

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS WORKGROUP MEETING

May 3, 2022, 10:30 a.m. - 12:00 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Steven Lane	Sutter Health	Co-Chair
Arien Malec	Change Healthcare	Co-Chair
Kelly Aldrich	Vanderbilt University School of	Member
	Nursing	
Hans Buitendijk	Cerner	Member
Thomas Cantilina	Department of Defense	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Steven Eichner	Texas Department of State	Member
	Health Services	
Rajesh Godavarthi	MCG Health, part of the Hearst	Member
	Health network	Marchar
Adi Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
Leslie Lenert	Medical University of South	Member
	Carolina	
Hung S. Luu	Children's Health	Member
David McCallie	Individual	Member
Clem McDonald	National Library of Medicine	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and	Member
	Medicaid Services	
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards	Member
	and Technology	
Michael Berry	Office of the National Coordinator	Designated Federal Officer
	for Health Information	
Al Taylor	Technology Office of the National Coordinator	ONC Staff Lead
	for Health Information	
	Technology	
Denise Joseph	Office of the National Coordinator	ONC Staff Lead
	for Health Information	
	Technology	



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

Mike Berry

Good morning, everyone. Thank you again for joining the Interoperability Standards Workgroup. My name is Mike Berry. I'm with ONC, and we are always glad that you could be with us today. As a reminder, we always welcome your feedback, which could be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled about 11:55 Eastern Time this morning. Let's begin rollcall of our workgroup members, so when I call your name please indicate that you are here. I will start with our co-chairs. Steven Lane?

Steven Lane

Good morning.

Mike Berry

Arien Malec? Kelly Aldrich? Hans Buitendijk?

<u>Hans Buitendijk</u>

Good morning.

<u>Mike Berry</u> Thomas Cantilina is not able to join us today. Christina Caraballo? Grace Cordovano?

Grace Cordovano

Here, good morning.

Mike Berry Steven Eichner?

Steven Eichner Good morning.

<u>Mike Berry</u> Adi Gundlapalli or Sanjeev Tandon?

Sanjeev Tandon Yes. Good morning.

Mike Berry

Raj Godavarthi? Jim Jirjis? Ken Kawamoto? And we have a new workgroup member, Dr. John Kilbourne from the VA. John?

John Kilbourne

Good morning.

Mike Berry



Leslie Lenert? Hung Luu?

Hung Luu Good morning.

Mike Berry David McCallie?

David McCallie Good morning.

Mike Berry Clem McDonald? Mark Savage?

Mark Savage Good morning.

Mike Berry Michelle Schreiber?

Michelle Schreiber Good morning.

Mike Berry Abby Sears?

Abby Sears Good morning.

Mike Berry And Ram Sriram?

Ram Sriram: Good morning.

Mike Berry

Good morning to all, and thank you. Now, please join me in welcoming Steven and hopefully Arien is with us now for opening remarks.

<u>Arien Malec</u> I'm here. Good morning.

Co-Chair Remarks (00:02:04)

Steven Lane



Wonderful, perfect timing; well, thank you all. As Mike said, we are glad you are all here to join us. There are a few members of the public who have joined us already and some may be joining yet. We really do encourage all of you to participate in the public chat and to take advantage of the public comment period at the end of our meeting, five minutes before the hour when we finish. I do want to especially welcome John Kilbourne, who is joining us representing VA. I have had a chance to work on a number of task forces and committees. John, do you want to introduce yourself briefly to the group?

John Kilbourne

Sure. My name is John Kilbourne. I'm a family practice doc by training, but I haven't practiced in quite some time. I work at the VA primarily in the realm of terminology. Before I was at the VA, that I was at NLM, where I was in charge of Rx norm. Before that, I worked with Silmed. Terminology is my area of focus, but at the VA I am representing all sorts of informatics issues at the VA. Thank you.

Steven Lane

Thank you, John. Obviously, that is a background that plays heavily into the work that we are doing here. A number of folks have joined since we did the roll call. Thank you for announcing yourselves in the chat. It is good to have everybody here. Arien, do you want to share any remarks?

Arien Malec

No, I am just really excited to get into it. I think we have done a good pass on the lab recommendations. I think we have a lot to talk about today, and then the workgroup members have done a fantastic job of filling out the spreadsheet with a large number of ISA recommended items for the ISA to track. So, I think we've got plenty of content to go through today and through to the end of our recommendations. I appreciate all the work that has gone into that.

Steven Lane

I will also add that both Christina and Grace have offered some specific recommendations regarding the structure and organization of the ISA as we have done in the past with the USCDI. I think there are opportunities to tweak the formatting and the tools available through the website to make it more understandable, especially to lay members of the public who might want to get involved in this work. I think we will be working with you and C team to review those recommendations in particular, which are more structural than content-oriented and see what we can do with those.

What I would like to do is just go ahead and go to the next slide if we can. Just a quick reminder of our charge; you will recall we are on to phase 2 of this work, where we are identifying opportunities to update the ISA to address HITAC priority use cases of health IT, including the related standards and implementation specs. I think it is important to realize that we have not been handed a discrete list of HI TAC priority use cases. Certainly, many of us are on the HITAC and have been through this.

We have discussed use cases both in the context of the annual report and in the original charter of the HI TAC itself. I did reach out by email to the ONC team and suggested that perhaps it would be helpful if we had a discrete list of what we are considering the HITAC priority use cases, since it is called out here, or HITAC priority uses I should day. They don't use the word use case, but I think most of us have an intuitive sense of that, but as we go through our work I think it is worthwhile to be crystal clear about that because



as we have said, updates to the ISA can be in terms of its content, specifically again the notion of data elements, standards, specifications but also its structure.

Updating to the ISA can be structural updates as well. That is my dog chiming in in the background. We will see if she can figure that out soon. Anyway, we are dealing with our phase 2 charge with the due date of mid-June to present to the HITAC a set of recommendations, so that's what we're up to. Next slide?

Arien Malec

Just to remind everybody that we are in early May, so we're going to need to quickly get to recommendations draft by the end of this month to be able to prepare for the mid-June deliverable to the HITAC.

Steven Lane

My bad; I did not fully review this slide deck, and here the ONC team has given us the slide that I had asked them for, which is wonderful. These are, again from the original HITAC charter, and I think they may have been massaged a bit over the past four or five years, but these are identified as the priority uses of health IT. Let's see—how did they phrase this? From the Rule; use of technologies to support public health –thank goodness, we are all supporting that – interoperability, privacy and security, and patient access. So, a pretty broad charge in terms of priority uses and not a list of specific use cases per se. Mike or anybody from ONC, do you want to comment on this at all in terms of providing any guardrails or directionality to the work we are doing as we prepare our recommendations?

Arien Malec

I think that is the ONC signal for you are on your own.

Mike Berry

This is Mike. I just want to say that the Office of Technology team will weigh in maybe to provide some guidance on some topics that we'd like the workgroup to focus on for your consideration and we can talk about during the co-chair debrief later today.

Lab Recommendations (00:08:27)

Steven Lane

Thank you. That is great. Clem, sorry to hear about your voice, but we are looking forward to see your comments if you want to type them in as we go.

All right. So, let's dive into the lab recommendations. We did do some early work on this, and there is the online document that you should all have access to. I know Arien, you went through this with a fine-tooth comb yesterday, I believe. Did you want to maybe guide us through the comments that have largely come from Ricky, Hans, Hung, as well as with some input from others?

Arien Malec

Sure. What I tried to do was take the recommendation or turn this into recommendations text. I don't believe this text is aligned with – sorry I am looking at the wrong thing here ... here we go, perfect, thank you – what I tried to take the text and turn it into recommendations. It is often easy to describe what you want the real world to look like in an ideal state and harder to point out where ONC can drive specific actions. Just

casting things in terms of, we recommend that ONC do block sometimes help sharpen the pen in terms of making more specific recommendations.

I think we had a good conversation last meeting, and we agree that lab results should be resulted with a LOINC code for the test that if numeric should include the numeric result with the UCUM code indicating units of measure, if qualitative should include a SNOMED CT code and then in all cases should be accompanied by the UDI for test kit and other relevant device data if appropriate. The question is, how do we go, what recommendations do we have that ONC go there?

I think we made some good progress in our last round on the USCDI to sharpen up the USCDI recommendations to be more aligned with CLEA recommendations. Here, we are explicitly, the way I've casted this is we are explicitly recommending the ONC coordinate with and other agencies and partners, SDIs and other stakeholders to find an interoperable information model and communication standard aligned to, yada, yada, yada. And then, including the notion – thank you for removing the extraneous period there – including the notion that we should specify orders via LOINC codes and then specific results with the content model noted, and then also making recommendations relative to what laboratory results should include, which again, I think is aligned with what we said in USCDI, except for USCDI not being able to accommodate currently reference ranges or interpretation codes. Anyway, that is paragraph one. I will just pause there and see if there is any feedback from the workgroup.

Steven Lane

And Clem, I know you are not in voice-enabled today, but you had some comments about this. I know the language has been tweaked a bit along the way to try to accommodate that, but if you still have concerns about some of this phrasing, be sure to let us know.

Arien Malec

Drop it in the chat if you can to make sure we've got this right. I think Doctor Kilbourne would also be somebody who might have some good comments here, and there are a lot of folks on this call to go deep on results.

Male Speaker:

I have a question then, maybe. You mentioned interpretation codes, and in the text area it mentioned SNOMED for – my eyes aren't finding it – but for qualitative results. I wonder if you want to call out interpretation codes as an additional category of code, or are you thinking interpretation codes are a part of qualitative results?

Arien Malec

Thank you. This is the – I forget the term of art – but this is the HLHHLL set of flags that often accompany results. I am sure that somebody has sat down and standardized the content of those fields. There is a set of informal conventions that govern the interpretation plant that goes along with the result.

Male Speaker:

Is that also in SNOMED?

Arien Malec

Well, it wouldn't be SNOMED because typically the code is the literal text, H or HH, or the literal text L or LL.

Male Speaker:

Oh, high or low; that's what you mean by interpretation?

Arien Malec

Correct.

Male Speaker:

I see. That is hypertension or something like that that phrase?

Arien Malec

That's right.

Steven Lane

Should that be called out, those interpretive fields? Is there a published standard for that or just a convention?

Arien Malec

I am not aware of a published standard. I'm sure we've got all the folks on who would be aware if there were a published standard for use of test interpretations.

Clem McDonald

There is a published standard. It's in HL7. It's been around for 20 years.

Arien Malec

Fantastic. Thank you. The test interpretations are often called the abnormal flag. Thank you, Clem. We can look up and point to the HL7 standard. This would be specified in the LRI guide, I would assume, and I would not ask you to abuse your larynx more.

Mike Berry

I can get the links in the chat if you want them.

Arien Malec

Thank you. Go ahead.

Male Speaker:

Arien, might it be more beneficial if we just call it the abnormal flag? That way, we don't run into the confusion with the interpretation code. Some laboratory tests do come with a pathology interpretation.

Arien Malec

I am using the term that was used in USCDI level 1. So, we should probably call it test interpretation/abnormal flag.





Male Speaker:

The standard is called interpretation because it is neutral as much as possible.

Steven Lane

Does it include high/low or just normal/abnormal?

Male Speaker:

It does. It's a big list.

Mike Berry

I will get the link on that in a moment.

Arien Malec

It is usually a one-letter code. Anyway, that is recommendation number one. Recommendation number two is where the meat here starts to come in, which is that we recommend that ONC and NHS and other relevant agencies and other federal partners create policies sufficient to encourage, incent, require, or otherwise enable resulting organizations to support these consistent standards for orders and results when reporting this data via messaging documents, application programming interfaces, or other featured transport mechanisms.

So, in our last go-around at this in 2018, we made specific policy recommendations for what federal agencies or federal partners might get into the act. At the time, we contemplated that the FDA clearly has regulatory authority over the IBDs that CLIA has regulatory authority over clinical labs, and that ONC has the ability to create certification criteria that ONC's mandate is fairly broad and can create certification criteria both for LISs as well as for EHRs and public health systems.

Then, we also contemplated that CMS, in its role as the largest payer, has a role to play in terms of schematics. We could go deep there, or we could just stop here and say that we recommend that ONC work with other relevant HHS and federal partners to create policies sufficient to yada, yada. So, I'm just going to pause there.

Steven Lane

Any thoughts?

Clem McDonald

This is Clem. There are an awful lot of labs that do not send LOINC codes and SNOMED codes. At least, their clients and the big labs all do, but there may be a breakdown in whether the systems can accept them. I think some push by CMS would be very helpful.

Arien Malec

Yes. It's typically the hospital labs or the local/regional labs. I think you could look at this and say that the majority of labs are resulted with LOINC codes. That is really an artifact of the fact that the largest labs, particularly Quest, LabCorp, the other large nationals have put in the work. At the same time, I think that some of the issues are that the smaller labs – because there is a one-time and ongoing cost of coding and mapping – haven't they always put in the work to map their local codes to standards.





Clem McDonald

It might be worse. Steve says they are just burdened with mappings, so that suggests a lot of people are not sending the codes with their content.

Steven Lane

Actually, no; the suggestion is really more that they are sending codes but because of the way the systems function, there is still a need for bespoke mapping to occur. Hung, your hand is up?

Hung S. Luu

I would recommend just leaving it there in terms of not defining too much on the strategy of how you go about it and who should be enforcing want. I think what you have there is sufficient because I think that the issue is that we had meaningful use, and so what was actually the result of that?

Did it improve interoperability? What we found in studies is that about 80% of the LOINC codes in the systems of laboratories that went through coding their system is correct, and so 20% is incorrect. What is the impact of that if you try to use that for research? If your data is 20% inaccurate that is not great. I think we really do need to be able to make sure it works.

Steven Lane

Hold on, Clem.

Hung S. Luu

We need to make sure that it works and that labs that are trying to do the right thing are able to do it correctly before we start bringing the hammer down. Otherwise, we are just going to end up with the same results over and over and over again.

Clem McDonald

I would like to clarify the report they all made that the paper was prefaced and done by looking at a five percent sample of a survey from labs that only looked at ten tests. So, I do not think it's that generalizeable. We are looking at other sources, and it is much, much better than that but not perfect, so Hung is right. Maybe at the order of five percent from the commercial labs is probably in the order of a half of a percent error. It is true we've got to make them better, but it is not true that right now it's horrible.

Steven Lane

I want us to be clear that these recommendations are really more general. We are not providing specific content recommendations about the ISA itself. I think that ONC is cautious about how this fits inside of our charge, so I just want to be clear that we are carrying forward recommendations and modifying and amending recommendations that have been made by prior taskforces here. I think that this is valuable work, but we also need to be clear, or we would like to become clear how ONC will be able to receive and utilize these.

Arien Malec

lke has his hand up.



Steven Eichner

Thank you. I think two points; one, I think we need to make sure if we can in our recommendations Dr. Luu just shared that there is good alignment between the requirements and language about case reporting so that we are getting consistent rolling codes between what's of the initial electronic case report and a laboratory report. One of the things that we, as department state health services in particular has found is that we have a long history of onboarding laboratories for public health recording or ELR.

Quite often, we find there is a mis-mapping by the local and state onboarding process where they have not done a great job, at least initially, of making sure that their local codes match initial the national standards. I think if we can work it in language somewhere that part of the recommendation is not just to use local codes or submit local codes, but that there has actually been some work done along the provider side or the vendor side that actually validate that their mapping is correct at the local level.

Arien Malec

We do have recommendations later on that are specific to mapping. So, maybe when we get down a little farther we can pick that point up. Thanks, lke. The stuff that I marked here in yellow I think is already addressed in the first recommendation. It's more detail or appendix-level detail about that set of recommendations. So, if we scroll down, whoever is controlling the Google Docs?

Steven Lane

There we go.

Arien Malec

Perfect.

Steven Lane

Arien, you had a comment here about potentially deleting that big yellow paragraph or removing it to an appendix. Did you want to comment on that?

Arien Malec

Yes. The actual text is detail that's summarized in the recommendations. So, it can either be preamble or it could be appendix-level material, or we could just delete it as understood. It is one level down in detail from the set of recommendations in the first paragraph.

Clem McDonald

So Arien, I put a comment in about that.

Steven Lane I'm sorry, Clem?

<u>Clem McDonald</u> I put in a recommendation.

<u>Arien Malec</u> I see a comment there.



Clem McDonald

I put it in the chat. The current recommendations for lab, SNOMED CT, and I think that's the predominant one and a good one. I cannot say why because one, because it's a text string code and SNOMED is concept code. Lab vendors have to put into the package insert sometimes the exact strings they want showing so that they're conflicted if they have to change it to a code that does not say the same string.

Arien Malec

Thank you. I appreciate that. So, we can get that in. Here is where, how do we take shield into effect? And again, this is consistent with the recommendations that we made in 2018. We recommend that ONC coordinate with other federal partners and with SDI's industry partners in standards and innovation guidance policy. That occurs as LOINC and SNOMED encoding as early in the process as possible. For orders, communication of an order should include the appropriate LOINC code where available any ask-and-order questions. Similarly, these LOINC codes were available for the question and SNOMED codes when available for the answers.

Basically, we want to get the content normalized at the item and not the order wherever possible. Then, in the second set of recommendations we really go down on IBD to LIS. So, we recommend that ONC, in coordination, yada yada, create sustainable mechanisms that lead to IBD test devices and LISs to automate mapping and translation sufficient to enable test resulting following the standards noted above.

Again, note that IBD or the LIS should be able to enable the correct code to be included. We call for guidance on which LOINC and SNOMED codes are the most suitable and that that guidance should be available by the IBD test manufacturer. One could imagine that a way to get at this recommendation is to coordinate the device registration requirements by FDA with appropriate standards and certification from ONC.

Again, we are trying to keep it nonspecific in terms of the how, so I am going to pause. Then, the last one is about making sure that ONC and other federal partners and SDOs make sure there is a well-managed, appropriate resource process to deliver initial LOINC codes when available when needed. For new tests, we need the variations of existing tests. Again, this is not a one-and-done situation. This is a set of activities that need to be ongoing. Hans, you had your hand up?

Hans Buitendijk

Yes, just a quick example within the indicators and that we are not trying to prescribe how. There clearly is the opportunity to make such mapping data guidance available electronically that LISs can take advantage of as part of the configuration process. Another one, not an alternate, but just an additional or an earlier perhaps is that the work that, for example CDC has done, for the specific set around COVID-related tests to make that available more easily; one can envision a variety of different ways, but it's ICC and NLM, FDA, whomever is appropriate. I think that Ricky highlighted that as well. If those mappings are available in a registry, catalog, source aggregated, it can already help anybody who needs to do configuration at that point in time. So, there is a variety of different ways in which this could be done and not be mutually exclusive.

Arien Malec

And not mutually exclusive; that's exactly right. Again, the point here is that through the variety of oversight mechanisms that the U.S. Federal Government has, there is literally no part along the pathway that is not covered somehow through regulatory oversight, guidance, et cetera. So, through NLM, through CLA, through CMS payment rules, through FDA registration requirements, and through ONC and through CDC, we really do cover every single portion of the ecosystem.

No need for us to go into the mechanics for how; I think what we're doing is saying, "Hey, this is a problem that has burdened on the U.S. healthcare system in terms of all of the manual mapping that's required and also in terms of usability and quality of data. We saw that problem play out in the pandemic. It is a good opportunity for us to take a step back, and with the Shield Project, look at how we can make the next turn of the crank to fix this problem. Here is a set of recommendations we are making relative to ISA advancement because all of these standards are in the ISA." We are calling for these standards to be advanced in maturity. We are calling for ONC to work on the policy levers that help these standards be advanced in the ISA. All right. If we go to the next section?

Clem McDonald

I have a question on that section. When it says formal support, does that mean funding support? It's the third line from the bottom.

Arien Malec

So, we say we recommend that ONC in coordination, yada yada, ensure there's a well-managed and appropriately-resourced process.

Clem McDonald

When it says this could take a more formal support, does that really mean funding?

Arien Malec

That is what appropriately resourced is intended to mean. It is not just funding. It is people, it's talent, and it's all the good stuff. All right. Now, we get into – and again this may be we could tone this one down a little bit – but we recommend that ONC in coordination and then just some standard language there inclusive of guidance, certification, criteria, and inner programmatics lead to EHRs, LISs, and re-eligibility information systems within those that allow clients and users to map internally-generated result codes to standard vocabularies in cases where coding is not done on the source. This one, I just took the text that I think Hans, Hung, and Ricky created and turned it into a recommendation.

It may have gone a little too far in terms of toning this one up, but the point here is that there is always going to be a need to map internally-generated codes to standard vocabularies. It would be useful for systems to be able to provide user supported mechanisms to be able to do that. That feels like a good thing to call for and then the question is, okay, but we're making recommendations to ONC, so what recommendations should we be making to ONC? Thoughts here?

Steven Lane

John?

John Kilbourne

Yes, this is complicated. "To provide a mechanism that allows users to map internally generated results," that is an easy phrase to say, but provide a mechanism? There isn't really a mechanism. I wonder if we need to tone this down or alter a little bit. We want ONC help to make this possible or make it easier to do, but there isn't really a sheet feeder where you can feed in your paper with the codes you want and then out comes the codes you mapped to. There's lots of processes and policies that might help, like certification and education, and those are the things that can help somebody map, but at the end of the day, some person has to look at a spreadsheet and say that this code here is the same as that code there. I am just trying to bring this into reality, the experience of actually doing this.

Arien Malec

I am with you. This was one where, as I said, I went through and took some really well-done statements about what we want the world to look like and then turned them into statements about what ONC specifically should do. This is one where reading it back, I have a little bit of heartburn about it. Hans, you have got your hand up?

Hans Buitendijk

Yes, I was wondering lines is that mechanisms might be very specific tools only, but maybe if it is shifts a little more to tools and guidance it is a mix of things. Going back to our prior conversation, it needs to not be mutually exclusive on how some of those things can be done. If you focus on tweaking it in that direction a little bit, it is still encouraging on how do you get people in that practice and the systems into the practice.

Arien Malec

Maybe the recommendation could be education and guidance?

Clem McDonald

Can I add to that? So, the real problem is that nobody knows what they have done. In Apple Health, you can click on it and see what codes they use. You can't do that in any of the major medical record systems. It's all buried in the mapping tables. Researchers tell me it's harder than hell to find them. We should ask for transparency so the big commercial labs publish their tables. So, if the big commercial labs publish their tables, maybe if they publish them, people could see if they are right and check them or know if they are really doing it.

Arien Malec

Yes. Again, where I am struggling here is that I think everyone can look at that statement and completely agree with it, and the question is; how far do you go in terms of policy lever? For example, do you literally require through certification criteria and payment criteria that somebody publish their mapping tables? And that actually might be a reasonable policy outcome that CLIA could be require or that EHR certification could require.

Clem McDonald

The commercial labs are not obliged by HIPAA to do that. I don't think we will get it right until we get more of it done. Some mappings are "correct." It's test A to other test, or test A to pathology report, but they don't tell you what you need to know. It's just a specific number.

Arien Malec



Lots of good stuff coming in the comments, it feels like. Hung, we'll come to you in one second. I'm going to just summarize where I'm seeing stuff in the comments. It feels like the sense of the group is focused on education and guidance supportive of the notion of transparency. So, we might contemplate changing this recommendation to call for education and guidance and to encourage transparency of resulting mapping. Hung, you've got your hand up?

<u>Hung Luu</u>

I would agree with transparency, but part of that has to be that the mapping has to be easy to access. Right now, it is not easy for any lab to actually see which test has the codes and to be able to see the test. To require that somebody publish their mapping; if that is not easy to do, it is putting more additional onus on the laboratories, which are already stretched thin with decreased staffing. Then, they suddenly have to say no matter how hard it is to do this, you have to publish your mapping. I think that that is not reasonable. There has to be the transparency in the system to be able to see to usually do that.

Clem McDonald

Let's not put it on the lab. Let's put it on the medical records system. They all have mapping tables. Cerner does, EPIC does, and it is just publishing it is trivial. It's just a matter of exposing it, transparency.

Arien Malec

Again, from a recommendations perspective, I think everyone would be in support of a good and smooth user experience, but where do we create recommendations that lead to that result? Are we literally calling for certification criteria that the system be easy to use? I think we have gone that direction a couple of times in the past and realize that that's a little harder than anybody contemplates. I think payment programmatics are the nuclear bomb in this area. I think we will take some more work and retool. We will go to the last one, Steven, and then go to see ISA table.

Hans, I agree with you. If we do anything, it is really about reducing the amount of manual mapping because we get it right at the source, which is where this one goes; "We recommend that ONC in conjunction with other federal partners, yada yada, create and implement mechanisms to support and ensure proper and consistent LOINCs, SNOMEDs, CT, UDI in coding encoding (we can fix that one) across result sources by resulting agencies such as mapping knowledge base, searchable by MED, manufacturer, and harmonize test, lab test methods i.e. the IDR, auditing and recertification by CLIA for laboratories." Basically, it would be pretty cool if there were a searchable database that helped people drive consistent coding. The U.S. Federal Government has a role. I think based on what we've heard from the SHIELD project, this might be as simple as funding the maintenance of the IDR, but we don't want to be so specific. So, thoughts here and then we'll go on to the rest of the ISS action.

Steven Lane

Just to Hans' comment, I think the term resulting agency is fairly well established unless others feel differently.

Clem McDonald

Could I elaborate on that? All labs don't go through the FDA. There's about a handful of them marked socalled laboratory developed tests. The bid process that Hans may be thinking about won't solve all tests. We have got to get whoever's making them to do it upstream, but it won't always be FDA approved.





Arien Malec

Yes. I think we previously have a term for the organizations that are resulting, and we can reuse that language. Agency is a little ambiguous as to whether we're talking about the FDA or we're talking about the clinical labs.

<u>Hans Buitendijk</u>

Correct. It is the public health agencies that might be going with all of the labs, but then we have all of the other reporting labs and radiology imaging centers, et cetera.

Steven Lane

All right. Well, thank you, Arien for walking us through those edits. On that very first recommendation left over from the ISP task force 2018, there are, I think five more here that a number of folks have made comments on. We will, as time allows, try to come back and turn each of these into specific recommendations, but we did want to spend some of today focused back on our spread sheets. So, we want to thank everybody for doing the ranking. You will note, if we can pop over to the ranking spreadsheet that we have the initial tab where we had the 12 items that we originally ranked, which captured our green and yellow in the table, and then we added the additional topics that folks have put in.

Quite a number of us have gone ahead and put in some rankings, so we are starting to get a sense there. Again, this is not to say that any of these are not worthy of our recommendations but more to try to see where people think the highest priority is so we can dive in there. Again, the goal is to try to come up with discrete recommendations. So, I think we don't need to belabor the ranking table at this point but maybe pop over to the spreadsheet itself where we have captured your observations and recommendations. I think that probably, Arien, unless you had another thought in mind, starting with those that that have ranked high and seeing if we are comfortable with the recommendations we'd like to finalize some of these and ideally move on to others.

Arien Malec

One more thing before we close out the orders and results piece; the process of turning the text into recommendations was relatively easy for the section we just went through. I struggled with the remaining sections. So, I might ask Hans, Ricky, Hung to think about for the remainder of the sections how we might turn them into recommendations of the form that we recommend that ONC adopt. So, if I could just have a call out to the team and to Clem as well, a call out to the team to recommend that ONC do X. What is the X, the more specific X that we are recommending to get to the more desired state of the world? Thank you.

Steven Lane

Okay, so in this spreadsheet, again I'm just thinking that we will start with the greens and then get on to others simply because those were the ones that the workgroup said were higher priority. What I would do, ONC, is scroll to the right a little bit so that we can see simultaneously the observations and recommendations. Mark, since your name is on this one relating to SEOH standards and the recommendations from gravity, which we all recently heard, do you want to walk us through this?

Mark Savage

Sure. On the observation, that's fairly straightforward, but I did add something more recently, and it goes back to your comment, Steven, about priority uses/use cases. Do you want me to go into that, or do you think you have covered already in this call?

Steven Lane

I think we are looking to ONC to provide us with some recommendations and guardrails in that area. Why don't you go where you need to go?

Mark Savage

Well, let me just add a high-level comment that may help you two in your co-chair debrief, which is social determinants. We talked about the ISA structure, but there is a section called Specialty Care in settings that does not appear in the general menu unless you go on the banner and then you highlight, and so forth and so on. Social determinants of health are listed under that, I'd say I don't think of social determinants of health as a specialty care or setting. It is the 80% to 90% of health status, and that's where this idea that's in my observations about use cases came from. People are looking for that, I think.

It helps to have a place where you connect things from across the different parts of the ISA, like vocabulary, services in exchange, et cetera. Some comments there specifically around social determinants of health, my own thought as well is that it applies more broadly than that. With that, I will jump to the recommendations section. The gravity project slide provided some detailed recommendations, high-level but detailed. I did not repeat them here. I didn't think that was necessary to fill the text box unless that is what you'd like for me to do. Instead, I just said review and consider them. I think they all made good sense to incorporate.

Steven Lane

I think what we do want here is to move this to text that begins with, "Recommend that ONC." So, I think bringing over and streamlining the recommendations from Gravity so that we can consider whether we want to make them our own and then give a chance for HITAC to embrace them and send them on to the ONC, I think is what we want to do in this recommendations column. We have got a couple of hands up. Hans?

Hans Buitendijk

Yes, I have a question for Mark, for both rows effectively. Can we point to specific implementation guides or other documents that are already published for each one of those that isn't as specific is that?

Mark Savage

For what the Gravity project recommended, yes; the data elements are in USCDI, V2. The SQ1 of the implementation guide is published as SQ2 is invalid, so yes there are links for everything and for the value sets, which we're the stewards for those and VSAC.

Hans Buitendijk

USCDI, the reason why I'm asking if that if the ISA already includes USCDI version 2, it has that data in it. Clearly, we can already look ahead and say, USCDI version 3, when it comes around, please just put it in.

Mark Savage



That is part of our recommendation. ISA does not automatically incorporate USCDI V2. There's work that needs to be done there.

<u>Hans Buitendijk</u>

That raises an interesting question, I think that we could generalize on this. Can we ask ONC to work with the standards organizations that create these guides that we already know about that are creating new versions that are up on publication? For USCDI, this we can go and see itself that they already proactively provide that information to indicate this is the latest available. We are, at times creating recommendations a new version that could have already been put "automatically." It is not something new. It's just a progression that's going on A to 7, NCBNP, et cetera. They're creating these new versions. Can they not just go automatically in there and make the process easier?

Mark Savage

Likewise, Hans, somebody kindly put into the other spreadsheet incorporating USCDI into ISA, and I think it got a lot of number ones as a priority.

Hans Buitendijk

Thank you.

Steven Lane

Clem, your hand is up. Plus, you just offered us a long comment in the chat. Clem, you're on mute. Clem, you are still on mute. Okay. Well, we can read Clem's comment here, which seems to be primarily related to the lab work here.

Clem McDonald

I just wanted to say that I support Mark's position on changing and internalizing the name, but I also wanted to ask him about use specifically. In the SDOH rules, it says to use LOINC answer codes. I think that was also related to the stream versus concept difference. Are you conscious of that?

Mark Savage

Well, maybe not. What I do know is that what we have published and what is integrated into USCDI V2. So, if it has been integrated in the way you are describing, fine. If it's not, it's still adopted by ONC. Does that answer your question?

Clem McDonald

Well, it's not a question. I am just trying to emphasize the survey instrument team are very fussy about the words in their answer lists. I'm not fussy in particular, and if you can't change them and then know that the thing is invalidated. And so, the issue between LOINC and SNOMED answer codes; they're quite different. They're complementary. One code takes a literal string in the answer list and so it gets it and gives it a code. SNOMED gives it a concept entity, which is very useful because you can search across things, but it doesn't satisfy the particular focus of survey instrument developers.

Mark Savage

I think my answer, Clem, is that I do not know the answer to your question or to your suggestion about how to say the way it works and what is in the current data elements in USCDI V2. Others may, but I do not.





Steven Lane

So Mark, we will ask you to go back and turn this into a set of discrete recommendations based on what we have heard from Gravity. For item No. 7, this has to do specifically with the race and ethnicity vocabulary set.

Mark Savage

Correct, and I think you have the same desire to turn it into a language that begins with "recommend," and I will do that.

Steven Lane

Perfect. Clem, your hand is still up. Did you have more to say on that?

Clem McDonald

No, sorry.

Steven Lane

No problem. If we scroll down, the next one that we got is green, which I went ahead and added a little bit of meat to, was Item No. 11 having to do with the eICR standards. I put in an observation that the standards for eICR are identified in the ISA but are currently out of date and require some revisions to reflect the latest technologies. While CMS promoting and operability requires the clinician send eICR, they do not specify a particular technical standard.

There is a standard out which is widely deployed and it would be reasonable for that to be a requirement so as to avoid the current situation where vendors are developing custom solutions, leaving public health jurisdictions to have multiple different types of data flowing into them. So, lke does it surprise me that you have your hand up?

Steven Eichner

Thank you so much for that. I most certainly agree with your comments and observations and note that effect a little bit further down. Most of public health is orienting towards the eICR now standards and information flowing through APHL. So, that's really I think the disconnect might actually be more on the provider side. Right now, at the end if they're implementing something different, they may have some challenges in connecting to public health.

Steven Lane

I believe, and ONC can verify, that we are going to have the APHL/CDC team come and speak to us for a bit next week so that we can hear their specific recommendations for updating the data and the ISA and potentially making a requirement. So, again under the recommendations here, I suggested that we review those recommendations, which were going to be today, and now I think they're next week, and then tum those into more discrete recommendations. And then, here this is the first time we're including a policy lever, the idea that we could look to health IT certification requirements and/or CMS promoting interoperability requirements as ways to move towards a common standard for –

Steven Eichner



And hopefully, just a follow-up to that particular point; as publicly known, the IPPS proposed a draft rule or proposed final rule is outfor comment. I believe comments are due from the public on June 17, if I remember my dates correctly, with a statement in the final proposed rule that says basically they expect a final rule to be published sometime in early fall for effectiveness for the start of the new federal fiscal year. From a timeline perspective, if there were a way that we can accelerate this particular piece, there is an opportunity potentially to get feedback in this particular area included in the current cycle of rulemaking without requiring special rulemaking authority potentially, or waiting another year for it to come to effect to IPPS. If there's a way we can accelerate this feedback to the HITAC as an exception to our regular process or the regular calendar that may be helpful.

Steven Lane

Hans, your hand is up?

Hans Buitendijk

Yes. I have two questions. One is at it relates to the eICR standard that is used and is referenced in the ISA, do we want to be more specific and actually point to the latest version that is available as opposed to the one that's already in there? The second part is that there is the distinction between to make it required to support that particular standard is a certification program topic. How do we want to organize a recommendation that is specific to the ISA versus those ones that we recommend sooner rather than later go into a certification program?

Steven Lane

Again, I think we are going to hear from the APHL team about the updated eICR standard. I would hope that we could consider that as a formal and specific recommendation. The chat is still going regarding lab data. That's great. We do encourage folks to provide specific recommendations in that Google document for our consideration at a future meeting. We won't belabor the eICR item for now knowing that we have, or believing that we have a discussion on that coming up. The next one of these, which ranked as high, Steve, I think also relates to eICR. This is a comment that you put in on row 29. It doesn't have an item number, but did you already cover this? Yes, I think it is what we just discussed.

Steven Eichner

Yes, it is what we just discussed.

Steven Lane

Very good. That was it on the green items, that is to say the green items where we had commentary introduced there in the spreadsheet. We also have high priorities on item No. eight and nine, which has to do with all of the lab recommendations that we were just discussing. So, those will be the recommendations that come out of that. Then, that was it on the prioritized items from before. We had a yellow prioritization medium up on row two item No. one to do with care plans and chronic diagnosis or chronic disease management. Mark, I know that you have given this a lot of thought and have done some work on this in the fire space with the fast community. Do you want to make a comment about this or are you planning to put specific recommendations here?

Mark Savage



That is the plan, Steven. Abby has agreed to help us, Grace and me as well, so we will work and try to get together this week to come up with some specific recommendations. For background, the work that I did with the fire scale task force that was on the ecosystem use case Tiger team. We worked on a framework for exchanging, notifying members of the care team about updates to the shared care plan. It was not work on the content of a shared care plan itself. It was a model for a dynamic longitudinal care plan, so not plan of care, but actually care plan combining episodic care plans, the kind of thing that the patient experiences 24/7 but maybe not the specialist. It's important work, but it's on the exchange and used a subscription model so everybody could get updates in real time according to whatever their preferences might be. If that was useful here as well, I am happy to plug that in as well.

Steven Lane

Arien?

Arien Malec

Just as a call-out to the workgroup; in the recommendations column, it is going to be really easy for us to consider recommendations that are of the form, "We recommend that ONC update the ISA to do [blank]," and where blank is, track this specific use case, or track this specific standard, or track the HL7 accelerator, FHIR accelerator, and keep the standards attached to this use case consistent with that accelerator. If we have recommendations in that form, it's going to be really easy for us to turn those into recommendations text in the final recommendations letter.

Just to pick on Mark for a little bit, when we look at the Gravity project recommendations, if we can turn those into the form – and I know that Mark is already done a bunch of stuff in terms of the use cases – but if we can turn this into a recommendation of the form, "We recommend that ONC update the ISA to track the priority use case achieving health equity by design and list the standards and certification criteria tracked to the Gravity project accelerator inclusive of X1, X2, X3." That's going to be a really clean recommendation for us to include in a recommendations draft.

Independent of the priority matrix we are putting together, if you've got a specific item where you can tum that into recommendation text that follows the format, it is going to be much easier for us to turn that into recommendations that go into the final transmittal. To the extent that you have a heart that you can describe the outcome of the world that have a harder time tracking the ISA changes that are required or any other ONC changes that are required, it is going to take more conversation and discussion. A word to the wise is that if you can find solo a way of turning the recommendations column into text that matches that pattern, it's going to be much easier for us to turn that into transmittal text.

Steven Lane

Mark, your hand is up?

Mark Savage

May I ask quick follow-up question? Any guidance about what level of detail to include following that structure that you described?

Arien Malec

If you look at the format of the ISA, follow the form of the ISA unless you are making structural changes to what the ISA should be changed to. I think we may make some recommendations in terms of overall mechanisms in the ISA, but if you look at the rows of the ISA tables, they are usually of the form tracking, standard, or implementation guide X parameterized by use case Y.

Mark Savage

Okay. I'll figure it out and work to make less is more.

Steven Lane

Could we hand the mic to David McCallie, who is putting some thoughtful comments in the chat?

David McCallie

Hi. Thanks, Steven. I was on the suggestion from Arien just that that last suggestion I think makes a sense, but maybe a template or an example that would be done in a way that you would consider as ready for submission to HITAC would be useful to us. Just take one of them and work it through so we can cut and paste. I agree that most of the ones I submitted would quickly fall into that pattern. They don't need discussion. They just need to get into the ISA.

Steven Lane

Thank you for that, David, and perhaps with that introduction since we don't have other prioritized items that we are pushed to address next, why don't we go to your suggestions if, as you say, they are pretty straightforward? I think you did include both some observations and recommendations. This would get us started on item No. lucky 13 on row 14 having to do—you have a whole series of these having to do with supporting the various HL7 FHIR accelerators. Do you want to walk us through those observations and recommendations? It's row 14 for whoever is doing the display here.

David McCallie

All I did was to look at the HL7 FHIR accelerator program listing, the ones that are active and underway, then searched the ISA to see if there was any mention or reference to those programs. You see here bulk and Helios and Code X, and at least to the degree that I was able to master the ISA search tool, I didn't find any specific reference to this implementation guide work that aligns well with the priorities. My basic thought is, at least ISA should track these by listing them under the appropriate categories and priority use cases. So, it's not a terribly sophisticated thought but just doing the searching and matching.

Steven Lane

Anyone feel positive or negative about David's comment recommendation here?

Arien Malec

I think it might be useful if whoever is controlling the presentation can go to the work example that I pointed out here. If we look at the Helios project, I think the Helios project might well go under an existing use case relative to public health. Here, the example that I pointed to, if people can navigate on their own to the text in the chat? Under the prioritized use case referral to a specialist, status update, request, status updates, outcome, and then you can see that we list in the ISA the specific either implementation specification standard, vocabulary standard, emerging implementation specification. And so, here we list the consolidate CDA and we list the 360 X project.





If we take that and apply it to the Vulcan project, this is about supporting clinical research, so the use case here would be something on the order of supporting clinical research. Let me see quickly if there is already a clinical research—there is a research tab. If you go down to the research tab, there are no existing use cases associated with collecting research data for a real world clinical trial. So, we might want to create a new prioritized use case under the overall research category and then list the Vulcan implementation guide as an emerging specification under the ISA. That would be an example of the way we should track the Vulcan into more specific guidance for the ISA. Does that make sense?

Mark Savage

Do you want us to do that, or is that an ONC, ISA expert's job? I am just unclear on how far we go in trying to design ISA.

Arien Malec

I think to the extent that we can make ONC's job easy, if it is really obvious, then we should contemplate making ONC's job easy. A recommendation on the order of we recommend that the ISA track the use case collecting data for research, collecting data for translational and clinical research inside EHRs, and then we recommend that ONC include the appropriate implementation guides and standards tracked by the Vulcan project. This might be the right level of detail. I agree with you that we don't necessarily need to go item by item, but I think we need to give ONC enough hints to be able to figure out how to track and prioritize. Otherwise, we are throwing the work over the wall to a thinly-stretched ONC team.

Mark Savage

I can do that for the ones that I have suggested here. My attitude about the ISA is that it is not a value judgment. Being in the ISA doesn't mean that it is a standard that is going to get implemented or should be implemented or even as a very well-done standard, but at least it should be available for people who are trying to find what is going on in the space.

Arien Malec

That is exactly right, to the extent that something exists should be catalogued. And then, in the areas that we prioritized high as we have, we can contemplate going above and beyond and thinking about how we actually drive ISA standards advancement. To the extent that we can make a clean recommendation that the ISA should track X, I think we are doing at least that cataloguing job a service.

Steven Lane

And rew Hayden made a comment that there are two research sections in the ISA. Do you want to flesh that out?

Arien Malec

I'm having a hard time tracking that.

Andrew Hayden:

The ISA is complicated to explore. It is not a simple two-dimensional model.

Steven Lane



Yes, and there is not a lot of cross referencing, which I think is what some of the comments on the structure have gotten to. Thanks, Andrew. David, again if you can take a stab at fleshing out those recommendations for items 13 to 15? Let me see. Does the same apply? Your items 16 which has to do with CARIN. Is it similar or different?

David McCallie

It is essentially the same. I think the CARIN work on supporting a trust framework for identity proofing is actually an HL7 accelerator. I think that it may be very similar to these here, but again I couldn't find any mention of it using the search function even though I believe some HHS entities are involved in that work. It is just not listed as best I could tell so same problem. It ought to be listed. I also think it is really valuable work. It clearly falls under the priority use case of consumer empowerment, the idea that you could pick your own identity validator and have that be trusted by whichever organization you request your data from, be it a provider or a payer or some other kind of aggregator. That seems highly valuable.

Grace Cordovano

I think we should make a recommendation to have references in ISA to all of the HL7 accelerator programs as an overarching recommendation and then potentially work with the leads in HL7 who can help fill out just the categories within ISA to make is more robust. We could take a first pass based on what we know. To Arien's point, let's make it easier for ONC, but in general we've already identified the accelerator programs as high-priority, and they should all be included in ISA.

Arien Malec

That is a great point. We could make a generalized requirement. We recommend that ONC work with HL7 and other SDOs to automatically track in the ISA prioritized accelerators. That might also go for—there are a whole bunch of HL7 accelerators that might also go into some of the work that ONC is engaged on with FAST. That also might go into prioritized use cases in NCPDP or IHE or any of the other SDOs where there's coordinated prioritization work. That work should automatically be tracked in the ISA.

David McCallie

I like that idea, although maybe even a more generic thing is for the ISA to have a submission process analogous to the – what do you call it, on deck or whatever it was for the USCDI – where vested entities can push their ideas for consideration. I would put the burden on HL7 to say, if you think your work should be mentioned in the ISA, there should be a submission process to describe it and categorize it so that ONC can evaluate it and add it if they agree.

Arien Malec

No doubt, there is a set of recommendations that we can make about the workings of the ISA itself. Again, to the extent that we can do thought now of how to turn that into recommendations text—I think those are going to be easier for us to contemplate and turn into formalized recommendations. I have heard, for example that we need the need for crosscutting outcomes-based labels that will allow you to index into content plus transport plus vocabulary.

I think we have already made the recommendation about automating some of the cross-mapping in areas where there is already work in accelerators. To the extent that we can just take some of those higher-order



recommendations and turn them into recommendations that we can contemplate going into to our recommendations letter that would be fantastic.

Steven Lane

Steve Eichner, your hand is up?

Steven Eichner

Yes. Thank you. I believe there actually already is a process for submitting materials for ISA that is actually available year-round, and the ISA online version is maintained on a much more regular basis with an annual published copy coming out sometime in the spring.

To build on the idea of commonalities across the ISA and looking at linkages between entries, another key component as we're seeing with things like eICR now and eICR that morph with other tools is that there are common, back-end apps that are supporting these interface standards. So, it would seem to be another dimension that we might want to consider as a recommendation is a way of identifying what the mechanisms are in that census, whether there's an app, a back-end app that's being used and where it's being used across different ISA standards. So, so that would help me to say, yes, you the provider can use the same back-end app with some modifications to do A, B, C, and D.

The provider could also look at the ISA and say, "Oh yes, you're right. We can, and that would be easier across the board and help resolve some of the linguistic differences about eICR is calling something eICR now and then workers calling it a back-end app and Stater is calling it something different. So, it's a way of harmonizing language between without having using the same remaining loose with the exact same term within each of those verticals. Thank you.

Steven Lane

Hans?

<u>Hans Buitendijk</u>

Yes. On the comment of submitting to ISA from the SDOs, I really want to support that SDOs that there is a process that's clearly defined between ONC and the SDOs that they can more easily submit because we know the source and we know where it is coming from. Therefore, it should have a fast track to get them in and that it is triggered by publications or key work efforts that are in flight because today what we do see is that the ISA is not up-to-date. Even though it can be updated more frequently, it is not as up-to-date with what is actually available from the different organizations.

That would be tremendously helpful for everybody understand what's out there, so I fully support a recommendation on the mechanics to improve on that flow. It has been debated in the HL7 as well to consider that. I think between ONC and the SDOs there's some discussion around that that will be fairly easy to achieve.

Steven Lane

I am trying to capture some of these comments in the recommendations column F in the spreadsheet with the anticipation that those of you who have been making these recommendations will go back and flesh those out and make them more actionable.





Arien Malec

Steven, while you are doing that fantastic work, one other that I heard – and I forgot from whom; now my brain is gone, it will come back to me – I am just trying to track these larger, higher-orbit recommendations. Now, I've got it. We should track these specific rather than what is federally required. We should track the specific program because we are going to have multiple programs. We should track the specific program under which a standard or implication guidance is required.

Steven Lane

All right. We are coming up on public comment, and I do not see any other hands raised. There have been a number of comments in the chat. Andrew Hayden, do you want to put voice to any of the great material that you have been providing us?

You are a quiet man today. All right. Clem and Hung have continued the dialogue with regard to labs, which we hope to see instantiated into some more specific recommendations text in that document. So with that, perhaps we can shift to public comment?

<u>Hans Buitendijk</u>

Steven, just a quick note?

Steven Lane

There you are. There's your hand. Sorry, Hans.

Hans Buitendijk

That's okay. Do you want me to create a new row in the table on the process topic of how SDOs and ONC can improve submissions and staying up to date?

Steven Lane

Yes, I think that would be wonderful. I was taking notes in David's item, but that really warrants a row. All right.

Public Comment (01:24:08)

Mike Berry

All right. Thank you, Steven. We're going to now up our call for any public comments. So, if you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone, only press star 9 to raise your hand, and once called upon, press star 6 to mute and un-mute your line. Let's pause for a moment to see if we have any public comments. I am not seeing anything, so I will turn it over to our co-chairs.

Steven Lane

Great. So David, I think you talked us through most of your items. You did include one more which you had discussed briefly the other day about this non-health IT provenance standard. You have called that out, you've made some observations, and suggested the recommendation that ONC should add this emerging standard to the relevant section of ISA to deal with provenance. Does anybody have questions about that or do you want to add to that?



David McCallie

Let me explain in case it is unclear. A number of the major content vendors, Adobe, Microsoft, others, are collaborating on a new provenance standard initially targeted at ensuring that news sources can be verified to be trustworthily mapped back to the news organization that produced it. Can you trust that this hasn't been tampered with?

My thought was the ONC, even though in healthcare we have a specific set of healthcare-specific provenance tracking tools, those are not widely deployed in browsers and PDF readers and things like that. Whereas, this work from the C2PA group is likely to become standard fare on everyone's smart phone and desktop. So, the thought would be that maybe healthcare organizations should look to these commercial standards at some point in the future to digitally authenticate their works so that a standard PDF reader, for example, could verify that is has not been tampered with since it left the Mayo Clinic or Partner's Health or whatever. So, that is the thought. Should it be tracked? If it becomes publicly accepted in the commercial domain, healthcare organizations should take advantage of it.

Clem McDonald

David, could you send that to Hans? HL7 should know about it because there's no way we're going to dominate the universal codes, standards in healthcare.

David McCallie

The link, I think is in the spreadsheet, but Hans, if you want more, it is C2PA. I do not know how well it is going. I just know that major organizations are behind it and the spec seems very thoughtful as you may expect. Whether it gets adopted or not, it's maybe a little early to tell, but it should certainly be tracked.

David McCallie

It may be important to get it in some of the FHIR activists, too.

David McCallie

I will bring it up with a couple of the security, the folks that manage consent and provenance and otherwise the security group, et cetera.

Steven Lane

I will point out that at Grace's suggestion we have added a new column, column D to the spreadsheet, which is entitled Background and Supporting References. I just actually grabbed the C2PA link and put it in that column, on your Item 7, David. I think that was a great suggestion that Grace had, and Grace, maybe you want to take a moment and explain what you were thinking there?

Grace Cordovano

Sure. I would be happy to. Thanks, Steven. As I was going through all of the different ISA topics that we are considering, I am not an expert in all of the different fields and topics that were suggested. So, I found myself trying to go back, Google, search, read. I couldn't tell if I was missing things. Some of the descriptions and latest work seemed vague and broad. I couldn't tell if it was in startup mode or if there was more. I didn't know who a project lead would be or a point person would be. So, I reached out to ask if people could put in any pertinent materials, references, or project updates, blog pieces, websites to work



that would help point and bring people up to speed who may not be experts in all the different topics because if you are not an expert, you cannot fairly weigh priorities. So, that was my thought process.

Clem McDonald

Great thoughts.

Steven Lane

Absolutely, and David, I just threw on a couple of words on your item No. 17 and put into the "Recommend that ONC," format. I think we may have our first approved recommendation. Does anybody have any concerns about that one, the C2PA? What we want to do is we want to knock these out and return the recommendations. I guess we were using purple last time, so we will do that again once they are finalized.

All right. That brings us to the top of the hour. Thank you, everyone as always for your time and attention. Next week, as mentioned, we will be hearing actually two presentations. It will be fast and furious, so hopefully Grace et al will be presenting on the desirable functionality to support individual corrections to their health record data and the CDC/APHL team will be presenting on their eICR recommendations. We will hear those and discuss them next week and then come back to work on our spreadsheets the week after, which will be the 17th.

Arien Malec

Just again, just as a comment, we're going to be taking probably the 7th and the 14th focused on the final recommendations. So, anything you can do in the spreadsheet the next couple of weeks is going to be much easier to incorporate into the final recommendations. So, don't delay.

Steven Lane

Very good, all right. Thank you all, and we will see you next week.

Arien Malec

Thanks.

Adjourn (01:30:47)

