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

May 24, 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 Nursing	Member
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 Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
John Kilbourne	Department of Veterans Health Affairs	Member
Leslie Lenert	Medical University of South Carolina	Member
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 Medicaid Services	Member
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards and Technology	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	ONC Staff Lead

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

Michael Berry
Hello, everyone, and thank you for joining the Interoperability Standards Workgroup. Before I begin roll call, I would like to remind everybody that your feedback is always welcome, which can 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. I am now going to begin roll call of our workgroup members, so when I call your name, please indicate that you are here. And, I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Arien Malec? Kelly Aldrich?

Kelly Aldrich
Good morning, everyone.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
I know Thomas Cantilina cannot join us today. Christina Caraballo?

Christina Caraballo
Good morning.

Michael Berry
Grace Cordovano?

Grace Cordovano
Good morning.

Michael Berry
Steven Eichner?

Steven Eichner
Good morning.

Michael Berry
Sanjeev Tandon?

Sanjeev Tandon
Good morning.

Michael Berry
Raj Godavarthi? Jim Jirjis? Ken Kawamoto? John Kilbourne?

John Kilbourne
Good morning.

Michael Berry
Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
David McCallie? Clem McDonald? Mark Savage? Michelle Schreiber?

Michelle Schreiber
Good morning.

Michael Berry
Abby Sears? And, Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Good morning to everyone, and now, please join me in welcoming Steven for his opening remarks.

Steven Lane
Actually, Arien is here too, so we are in good hands.

Arien Malec
The morning reboot.

Michael Berry
Good morning, Arien.

Co-Chair Remarks (00:02:01)

Steven Lane
So, once again, thank you, everyone, for joining us this morning and for your time that you have invested getting us to this point. We are very much on the home stretch, working on our final recommendations to prepare to deliver to the HITAC next month, and we do not want to waste any time today because there are just a lot of recommendations that have been finely crafted for your consideration today, so lots of you

are going to get to hold the mic. We can go through the slides quickly here. Next one up. Can we proceed on the slide deck? There we go. These are the HITAC priority use cases that we have been presented with to focus on supporting public health, interoperability, privacy, security, and patient access. You will see that throughout the comments that we have today. Next slide.

And this, of course, is our task, closing in on a final set of recommendations regarding the ISA to address those high-priority use cases, and on the next slide, this is how we are going to organize our initial work here. Grace, Christina, Mark, Hans, and David are going to present some recommendations that they have been preparing for our consideration, and then we have a bunch of lab recommendations, and Hung Luu and Hans will hopefully walk us through those, so we do not want to waste any time. Do you have anything to add, Arien, before we jump right in?

Arien Malec
No. Let's get to it!

Review of Recommendations (00:03:39)

Steven Lane
Okay. Well, Mark, I am glad your car avoided the street sweepers there in Oakland. It is a dangerous world out there. Great. Grace, I heard your voice. Are you prepared to take us on a trip through Item No. 12? Let's have somebody pull up the spreadsheet here so we can make reference to it, and I want to remind everyone that we have tried to separate things out. Grace's recommendation did have some structural recommendations as well as some content recommendations. I think most of the structural issues have been pulled off into another set of recommendations that Christina will be taking us through, but Grace, why don't you share with us how you have crafted this recommendation based on the presentations that we heard a couple weeks ago?

Grace Cordovano
Okay, wonderful. Thank you so much, Steven, and I apologize, I am on my phone. I do not have a solid internet connection. They are working on power lines in my neighborhood after a really bad storm, so, thanks for your patience as I try to work through this. I am focusing on the **[inaudible] [00:04:43]** HIPAA right to request corrections to one's medical record, and as Steven mentioned, there were some structural recommendations that I had included in this, but they are really also going to be touched on in the recommendations **[inaudible]** as worked on as well. Really, the point of emphasis here with respect to…

Steven Lane
Grace, your audio stinks, so why don't we pause and see if there is anything that you can do to improve that rather than painfully go through that? You might not be hearing me at all because it sounds like we might have lost you. I would suggest that we hold off on Grace's work for a few minutes and jump ahead to Christina and No. 18 just so that we can keep rolling along. I will reorganize the screen as we do that so that we can see this a little bit better. Christina?

Christina Caraballo
Sorry about that.

Steven Lane

You are good.

<u>Christina Caraballo</u>

Okay, perfect. So, if we are taking down to Recommendation 18, I did a little reformatting here just to orient everyone, and what I did in 18 was put all of the content updates, so I kind of took 18 and 20 and pulled information from 20 that was more like structural content recommendations for the overall ISA, and put them into 18. In 20, I believe it is still crossed out for reference so people can see what I pulled up if you would like to reference it, but I am going to jump right into going through the recommendations that we have so far, and I did work with Mark and Grace a little bit on Friday as well to incorporate some of their content and overall structure of ISA recommendations into this one, which is reflected in Recommendation 1 under this, which is to change the specialty care and settings to use cases under the ISA content section and include use cases in both 1). A tab under the ISA content, and 2). As reference editions.

This was kind of a bonus recommendation that was put in over the weekend. I was personally trying to find these specialty care settings and was having trouble navigating it, and realized that these specialty care settings/new proposed use cases are not in the reference edition or in the overall navigation, so this is where this comes in. And, I think this is going to be really important for one of Grace's recommendations that is not included yet, but off to the side, Grace had put in our recommendation, which I think has disappeared by minimizing the screen, so just bear with me as I go by memory, but more to have a way to find things more easily.

It is really hard to sift through ISA and figure out specific use cases, or purposes, or where different things may align and overlap. So, instead of having that recommendation incorporated this round, we think that adding this use case interactive place in ISA will start to address this concern because it is going to give bundles or packages of standards for use-case-specific needs, so that will be kind of Round 1 of our recommendations, and that is why you do not see Grace's other recommendation reflected in here. I am happy to talk through anything else or address concerns, but that is the intent of this one.

The second recommendation here is that ONC add a tagging and/or prioritization schema to highlight use cases that ONC believes warrant particular focus on national priorities, so, some kind of starring or flagging system. In this use case section, we are recommending that the ONC expand the use cases. At a minimum, we are recommending that ONC expand to include the use cases identified by the HITAC in September of 2021. We also are recommending to add a few additional use cases, which you will see as A and B, which include achieving health equity by design, patient requests for correction, price transparency, and all of the FHIR accelerator use cases. If there are any others that were in our overall recommendations that I have not captured, please draw that to our attention now as well. I almost just added public health right before the call as Steven was putting up the priority slides, but that is one of the HL7 FHIR accelerators with HELIOS, so I am assuming that was covered indirectly.

So, here, we have those recommendations. Moving on to the next one, we recommend that ONC review all the high-priority use cases submitted via the USCDI submission process and include relevant information fields from the USCDI submission form, such as links to project pages, overviews that people have submitted on the importance of the use cases, etc. Sharing this information in ISA will enable communities of interest to more efficiently and effectively engage in identifying gaps and advancing interoperability needs for high-priority use cases regardless of USCDI level or inclusion. Part of this was just to create a platform

that is very transparent. One of the intentions that we had with USCDI originally was to have a place where people could start really contributing to high-priority interoperability needs, and I think that this could potentially be partially shifted into ISA because it is more expansive than just the USCDI, so that is kind of the catalyst of that recommendation.

The next one is that we recommend that ONC add challenges to the limitations, dependencies, and preconditions for consideration with guiding text to encourage capturing information that aligns with the USCDI submission form. For example, any restrictions on standardization and use, privacy and security concerns, and implementation burdens you will see very heavily reflected, incorporating a lot of the really robust data that is captured in the USCDI submission form in these recommendations.

The next one is that we recommend ONC add accelerator to the standards process maturity classification. This would update the ISA to include four classifications. For reference, right now, classifications are "final," "balloted," "draft," and "in development," and we are proposing to add "in development, noted as accelerator." The next one is for ONC to include in the ISA the USCDI versions a standard is mapped to, where relevant, where a standard implementation guide or similar is required by federal programs. And, the next is that ONC expand the federally required characteristic beyond a simple yes/no to list federal programs in which an ISA item is named and/or required, including specific certification criteria. And then, the next one is that we recommend ONC provides the source that can be reviewed for each of the maturity adoptions of standards. I think this was edited as I was reading, so, sorry, I just got a little disoriented as the screen was moving around. I had a note in here. My proposed recommendation just disappeared in front of me. I do not know what just happened.

Steven Lane
I do not think so. I only took out my own.

Christina Caraballo
Okay, hold on.

Steven Lane
I apologize. I am just trying to help us clean as we go.

Christina Caraballo
You are fine. I was unclear on this next one. Steven, stop messing with the Google Doc while I am reading. Thank you very much. Hold, please. I might have it. I was doing my own little spellchecks in here because I am an awful speller. I would have to find it. Hans, this was one that you had added, and I revised it.

Hans Buitendijk
Correct.

Christina Caraballo
You guys are going to have to give me a second. I am going to look and see if I have it anywhere.

Arien Malec
Is the intent to provide the evidence?

Hans Buitendijk
That was the original intent when I wrote it down and talked about it, to better understand that if there is a statement that is highly adopted, still immature, or whatever the statement might be, there is a better understanding of what that is based on and what drives it. Is it a survey? Is there a number of certified systems in the chapel that then reflect, then, a percentage of likely users? What is it that leads us to say that that is why this is high, low, medium, whatever?

Arien Malec
Got it. Hans, there is one thing that is tripping me up, which is "accelerator as a standards process" maturity classification. I think about an accelerator that could bring a standard all the way through to final. I wonder how you think about that, because you have been closely involved in the standards community.

Hans Buitendijk
When I read that, I was not sure how that would help clarify, other than awareness that that is the track that it is on, so there is high visibility, high focus, but being part of an accelerator does not necessarily mean that it is more or less mature, so I think those are separate parts, so I can see value for denoting something, and perhaps also indicating which one, and in a number of times, that might already be happening, but to make it a level of maturity would be a challenge because that really is not the function of being an accelerator. It just means it is hopefully going to go faster.

Arien Malec
Yup, that is my take as well.

Steven Lane
Christina, FYI, that recommendation was still there. You had it at the bottom, but you had it marked through, so it did not disappear, you just duplicated it, but that is fine. Whoever is doing the display, can you pop out and back in or refresh the screen? You are not showing the latest. There you go.

Christina Caraballo
I did find this. I wanted to make sure. I had been a little confused on this one.

Steven Lane
Go back to 18. Okay, now it is in there twice, so I will remove the second one, just so we can be clearer.

Christina Caraballo
Yeah, and what I had just put in, I revised this one a little bit, and based on this conversation, it might not have captured it, but it was basically a recommendation that ONC review how the maturity and adoption level are determined and provide guidance on how specific ISA items are categorized with links to any relevant resources used in the assessments.

Steven Lane
So, get us back to 18, whoever is doing the display. Terrific, all right. I think we can see almost all of it. Let me just shrink C a little bit again. All right. So, we are looking for questions, comments, votes of confidence in this list of recommendations, if you can now all see on the screen.

Arien Malec

So, I think Hans and I are proposing that we remove the "accelerator as a standards process" maturity classification." It may be a relevant piece of information to add into the ISA, but it is an orthogonal access to standards process maturity.

Steven Lane

Christina, are you comfortable with that?

Christina Caraballo

I was thinking that…

Steven Lane

They are suggesting that the new one that you put in here that I will change the color of not be necessary.

Christina Caraballo

Yeah, I was following. I was just thinking through it. I think we have some hands up.

Steven Lane

Okay, well, think about that. David?

David McCallie

I think the fact that a use case is being addressed via an accelerator is a substantial flag of interest and should be tracked somewhere. I agree that it is not a definition of a standard maturity per se, but I would hate to see that flag lost. I am not sure exactly where best to put it.

Arien Malec

So, David, maybe the recommendation is that ONC add an indication if a use case is being addressed through an accelerator.

David McCallie

Yeah, find the right place to put it, because at least the way accelerators are currently constructed, they reflect a broad engagement of community, not just a single SDO, but, in fact, entities in the real world doing real work, and that is a really important…

Arien Malec

Important thing. And, I think we are making recommendations that they be included in the highlighted use cases as well, which, again, is a good place to raise their priority, but then, maybe also recommend that there be some indication that it is covered through an accelerator.

Steven Lane

How do you like that phrasing, gentle people?

Arien Malec

I like it, but I would not confine it to HL7 FHIR.

Steven Lane

Okay.

Arien Malec

[Inaudible – 00:21:07] an SDO accelerator.

David McCallie

Right. There could be others, like IEG and other entities, that are profiling bodies that address these concerns.

Arien Malec
And then, we would want to strike the second sentence.

Christina Caraballo
So then, we are going to take out the recommendation in red? This makes sense.

Steven Lane
No, no, I think we are going to leave it modified. Update the display, please, presenter. Thank you.

Hans Buitendijk
It is visible.

Steven Lane
Back to 18. Sorry about that. It seems like every time you update, we get lost. I apologize. All right. Other comments? Steve Eichner, you have made a number of comments about public health.

Steven Eichner
Yes, and just to re-emphasize the discussion in chat, public health does need to be included in the list of priority areas, and looking at that bolded list, a number of the listed areas touch on public health, if not being completely underneath it, so I wonder if there is a way of denoting that almost as a cross-reference approach. Also, thinking about the way USCDI Plus may be developed, again, as a cross-cutting intersection, but I do not want to lose public health.

Steven Lane
Again, as I put in the chat, Steve, ONC has already identified use of technologies that support public health, interoperability, privacy and security, and patient access, so we either should add those to this list or take out the ones that are already acknowledged.

Arien Malec
Steven, I made the edit to SDO. I think what is going on is if you are in the cell… Oh, there we go. So, if you are in the cell and make the edit, but then do not hit return, it does not reflect.

Steven Lane
Right. So, did you make an edit?

Arien Malec
I made an edit; you just made an edit. It flipped back. It is all right.

Steven Lane
Sorry, I got out. Go ahead, it is all yours. David?

David McCallie
Yeah, just a little bit of a picky point about priorities. I am a little bit less clear: Are we asking the ISA to identify that a use case is a priority, or are we just picking some use cases that we want to make sure have a place in the ISA?

Steven Lane
Both.

David McCallie
Well then, how do we timestamp the priorities? Because priorities change.

Steven Lane

I do not know that we need to comment on that, but I think the point is that we have a recommendation here to have a more comprehensive list of use cases, which we call priority use cases, but then, a prioritization schema amongst those. That is the second recommendation.

David McCallie

Well, I would suggest that the prioritization schema is orthogonal to the list of use cases. Again, what was a priority in 2009 when this all got started is different in 2022, and will be different in '25.

Steven Lane

Agreed. How can we modify the language to make that clear?

David McCallie

I am not sure. I think the addition of these priorities that might be missing makes a lot of sense, but that does not mean they are the prioritization. Precision medicine may be a priority, or population health. Those are gigantic, broad notions researched. My gosh, it is kind of meaningless to say that is a priority.

Arien Malec

I do not think we are saying that they are priorities. So, I think what we are saying is these are high-level use cases that are cross-cutting to the rows in the ISA, and that there be a place where one can see all of the content of the ISA that is cross-cut by the use case, and this is exactly the reason why we took out the word "priority" from "priority use case" when we discussed this last time. So, I do not think we are making an assertion of prioritization. I think what we are proposing to ONC is that it is useful to have a view that somebody might want to look at that lists all of the stuff relevant to a particular area.

David McCallie

Yeah. A given administration will have their priorities that will involve where they put their policy work, their funding, etc. That is independent of the list of things in the ISA.

Arien Malec

That is right. Are you recommending changes to what is here or additions to what is here? Because I think what we are saying is to change specialty care and setting to use cases, at a minimum, include the priority use cases voted September 9th, add the additions and accelerator use cases, and add a tagging and/or prioritization schema to highlight use cases that ONC believes are not a particular focus at the present time.

David McCallie

I am good, Arien. I am good. At the present time, as long as that is tracked, is this the notion that priorities shift? They cannot all be a priority at the same time.

Arien Malec

Yeah, classic prioritization trap. All right.

Steven Eichner

And, priorities to whom in terms of looking at size and scope?

Arien Malec

But, this is up to ONC. This is ONC's list.

David McCallie

Yeah, it is an administration's decision as to what their priority is. Got it. They will figure it out. I think we have registered the concern to make it clear that you cannot have everything be an equal priority. Otherwise, there is no priority.

Steven Lane
Al Taylor?

Al Taylor
I wanted to add something and actually ask a question about what this recommendation is going to do. Is it the assumption that once these use cases are recommended, some of which are priority/high-priority, is the recommendation going to assume that ONC is going to identify or research each of these use cases and then sort through all of the ISA entries to figure out which of each of the interoperability needs is associated with each of these use cases, or is that going to be proposed by this body or just someone else in the general public as far as some advocate of those use cases?

Arien Malec
Al, I think right now, what we are saying is that a view where one can interleave across terminology, content, transport, and administrative standards to address a particular topic area is a useful view. I think you are asking important questions about the process by which that view would be updated, but take this right now as a reflection that it is a useful view and we want more of it.

Al Taylor
I guess it might be helpful for me to explain why I asked that question. In order to tag these pages, each page has to individually be edited to associate a tag with it, and so, we are looking at 10-plus use cases here that are not part of the current specialty care areas. Each page that might be associated with each use case would have to be manually edited and tagged with each of these use cases as appropriate. Multiply that by the number of hundreds of… I am just asking. If that is the ask, that is the ask.

Arien Malec
So, I think a useful selection of technology that allows for a tagging access for information and allows for views to be assembled from that tagging access could address the problem, as opposed to manually maintaining an index, and I get it. If the intent here is to manually maintain the index and there is a human at ONC who has to manually maintain that index, that is going to limit the applicability of these cross-cutting areas.

Steven Lane
Hans had a suggestion to remove the word "high," as I have highlighted in red here, from the fourth recommendation.
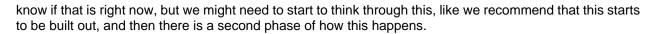
Hans Buitendijk
Actually, I was going one step further, also the word "priority," so that we talk about use cases that came in from USCDI, use cases that came in from other places, and orthogonal to that is where there are priorities to priorities, but that recommendation seemed to be appropriate in regards of the "priority," however we talk about it.

Steven Lane
Any objection to that change? Okay, Christina?

Christina Caraballo
No objection. I was just going back to Al's point or question. This does raise a concern. We have a pretty big list on here, and I think they can all be argued that they are definitely a priority. Then, how does ONC then go and make sure that we have these nice bundles of use cases that are easy to navigate within ISA and gets us to more of a place where we can go in and have those standards all tagged in nice packages that we would like to see, and what is ONC's capability in the next year to be able to build this, and then, what are our real priority recommendations based on the amount of work that we are asking to do that I think is really important? And, this also goes to the heart of Grace's point, where we need to have a way to navigate ISA for these specific use cases. So, do we then make an exercise to order them? And, I do not

know if that is right now, but we might need to start to think through this, like we recommend that this starts to be built out, and then there is a second phase of how this happens.

Arien Malec
Yeah, it feels like what we are saying is we recommend that ONC review the human factors associated with the ISA search and consider technology and usability changes to make the ISA more useful for ISA users. I am trying to phrase this in a way that is not making recommendations to ONC to pick certain technology or to add certain features, but I think what we all have experienced is that the usability of the navigation associated with the ISA right now is suboptimal, and I think we just had a conversation that said that the process that ONC uses to update the ISA is pretty manual and onerous. Those are interesting reflections. It might be useful for us just to make a recommendation about the overall usability and human factors associated with the ISA and for ONC to look at whether it is possible to change the usability/human factors, which might include a technology change, but that is really not for us to say. Does that make sense?

Steven Lane
I think so. I think we have given this enough time. I do not think we are prepared to tackle how ONC goes about tackling these recommendations or addressing them. One thing I will note, Christina, is that down in No. 20, we had a recommendation that the ISA include the prioritized use cases and the FHIR accelerators. I am assuming we can take that out of 20, as we have now kind of mentioned it in 18. Is that true?

Christina Caraballo
Hans, are you okay with that?

Hans Buitendijk
I missed the one that was going to be moved or removed from 20.

Steven Lane
It was "ISA includes all the prioritized use cases across all HL7 FHIR accelerators, as well as the Paseo project."

Hans Buitendijk
Yeah, it seemed that that was not totally addressed in 18 explicitly to say, "Look at these accelerators to pick it up." So, there are references in 18 to this. That is why I think it landed here, to not have the individual references that David McCallie had…

Steven Lane
Okay, so you are saying leave it in 20 so we do not need to re-reference it in 18.

Hans Buitendijk
Correct, and then we can come back to 20 and the other ones to make sure we have the full list.

Steven Lane
All right. Anything else, then, with regard to either 18 or 20? Would we like to finalize 18? Going once, going twice? All right.

Arien Malec
I am putting a recommendation along the line of what I just noted. I am happy to delete that if the workgroup thinks that is not useful.

Steven Lane
You want to highlight it, Arien?

Arien Malec
I am just about to put it in, just to basically redesign the usability factors.

Steven Lane
Maybe put it in red.

Arien Malec
Why don't you keep going, and then we can circle back?

Christina Caraballo
Hold on. I think we need to look at I and J really quickly because that is not finalized. I think J was my revision of I, and you can see my note.

Steven Lane
Ah, yes, they are sort of duplicative. Can we just go with J and remove I, or is there some we should pull over?

Christina Caraballo
Any objections? Does J capture the intention of I okay?

Hans Buitendijk
Yeah, I think they can be merged. I think J is fine because you are putting in there any relevant resources used in the assessment, and that is essentially what it is trying to get at.

Steven Lane
Arien, are you in that cell? I think you are.

Christina Caraballo
I am in here. I will delete I.

Steven Lane
Perfect. Delete I. All right, I think Arien got pulled away. No, he is back.

Arien Malec
Sorry, I was on mute. I am in here. Do you want me to delete I?

Steven Lane
No, I think it is done.

Christina Caraballo
I already did it.

Arien Malec
It is just that I am in here as well, making edits, and we do not want multiple edits.

Steven Lane
Copy your edits, Arien, so you do not lose them because you may lose them as soon as you hit return. All right, we are being a little inefficient here. Okay, you threw in the K?

Arien Malec
Sorry, I threw in the K, and mine overwrote Christina's. So, we want to delete I as well?

Steven Lane
Yeah, we want to delete I, and then we will renumber real quick.

Christina Caraballo

Yeah, I am getting out of here.

Arien Malec
I got it.

Steven Lane
Sorry, folks. We try to be more efficient than this. Okay, so, K is the new one. "We recommend that ONC review the usability and human factors of the current ISA content and assess human factors and technology changes that might be warranted to improve the overall usability of the ISA." All right. Anything else on this list? It is an amazing set of recommendations, which really plumbs deeper than this workgroup or its preceding taskforces have gone in the past. Anything else? Terrific. All right, now, let's go back and see if we can go back up to Grace's, No. 12. Grace, how is your audio? Are you with us, Grace? Maybe not.

Grace Cordovano
Can you hear me?

Steven Lane
There you are.

Grace Cordovano
Wonderful. Okay, thank you so much. All right, take two on HIPAA right to request corrections to one's medical record. I have four global recommendations and two granular. I will go through them quickly. The four global recommendations: 1). We recommend ONC ensure that the general public and healthcare sector recognize that the HIPAA right to request corrections to one's medical records use case broadly applies to all information in the designated record set in all EHIs. 2). We recommend ONC establish a certification criteria to enable the HIPAA request for correction amendment process via patient access FHIR API. 3). We recommend ONC ensure that patients, at minimum, can make their corrections through the patient access API for all data available through the API. 4). We recommend ONC collaborates with the HL7 Patient Empowerment Workgroup to help address gaps in standards, capabilities, and implementation of patient requests for medical records corrections.

Those are the four global recommendations based on the presentation and also the corresponding policy levers that you can find to the right in column G, and on a more granular level, there are two recommendations. We recommend adding patient requests for corrections to the services/exchange consumer access and exchange of health information and any corresponding terminology and exchange standards, where applicable. Similarly, we recommend adding patient requests for corrections to administrative transactions to support clinical care, and again, any corresponding terminology and exchange standards.

Steven Lane
Thank you, Grace. Very tight and very well spoken. Let me just ask about the one at the top here about including the use case. We have already captured that up above now, correct? So we can get rid of that one.

Grace Cordovano
That is correct.

Steven Lane
Okay, that one goes away. All right. So, now we have these specific recommendations.

Arien Malec
Sorry, to be clear, Steven, are you in this?

Steven Lane

I am out.

Arien Malec
Cool, cool, cool. If people are in the cell and making edits, we need to call an audible

Steven Lane
Yeah. Michelle?

Michelle Schreiber
Can you go back up to where we were? Because I had a specific question about the language. I think it may have been higher up. And, Grace, it was about patients being able to make correction directly through an API. I am all in favor of patients being able to request correction, but I want to make sure that we are not giving patients the ability to go into their electronic medical record and change it without that being reviewed.

Grace Cordovano
That is correct. Patients are not going in to make their own corrections, but it is to request the correction.

Steven Lane
So, I think No. 3 does say "make their corrections."

Michelle Schreiber
Yeah, it was No. 3. That was the issue. It says "can make their corrections." I would hope it is "make a request for their corrections."

Grace Cordovano
Thank you for pointing that out. Yes, we can clarify. I agree.

Michelle Schreiber
Okay, thanks, Grace.

Steven Lane
All right. Is that okay? Do you like that?

Michelle Schreiber
Thank you.

Steven Lane
All right. I will just pop in and out unless somebody tells me they want to go in and work. That way, we will not step on each other. Hans?

Hans Buitendijk
Thank you. On No. 1, in that same list, at the end, a small wordsmithing. It states "and all EHI." That might give the impression that there is a different data set than designated record set. Perhaps we should say "and therefore all EHI" because EHI is a subset of designated record set. It is not a new, separate set.

Steven Lane
Okay. Ike?

Steven Eichner
Yeah, I was going to reemphasize that point because for public health as a hybrid entity, or often, in a hybrid entity, HIPAA applies to some of the data that public health possesses, but not all data and not all systems.

Steven Lane
Okay. Other thoughts?

Steven Eichner
This is Steve again. Just so that there is clarity, again, looking at the scope of patient access, patient correction is constrained to HIPAA-covered data sets, which is…unless other statutes may apply.

Arien Malec
So, this is an area where I think we could be more effective by giving ONC more flexibility, unless we strongly believe that the right mechanism is a certification criterion, because I think there is actually more in the policy framework than certification for criteria. So, I was typing out something on the order of things we have done in other places, "recommend that ONC work with federal partners and other stakeholders to increase the adoption and use of patient right to HIPAA correction via API," or something of that nature, and I am more than happy to work on language there that will provide a more flexible set of policy tools. And then, Grace, on the first bullet, "recommend that ONC ensures the general public and healthcare sector recognize the HIPAA right to correction." It is a HIPAA right, right? So, what are we saying in the first one? Is this about ONC working with OCR to increase understanding that it is a HIPAA right?

Grace Cordovano
Thank you for that question. I think this really comes from the patient care partner and consumer perspective. It seems that this has really been swept under the rug, and it is there in the policy framework, but no one really pays attention to it. It is a consumer, health citizen, and patient advocacy educational standpoint, and also to bring industry and all the stakeholders on the same page to make sure everyone recognizes this is not something that is just nice to have, it is a right, and I feel that has not been emphasized enough. I feel there is an educational component and an awareness component that really can be better amplified across the board.

Arien Malec
Got it. So, what we are recommending here is that ONC, with other federal partners and other stakeholders, improve education around the existing HIPAA right to correction?

Grace Cordovano
Correct, and I would even go so far as to say it took quite a bit of digging to get all the different policy levers, and even people who have been focused in this area were surprised to learn of some of these policy levers that I have listed, and I would imagine even an article or a piece summarizing these policy levers as a reference and including others if there are other ones that I have missed would be extremely helpful for anyone that is interested in this space.

Arien Malec
Okay. So, Steven, if you are in there, I think what we are saying is…

Steven Lane
I am in, and I am out. I tried to put it in there.

Arien Malec
Tell me because I can make the correction that the request is for broader education and promotion.

Steven Lane
Good. Go ahead and add it. Other thoughts? John Kilbourne?

John Kilbourne
Quick question. Is there a necessity that we say something about what happens to these requests? Presumably, the API receives the requests, and they go into some log file somewhere. Do we have to say something about how someone should look at that log file?

Steven Lane

I do not think we do, John. HIPAA already says how that works. This is really about the technology to support the submission of the request. That is my understanding.

John Kilbourne
All right, thanks.

Grace Cordovano
That is correct. We are not dictating how any healthcare delivery organization or stakeholder is required to process and organize that. This is specifically, at this juncture, how to initiate that request and be able to use technology to do so and digitize it.

Steven Lane
Anything else, John? Your hand is still up. Okay. Ike?

Steven Eichner
Yes, just reconciling B and C. I think they can be combined because it looks to me like C is constraining, at least initially, the requested corrections, or just constraining B just to make a request for correction, not necessarily making the correction itself, so it would seem like they could be combined, if that makes sense.

Arien Malec
I am in there. I will make a proposed edit and see if we can agree on it.

Steven Lane
Perfect, okay. All right. Any other thoughts on this? I am sure we will capture that. All right, then we are going to be ready to move this one to "complete."

Steven Eichner
Again, how does B and C combined differ from E?

Grace Cordovano
Under the global recommendations?

Steven Eichner
Yes.

Grace Cordovano
No. 2 was more on the certification criteria, and No. 3 was making the request that at minimum, establishing a floor that corrections should be made through a patient access API, if that helps clarify.

John Kilbourne
And I think, for that reason, B and C are different.

Grace Cordovano
Correct.

Steven Lane
Arien, are you still in there?

Arien Malec
I am. Sorry, B and C are different? I think I was tracking it up until that last point.

John Kilbourne
In my mind…go ahead, Grace.

Grace Cordovano
Point 2, or B, as it is being referred to, is really a recommendation to establish the certification criteria to enable the request.

Arien Malec
Okay, I got it.

Grace Cordovano
No. 3 is really the **[inaudible – crosstalk] [00:50:12]**.

Arien Malec
I think we can combine them. I got it. I will propose something, and we can come back to it.

Steven Eichner
Actually, I guess B would be to require support for the HIPAA request, not to enable.

Steven Lane
And then, I think we are going to want to come back and ask ourselves how many of these are really ISA-specific recommendations and how many of them are more ONC recommendations, but today may not be the day for that. I do want to keep moving while Arien is making those edits, so if we can shift our focus up to Item No. 1, Mark, I think you were going to take us through that next.

Mark Savage
Yes. Based on the conversation last time, I heard two overarching points. One is that it is not just about shared care planning, but the care coordination, and the other point I heard was the importance of including some kind of a specification about what a dynamic longitudinal care plan is. So, the edits in red pull in both of those suggestions based on the group's conversation last week, and I think capture everything that people wanted.

Steven Lane
Does anyone have any thoughts about this? I think you did a great job, Mark, in capturing the question and responding to it. I do not remember. Dave McCallie, were you the one who raised the issue last week about this?

David McCallie
Yes. I am just reading this, but it looks pretty good.

Steven Lane
All right. Does anyone else have any concerns or questions on this one?

Hans Buitendijk
Just a question.

Steven Lane
Yes?

Hans Buitendijk
[Inaudible – crosstalk] [00:52:17] the strength of "and even automatically" in the red text at the end. I am not sure in what circumstances we would call "always can assume it is automatically" when we can say it is. I am just hesitating a little bit there, but I think I am okay with the intent, but I am not sure whether the wording is that it drives automation in areas where that might not always be feasible or appropriate.

Steven Lane
So, you are talking specifically about the "even automatically" phrase?

Hans Buitendijk
The "even automatically." If it were to say "and where appropriate, automatically," I think that would work, but it is the "even" part.

Steven Lane
Why don't you go ahead and make that edit, since it looks like you are in there, Hans?

Hans Buitendijk
I could be in there.

David McCallie
While Hans is working on that, I will just ask the question, Steven, that you prompted me for a second ago. I think the phrase "shared care coordination and plans" in that first sentence probably addresses it, but I will ask Mark to comment. I think the ground floor of care plan management is communication, is the tools to enable members of the care team to talk with each other about the care plan, and it would be a mistake to try to put some kind of an automated system in place before you enable just easy communication, in my opinion. Mark, does coordination include communication? Does my question make sense?

Mark Savage
Yes, as does the planning and the word "shared." I think they go together.

David McCallie
My concern is just that "plan" sounds like something written in a list. Much of care coordination is just simple "Should we do this or not? Should we get the CT now, or wait a week?" It is not necessarily something that is ever going to get written into a plan. There is a dynamicism that "plan" seems to…

Mark Savage
Yeah, that is fine. The word "dynamic" is there. There is a fuller description available in some of the links in the left-hand column, but to keep it succinct, some of these words catch a lot of detail, and to your point, I think "dynamic" is the one that is used to flag that it is not a static document, but it gets adjusted in real time.

David McCallie
Okay, I see the "dynamic" now.

Steven Lane
I just separated the noun and the verbs. All right, anything else? I do not see any more hands. Can we turn this text black and boxes purple? Going once, going twice? Excellent, thank you, again, Mark, for your work. Arien, are you ready to take us back to the prior item?

Arien Malec
Ready to do it.

Steven Lane
All right, let's go back there.

Arien Malec
It was 12.

Steven Lane
All right.

Arien Malec

So, a lot of red here. I think we have already addressed the first bit of red. "We recommend ONC, with the help of federal partners/stakeholders, increase education and outreach around the existing HIPAA right to correction." I think we have already addressed the "therefore" here. The proposed Recommendation B is "Recommend that ONC work with other federal partners and other stakeholders to establish a policy framework that increases the maturity, adoption, and use of practice of FHIR APIs that enable patients to exercise the HIPAA right to request for correction amendment process integrated to health IT in use," and then propose striking B and C and renumbering the proposals. The new B is inclusive of B and C.

Steven Lane
Christina, you are the owner here. How do you feel about that? Sorry, Grace. My bad. Grace, you are the owner. Are you comfortable with Arien's suggestions? Do we still have you, Grace?

Arien Malec
Mark has his hand up.

Grace Cordovano
Hello?

Steven Lane
Ah, there you are. Go ahead.

Grace Cordovano
Okay. I just wanted to make sure when we collapse B and C that we still keep the certification criteria distinction versus the minimum floor.

Arien Malec
Yeah. I am trying to be careful because I think we have gotten requests from ONC in the past not to be too prescriptive with the policy programmatics, and so, I am trying to be careful to talk about maturity, adoption, and use and practice, which I think covers what certification and meaningful use or CMS programmatic inclusion is intended to get out.

Steven Lane
So, Arien, are you in there?

Arien Malec
I am no longer in there. Mark, are you making a comment on this topic as well?

Mark Savage
I am, and I am not seeing a shared screen anymore, if that matters to anybody.

Arien Malec
Yeah, they stopped displaying.

Mark Savage
I do not know that this needs to change anything, but just a reminder that I guess the policy committee had recommended some certification criteria that both the amendment happen and that there be a separate criterion for forwarding that change to anybody who had received the corrected information. So, I am just flagging that historically, there have been some things done around certification criteria, and to make sure that we do not lose track of that in whatever amending we are doing.

Arien Malec
Got it, and David has some edits that the policy framework could include certification. I think Steven and I are trying to be really careful because we are the ISP workgroup, and so, we are talking about standards that want to get used and adopted as opposed to the specifics of the policy mechanisms, but I think noting

that the HIT policy… So, I think it is right here in the policy levers that we can include as reference information in the transmittal the notion that the HITBC recommended that ONC establish policy or certification criteria as part of the background to this recommendation.

Steven Lane
All right. I am trusting that everybody is in the Google doc currently and they can see the state of this one.

Arien Malec
Steven, I concur with your edits. I think that is well done.

Steven Lane
Right. So, I am going to go ahead and accept those changes, and we will have this one ready to wrap. We are now ABCDE. Any further thoughts on this one before we move on? No hands up? Do we think that Wendy is coming back, or should we have somebody else do the display for a bit? Mike, any thoughts on that? Did we lose all of ONC?

Michael Berry
Wendy is reconnecting, so give her a moment.

Steven Lane
Okay, great. Well, let's not dilly-dally. We will move on. How are we doing for time? I think we have a little bit more time here. Next up was going to be Hans and David talking about No. 13, which is just below here, where we captured more about the accelerators. Is this still required, David, given where we have been?

David McCallie
I do not think so. I think we have covered the broad principle, which is the one that matters, because it is flexible for future lists. I was enumerating these back before we had discussed the broad coordination of accelerators, so, Hans, if you agree, I think this can be dropped.

Steven Lane
And, that would be 13, 14, and 15. Those all now become redundant.

David McCallie
Correct.

Hans Buitendijk
I think it is even 13, 14, 15, 16, and 24.

David McCallie
Twenty-four is about FHIR endpoints. Is that in an accelerator anywhere? I was not sure.

Steven Lane
That is a little different, right?

David McCallie
And, that is CARIN, working with HHS.

Hans Buitendijk
And it is FAST. I thought it was under the FAST/CARIN efforts on both accelerators, but if we want to avoid confusion, then I would keep 24 apart.

Steven Lane
So, we are going to strike through 13, 14, 15, and now 16, correct?

Hans Buitendijk
Yeah.

Steven Lane
Okay, good, just for record here.

Hans Buitendijk
CARIN acts as an accelerator, so we want to make sure that everything they do picks up.

Steven Lane
All right, then if nobody objects, let's see if we can transition to the lab work. You guys are doing great, by the way. That brings us down to the bottom of the screen, and you are going to be pretty impressed by all the work that has gone into this. We are starting at No. 31, and this includes… Arien and I had our way with these, attempting to incorporate some of Clem's input, as well as the input of others, and then, Hung and Hans have worked really hard on these over the past few days, so do you guys want to walk us through them, top to bottom, starting with 31?

Hans Buitendijk
Hung, do you want to start?

Hung S. Luu
Sure. So, with 31, the intent of 31 is really to harmonize the ISA and the USCDI so that they resect each other more cohesively, and so, we know that there is now separation between what is included in USCDI versus what is included in other standards, so this is an attempt to realign everything and make sure that they reference each other appropriately.

Steven Lane
And, there is a recommendation and some explanatory text. So, just give folks a moment to read through that and see if you have any questions or concerns. This really is digging deeper on topics that this group and others have tried to put forward over years.

David McCallie
There are a lot of careful words there to parse, Hans. I am not sure to whom I should address it, but does this address the notion of comparability of lab tests adequately, such that a clinician or a healthcare system receiving lab results from outside labs has all information necessary to determine which tests are comparable to each other? Does this recommendation encompass that?

Hung S. Luu
No, that is in 32A.

David McCallie
Ah, okay. Lots to read here, sorry.

Arien Malec
David, in English, this one is saying, "Let's establish that there is a common information that needs to be carried with a result," and 32A is saying, "Here is all of the information that goes into the slots that is necessary to establish comparability."

David McCallie
Okay, I want to make sure we do not lose track of that goal because sometimes, the "Why are we doing this?" is really important to surface because you can get lost in the details if you do not know why you are doing it.

Hans Buitendijk

That is probably a good point to clarify in 32A.

Arien Malec
When we move this to a transmittal, we probably will want to have a preamble section that lists the why here. What I would memorialize as the why is that we actually have pretty decent adoption of electronic resulting. We have lower adoption of interoperable electronic ordering, but the lack of standardization in practice creates administrative workload on all of the actors associated with the supply chain and limits the comparability and broad use of lab data to improve patient health, improve care, facilitate public health, and broaden research. That would be the summary statement of why we are recommending all this mess, right?

David McCallie
Yeah, as long as you have, for example, "Clinicians cannot tell if the test answers the question because they do not understand the test kit." At a high level, you are eloquent as always; let's just make sure we have the details of a use case. As I related way back when we first started talking about this, in 1991, when we designed a flow sheet, we realized that we did not have enough information to know which tests could be put on the same row in the flow sheet, and that problem still exists today, 30 years later.

Arien Malec
Mark has his hand up.

Steven Lane
Mark?

Mark Savage
Yes. In 31, the last words of the bolded statement reflect the data in USCDI. I am just checking: Do we mean USCDI here, or do we mean ISA?

Arien Malec
We mean USCDI.

Hans Buitendijk
Yeah. I think the intent was to say that across all these different standards and capabilities, such as CLIA, various standards, FHIR, V.2, we have a rich data set that is already agreed to to communicate as orders and as results, and only a portion of that is in the USCDI, so it is a combination of both. We take that from the information and what we have harmonized and make sure it fits in the USCDI because that is our focus.

Arien Malec
This is the sibling recommendation to our recommendation in the USCDI portion, where we said, "Hey, we should expand the amount of data that is in the USCDI, and then we should link and harmonize it." Here, because we are in the ISA portion of our workgroup, we are talking about the standards and implementation specifications and making the sibling recommendations.

Steven Lane
So, I thought "reflect" was perhaps a little ambiguous, so I suggest "incorporate this data in USCDI."

Arien Malec
"Harmonize this data"?

Steven Lane
Is "harmonize" more appropriate?

Arien Malec
Hans?

Hans Buitendijk
"Harmonize" is fine, "incorporate" is fine.

Arien Malec
Okay, let's just keep it at "incorporate."

Steven Lane
All right. If there is nothing else on this one, I would like us to keep moving forward. 32A?

Hung S. Luu
So, 32A. "Recommend that ONC and other relevant HHS partners and other stakeholders…"

Arien Malec
You need to scroll down so we are looking at…there we go.

Steven Lane
Perfect.

Hung S. Luu
"Recommend that ONC and other relevant HHS and other federal partners create policies sufficient to encourage consent, require and otherwise enable resulting organizations to support the resulting information model and associated communication and content standards for orders and results when exchanging this data via messages, documents, applications, programming interfaces, and/or other future transport mechanisms." And so, this lays out the central strategy of SHIELD, in which we represent lab tests with a series of codes that represent the digital fingerprint of that test, and so, no matter where it goes in each healthcare ecosystem, we are able to have sufficient information about the test to use it for various primary purposes and also secondary purposes, like regulatory decision making and for research. And so, the intent of this is to thoroughly describe the test for every test.

Arien Malec
Because I was involved in breaking a mega-recommendation up, I would say that maybe 32A, B, C, and maybe D as well, taken together, really accomplish what Hung is looking for. This one in particular is saying, "Hey, this is important enough that we need to establish a policy framework that is inclusive of all of the actors along the resulting supply chain, and we have the same thing for all the actors in the ordering supply chain." And then, 32B, C, D, E, F, and maybe even more are a lot of the detail associated with each of the pieces that are required. So, keep that in mind as you are thinking about these things, that we try to separate them so that they are individually consumable, but they logically cluster as the set of recommendations associated with resulting.

Steven Lane
Yeah, the results actually cover 32 in its entirety, so, 32A through H.

Arien Malec
Through H.

Steven Lane
I cannot quite get them all on the screen. I am working on it.

Hans Buitendijk
Not to be confused with **[inaudible] [01:11:40]**.

Hung S. Luu
So, 32B just recommends pretty much that we remove the coding as upstream as possible so that we are not having to try and code orders and results after they have been performed, and so, to associate the code

with the order and with the performable test as closely at the point of generation as possible. I think 32C recommends that basically, we try to automate the process of mapping the codes and make it easy as much as possible because obviously, if it is not easy, nobody is going to use it. And so, this is an attempt to get the stakeholders together and to make sure that the IVD vendors and LIS vendors are working together to make the mapping as upstream as possible, but also as easy as possible with automation and scanning.

Arien Malec
Hung, as many times as I have seen and edited this text, I think for orders, "communication and orders" should include language that it should be moved over to the orders section. As early in the process as possible, clearly starting with the order, the two key parts are starting with the order and the IVD. That is the right way to think about this section, and of the two of them, the IVD is the one that is most impactful for the results.

Hung S. Luu
Yes.

Arien Malec
So, when we say "as early in the process as possible, we should say that what we are really talking about is starting with the IVD, and in some cases, the order itself, as opposed to the post hoc cleaning and mapping of this data in the LIS and in the EHR. I will volunteer to draft some language there. Hans has some…

Hans Buitendijk
Yeah, it is actually a two-pronged approach: Start with the order and start with the IVD test. The reason is not everything from the order can move into the IVD device, and anything that **[audio cuts out] [01:14:12]** move into the IVD device, you need to start it there. We need to tackle it from both angles.

Arien Malec
Completely agreed. All right, I will propose something and keep going.

Hung S. Luu
Okay. 32D: "Recommend that ONC, in coordination with other federal partners, SDOs, and industry stakeholders assure that there is a well-managed and appropriately resourced process to develop and deliver additional LOINC/SNOMED CT **[audio cuts out]** when needed for new tests or needed variations of existing tests." So, the intent of this is to have agility so that when a new code is needed, it can be developed quickly and there is a streamlined approach to requesting and getting these codes as needed so that we do not run into the issue of not having a code when we need it. We saw that during the pandemic, that organizations can move very quickly when they want to or need to, and so, this is an attempt to just make sure that they are given adequate resources to respond accordingly to the need of the community.

Arien Malec
Great.

David McCallie
A question to Hung. I was under the impression from earlier conversations that there is data in the SHIELD spreadsheets that is not in LOINC and/or SNOMED. Is that misinformation? And, if it is wrong, then I stand corrected. If it is true, should that be listed also here?

Hung S. Luu
This is separate in that this is just addressing the SDOs and code publishers that we need to work with. The leader, which you are referring to, actually will be addressed later.

Arien Malec

Quick review of my red language in 32B.

Hung S. Luu
Yeah, I am looking for… I do remember seeing "leader" here. So, part of the SHIELD initiative is to develop a central repository where all the coding resides and will be a source of truth for it, and so, that is where laboratories could pull the coding and also verify that their coding is correct, but that is separate from the intent of 32D. 32E: "Recommend that ONC, in coordination with the FDA, standard-developing organizations, manufacturers, and industry stakeholders, include SHIELD enhanced ability for test results to include identification of device and use to perform the tests using a device's model, device identifier, and preferably the UDI while streamlining the documentation of such notification as the test is performed and documented." And so, this also goes hand in hand with the need for the information on the test kit and instrument to make sure that there is adequate information for comparability when it crosses throughout the healthcare ecosystem.

Steven Lane
No hands? Go ahead.

Hung S. Luu
Okay, 32F: "Recommend that ONC, in conjunction with other federal partners, SDOs, and industry stakeholders, create policy levers inclusive of guidance, education, certification, criteria, and payment programs that lease EHRs, laboratory information systems, radiologic information systems to provide tools and guidance to allow clients/users to map internally generated results and result codes, including observations and values, to standard vocabularies and cases where coding is not done at the source."

Arien Malec
So, to restate that in English, other than this incredibly carefully crafted language, there is going to be some subset of laboratory-developed tests where the LIS-based mapping is not going to be comprehensive or lead to the right result, and so, we need to also incent, encourage, or otherwise enable LISs and RISs and the organizations that use them to create and maintain maps.

Steven Lane
All right.

Hung S. Luu
Can somebody scroll up?

Steven Lane
Wendy, can you scroll down so we can see all the way down to 32H?

Hung S. Luu
Okay. "Recommend that ONC, in coordination with the FDA, standards-developing organizations, manufacturers, and industry stakeholders, include SHIELD, provide the ability for testing devices and identifiers to be registered in the GUDID registry for additional device information, as well as linkage to the mapping and knowledge base." So, that, again, addresses the development of the UDI, so that is information on the test kit and the…whoops.

Steven Lane
Sorry. We are getting there. Okay.

Hung S. Luu
32G: "Recommend that ONC, in conjunction with other federal partners, SDOs, and industry stakeholders create and implement seconds to support/ensure proper and consistent LOINC and SNOMED CT encoding across results sources." And so, this is where "leader" is addressed, in which there is a central repository

for all the codes and will serve as a source of truth for the coding and provide a mechanism for dissemination of that code as automatically as possible to the laboratories.

Steven Lane
And, H is the last in 32, which is about as far as we can get.

Hung S. Luu
Okay. "Recommend that ONC, in coordination with the FDA, SDOs, manufacturers, and industry stakeholders, including SHIELD, provide the ability for testing devices and identifiers to be registered." Did we already address that?

Steven Lane
That might be a duplicate.

Hans Buitendijk
I do not think it is a duplicate.

Hung S. Luu
I might have skipped ahead accidentally.

Hans Buitendijk
It is not a duplicate because the earlier one was about having, on the result, the device that was used to perform the test and provide the answer. This one is about the device itself, independent of the result, being listed in the FDA's GUDID, which currently is focused on implantable devices and other devices, but it is in there as well, and from there, it can also provide linkages to the SHIELD's proposed laboratory directory, if you will, where the mappings and otherwise are so that those capabilities are connective so that you can really have the tools to look up by way of APIs and otherwise to get access to that information one way or the other, and GUDID is the one that is used by the FDA based on the device identifier information about that device that may not be elsewhere.

Steven Lane
So, a tremendous amount of work has gone into the recommendations that were just presented under 32 about the results. Specifically, 33 contains more information about orders, and then, 34 and 35 take this further, but I would like to see if we are comfortable accepting the 32 list of recommendations as a workgroup before we go to public comment. Hans?

Hans Buitendijk
Just a quick note. Ike made an earlier comment about, in 32B, changing the term "answer" to "response," with an additional suggestion from me that it should be "result value," so that may be something that still needs to be worked out to get the right word there.

Arien Malec
So, first of all, I have gotten proposed language for what we mean by "as early as possible," so I want to encourage people to look at that and see if that clarifies intent. "Answer," in this case, is responsive to "ask at order entry question," so this is the AOE question and AOE answer, and the actual answer text. And so, if you think we should change the word "answer" to "response," I am fine with it, but…

Steven Lane
Why don't we just label it as "AOE answer"?

Arien Malec
Works for me.

Steven Lane

Hans, you are in there. Do you want to make that change?

Hans Buitendijk
Yeah, I will make it.

Steven Lane
All right, we will cut to public comments.

Public Comment (01:23:57)

Michael Berry
All right, everybody. 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 *9 to raise your hand, and once called upon, press *6 to mute or unmute your line. So, we will pause to see if we have any public comments and continue to monitor until the end of our meeting. I am not seeing any comments at this time, Steven and Arien, so I will turn it back to you.

Steven Lane
Wonderful, and again, we always encourage public comment, so please feel free to jump in if you like.

Arien Malec
We have a big chunk for orders. We made a huge amount of progress today. I think we are pretty close to getting this thing wrapped up, so I would imagine that our next session is the last push to make sure that we have got everything fully in recommendations text prior to starting to wrap this up in a formal transmittal format.

Steven Lane
I just want to clarify to be sure. Does anyone on the workgroup have any further suggestions around the 32 recommendations, or can we consider those finalized? Okay, they are now purple. So, as you say, we will jump back in with the rest of the lab recommendations next week, 33, 34, 35. Steve Eichner, I see you moved your work that you had added at the bottom up above, so we do have a few more to go through, not too many. Let me just get a bird's eye view of our document here. So, I think we still have your No. 5, Arien, "data exchange for price transparency," we have Mark's No. 7, "SDOH standards related to race and ethnicity vocabulary," we have completed this one. We then go down. I think we took care of those. This is amazing. We have my No. 21, "tracking ISA standards to support bidirectional communications with community-based social service organizations."

Arien Malec
My price transparency one might already be addressed in 18, which would be fantastic.

Steven Lane
Why don't you consider that? So, just strike it out.

Arien Malec
Yup.

Steven Lane
David McCallie, you have 22 and 23. Are you interested in us getting to those next time? You want us to consider those, I assume.

David McCallie
Sure. They should be quick.

Steven Lane

Okay, very good. You also have 24 on the FHIR endpoints, so we will come back to that one. Oh, Clem has 25. Did Clem ever join us today?

Arien Malec
He did not join us today.

Steven Lane
Oh, this has to do with delivering. Okay, we can discuss that one. I think we will probably have time for that one next time if Clem is here to recommend it. And, I think other than that, we may be through the list, which is pretty remarkable. Anyone else want to provide any observations about our process thus far, or our direction? We are going to try to get through all of this next week. If we have a little carryover into the following week, so be it, but I think we are going to make it.

Arien Malec
I think we are going to stun and awe the HITAC. They will not know what to do with it.

Mark Savage
I am glad you guys are going to be doing the recommendations at that meeting, just to listen to this.

Steven Lane
It is going to be a mouthful, yes indeed.

Arien Malec
Steven now has the trick for USCDI, which has been very successful, which is to talk fast and present a lot of content, and then ask any questions, and you just stun the HITAC into submission.

Steven Lane
It is also helpful because we have given ourselves a couple of weeks to prepare for the presentation, so we will make sure that the Word document and the slide deck are crisp and clean and reflect what we want to say, and then we will also run it by the HITAC cochairs to make sure that they have any questions ready for us to address. All right, well, wonderful. We are at the end of our time together. Thank you again. We will see you next week, and please, anybody who wants to make a run-through, especially those things that are yet to be presented, make sure they are crisp and clean and ready to discuss. Have a great day.

Michael Berry
Thanks so much. Bye.

Adjourn (01:28:50)