analyte and insurance information that flows, and we are not actually using a spec like LOI and flowing through the contact and demographic information.

So, I think what we are calling for here is to make sure that we get it captured and it is actually flowing appropriately downstream so that we can monitor data for disparities. So, I am going to pause there. Those are our two major recommendations, and our last one is continued harmonization on patient address, and I missed the bolding for "The task force recommends" on the second recommendation. Clem? Clem, your hand is up. I do not know if you are on mute.

Clement McDonald

Oh, I am on mute. If we could put in "link and URLs" whenever we name these things. So, the thing you are talking about with CDC is in SINDAD, and things... Then, that would make it more... People who want to understand it could be built easier, and I do not think it costs much in space if you just put a link underneath the words.

Arien Malec

For this one, I would point over to USCDI that cross-references the SINDAD's CDC standard.

Clement McDonald

One of the problems with people criticizing the CDC standards is they do not look below the top five. It goes all the way down to Indian tribes. It has 30 Indian tribes in it.

Arien Malec

That is exactly my point. If you stop at the OMB categories, I think you might have a point, but if you actually look at the full terminology set in CDC, it is hard to see where you have a concern, so I wonder whether Bryant in the state of Washington is concerned. Anyway, let's bold this, let's make sure we have the cross-link over, and otherwise, any other feedback here? And then, I would love for volunteers who were actually at the Gravity hearing to put in the "findings" section.

Sasha TerMaat

This is Sasha. I just have a question. The top paragraph says, "USCDI terminology with proposed addition for gender, identity, and sexual preferences." When we make our recommendation below to achieve





demographic information, are we encompassing the additions of gender identity and sexual preferences, which I am not sure are part of all the standards, or do we mean just race, ethnicity, and address?

Arien Malec

That is a good point. I think we are saying that when those fields are standardized, they should also flow.

Sasha TerMaat

Okay. That makes sense to me, and I am supportive. Maybe we could adjust the wording so that there is not ambiguity.

Arien Malec

I appreciate it.

David McCallie

What would flow when fully standardized? I am asking privacy questions.

Arien Malec

The USCDI Task Force made a recommendation to the national coordinator that the Gravity standards should be included in USCDI and that we should add terminology sets for gender identity and sexual preference, which, if you remember, David, back in the day, we had a good, long discussion in the standards committee and made the same recommendations to the national coordinator at the time, and so, I think we are saying with respect to those adds, when they are adopted by USCDI, they also should be included in implementation guides for interoperability such that they flow at that time. I think Sasha is rightly worried about some of the implications that it should flow, but we have no interoperability space for it to flow.

David McCallie

But, to whom is some of those flowing? I am sensitive to the privacy concerns here, which may not be safe in interchangeable data.

Arien Malec

Yeah. In other cases, we have looked at “minimum necessary” as the controlling language here, and that is a particularly thorny topic, so maybe we should say “where appropriate.”

David McCallie

For public health purposes, the address information that is currently often missing is clearly something that should not be missing, but I am not sure sexual preference and gender identity is something that should automatically be assumed to flow.

Arien Malec

It depends, right? It clearly depends.

David McCallie

Does it not depend on what the person wants?

Arien Malec





It also depends on what the person wants, that is exactly right, so these are all particularly thorny issues, and I am thinking that maybe the language of “where appropriate” would be something that we could add here. Clem, go ahead.

Clement McDonald

One of the thorny parts is most of the interest in adding these data elements comes from that same community that has those data elements, and yet, I can expect there is a lot of sensitivity to that stuff being passed around, so “thorny” is maybe not strong enough of a word.

Arien Malec

Yeah. There is a strong desire to make sure we are using gender-identity-appropriate words or sexual-orientation-appropriate words. There is also a strong desire to make sure the data does not inappropriately flow where it is not supposed to flow.

Clement McDonald

The irony is that, for terms of race, at least in some hospitals and institutions, they do not get collected, and it is not because they do not have a field for it, it is because the people who are collecting or answering do not want to ask that question, so I think it would be a similar thing with these issues.

Arien Malec

No doubt. So, definitely, point taken that we need to be sensitive about the wording here and not imply that sensitive data should be flowing in cases where it is not appropriate for it to flow. Let’s go on to our next section. Let me do a time check. Okay, I think we have got 15 more minutes before public comment. I think we can get it done. EHR data use for research, real-world evidence, recovery trials, comparative effectiveness, list of specific recommendations... I think that “list of specific recommendations” is actually a typo. We probably should use Les’s “pragmatic trials” language here. So, our findings are that although the U.S. has the largest deployed base of electronic health records, U.K. did the lion’s share of prospective pragmatic trials for treatment for COVID-19. Many U.S.-based institutions invested in research data models to perform broad observational analyses, multiple research models, and lack of source normalization as significant issues.

David, as I am reading this, you and I talked about how... I think our observation was that our No. 1 problem by far was source normalization. That required substantial amounts of rework. No. 2 was making sure that interoperability, USCDI, and FHIR specifications were mapped to research needs where appropriate. And then, No. 3 is the multiple-data-model issue. So, I just want to make sure people understand the degree of pain... If you had one thing to go solve, it would be source normalization by far, and everything else is a distant second, so we need to make sure that is included there. And then, David, I think you are scrolling. Is that right?

David McCallie

Yeah. I moved it down because it seemed like you were talking more about recommendations.

Arien Malec

Yeah. Now, we are moving to recommendations. No. 1 is really memorializing Clem’s good feedback from last meeting: Better intent to reduce the effort needed to reuse clinical data for research needs, not to





prioritize research needs over clinical care as a primary task for deployed EHRs. We recommended that ONC support the catalogue of common research models and work with stakeholders to evaluate, develop, and harmonize to a common foundational research model mapped to the USCDI and cross-mapped to FHIR.

And then, we are primarily calling for the community to reduce duplicative deployed models rather than create meta-models to cross-map between existing models, which is a mouthful to even say, but to do is even more of a mouthful. We recommend that ONC work with FDA, CDC, CMS, federal healthcare providers, NIH, NCI, and other federal actors to harmonize the common research data model, and we make specific recommendations relative to consent, respective randomization, separation of research and clinical data, terminology for preapproved new chemical entities, biologics, and devices, and other EHR...and, my little Sasha bell is ringing here...not gaps, but other areas where EHRs could better support research. So, I am going to pause here...

David McCallie

I put "opportunity" in there. I thought that was the right word.

Arien Malec

Yeah.

David McCallie

It is in there.

Arien Malec

Yeah, it is just not here. It is just not in that bullet. Clem, go ahead.

Clement McDonald

I want to clarify. When you talk about standardizing source data, are you talking about going upstream as high as you can?

Arien Malec

Exactly.

Clement McDonald

That does not come across. That is the only problem.

Arien Malec

Okay. We will do another pass to make sure we get that done right. But basically, if your lab is sending you proprietary lab codes, your research life is going to be unpleasant no matter what you do, whereas if your...

Clement McDonald

Results [inaudible] [01:06:51] parts to it. People do send-outs, and the referral labs mostly have standardized codes, and they do not carry them, so it is not just doing it at the top, but using it and taking advantage of it.





Arien Malec

That is exactly right. And, the last incarnation of the ISP Task Force, as you remember, Clem, went into particular depth on this topic, so we might want to reference back to that report specifically for LOINC. Okeydoke. Hearing no other comments, harmonization of clinical and administrative data for burden reduction... And, again, waved hands here, so this requires a little more work. I was getting tired by this time. So, we endorsed the ICAD Task Force recommendation that is expressed in the ICAD transmittal, we recommend that ONC add sections to the ISA to track relevant interoperability priorities and track items being addressed to the extant Da Vinci, fast FHIR, X12, NCPDP, as well as HL7 FHIR accelerator projects, and we recommend that ONC harmonize the implied administrative data model expressed in X12 and NCPDP administrative transactions to USCDI to ensure that EHR clinical data capture is maximally available to address administrative needs at low patient and clinician burden. All right. Questions there? Cool.

Clement McDonald

I do not really have a question, but I do want to comment. X12 has been fairly cooperative with HL7 over the last 10 years, but some of the stuff they have done has never made it out the door to CMS for some reason. It is a tricky space.

Arien Malec

Yeah. The ICAD Task Force recommendations, which I would encourage people to read, went into some significant depths on that particular topic, recommending that we build a more flexible standards evolution process that encompasses administrative transactions for exactly that reason that there is a lot of deploy work in the standards community that has never been deployed in practice, primarily because of federal policy being somewhat slower moving. One could point to attachments as the classic example there. I think that has been just about to be ready for primetime or ready for prime time since the early 2000s. All right.

And then, we make recommendations relative to situational awareness, recommending that ONC list situational awareness priorities in the ISA and list SANER as well as related standards, corporate stakeholders and pilots in early implementation evaluate mature standards for broader adoption. And then, I think we heard very clearly, which probably should go into the findings, that one of the major issues here is the policy coordination issue. As in many areas of this space, we do not have aligned policy incentives and funding mechanisms to ensure that where standards are available, they are actually deployed and operational in case of emergency. All right.

So, we got through the whole document. At this point, I would like to remind everybody that we are looking for volunteers for each of these sections. So, we are looking for volunteers particularly for the executive summary, as well as some of the up-front material or front material on charge and status of hearings and the like. So, this is the material of if we synthesize out the detailed recommendations to something that somebody reads only one or two pages of, let's make sure that is right, and then, we are looking for volunteers by section for each of our major sections, and I think Sasha has already volunteered, but we are looking for additional volunteers for each of these sections. If you are a volunteer, what we will do is work with you on refining the text of each of these sections for full task force consideration. So, we get extra work and extra homework, but it is going to go directly into making sure that this text is as clean as it possibly can be.





And then, as always, we will review any changes in the full task force pursuant to getting a final set of recommendations in the meeting before the full advisory committee that we will bring to the full advisory committee. Any questions on process and what homework we are looking for folks to do? I just have one other meta comment. We are going to be working off the transmittal draft up until the last meeting, and on the last meeting, we will probably abstract slides out from the high-level recommendations and the executive summary that list the recommendations and recommendation text for delivery to the full advisory committee. I think we are in great shape. I think we have a pretty solid draft out of this meeting. We have gotten a lot of really good feedback that will go back into another good draft that will be sent out to the full task force for your consideration for review in the next meeting. Any other comments? All right. So, I wonder whether, if appropriate, we could go to public comment 15 minutes early.

Public Comment (01:13:36)

Michael Berry

We sure can. Operator, can we open up the line for public comments?

Operator

Yes. If you would like to make a 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 the handset before pressing *. One moment while we poll for comments. There are no comments at this time.

Arien Malec

All right. Well, I think, then, what we will do is give everybody back 13 minutes of their day, and we will take the feedback from this task force meeting, send out a revised draft as early as possible, and just logistically, sometimes, the way this works is David and I work on it tomorrow, and if we do not get it out by the end of the day East Coast time, we may keep working on it over the weekend, and then it will come out on Monday. So, expect no later than Monday to get a revised draft. If you have a particular desire to participate in more active wordsmithing, please volunteer. Otherwise, be prepared to read and review the draft on Monday and show up on Thursday, ready to tear it apart. Cool. Thanks, everybody.

David McCallie

Good job.

Arien Malec

Thanks.

Adjourn (01:15:26)

