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

June 7, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

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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
And, good morning, everyone, and thank you for joining the Interoperability Standards Workgroup. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting, or can be made verbally during the public comment period that is scheduled at about 11:55 Eastern Time this morning. So, I will begin roll call of our workgroup members, and when I call your name, please indicate you are here. And, I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Kelly Aldrich?

Kelly Aldrich
Hi, everyone.

Michael Berry
Hans Buitendijk? Thomas Cantilina? 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 will be joining us a little bit later. Ken Kawamoto? John Kilbourne?

John Kilbourne
Good morning.

Michael Berry
Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
David McCallie?

David McCallie
Hello.

Michael Berry
Clem McDonald? Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber? Abby Sears? And, Ram Sriram?

Ram Sriram
Good morning.

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

Co-Chair Remarks (00:01:39)

Steven Lane
Well, as always, thank you, everyone, for showing up this morning. We really appreciate your engagement here on the meeting, as well as in between meetings, we have just had fabulous participation in getting us to this point. We also want to welcome any members of the public who are joining us, and I see we have a number of folks coming today, some of whom have not necessarily been here in the past, so, welcome to our workgroup. Just a reminder to members of the public that you can participate in real time using the chat feature in the meeting in Zoom, and you can also take advantage of the public comment time that we have

at the end of the meeting to give your comments verbally. Any public comments entered in the chat to everyone or given verbally do become part of the public record, so they are a great way to provide input directly to the ONC process.

We are going to be reviewing our draft report, which you were all forwarded, and a number of you took a tremendous opportunity to go through that and really add value. We got a lot of helpful edits. We are also going to have a walk-on topic if we have time. Ram Sriram has brought forward a topic that we have not previously discussed. He has added that in our worksheet as Item No. 36, which we will hopefully have ready to display and discuss and see if it makes sense to us to try to squeeze that in at the 11th hour, and then we will have our public comment as noted. Arien, do you want to add?

Arien Malec
Yeah. So, again, I just really thank everybody for all the work that went into the final transmittal letter. Let's spend the majority of our time getting through the transmittal, making sure that we are in good shape for the final transmittal to HITAC, and then, if we are able to get through the recommendations, find a recommendation draft, and find a way to put it into the transmittal letter, that would be good. My bias would be to ride with the transmittal as it stands as our first option because it gets a little sticky if we are adding a lot of things at the last moment, but I am definitely open to surgical modifications of the transmittal as it stands. But, as I said, I think the transmittal came out reading really well, very meaty, and that reflects all of the amazing work that this workgroup put into this process, and I think we are in great shape for our readout tomorrow.

Steven Lane
Not tomorrow.

Arien Malec
Next week, thank you.

Steven Lane
Next Thursday the 16th, indeed. And, we have started with the ONC team on a set of presentation slides that are really going to simply reflect what is in the transmittal letter. We are currently scheduled to have a meeting next Tuesday to potentially file any edges or polish any edges off of that. I will see where we stand at the end of this meeting as to whether people think that such a meeting next week will be necessary. So, with that, ONC team, do you guys have anything you want to add before we dive into the draft report, which should be ready to display, hopefully? Why don't you also tee up the spreadsheet in case we have time to get to Ram's recommendation for that as well?

Arien Malec
Hung has a question right now.

Steven Lane
Go ahead, Hung.

Arien Malec

Okay, it was a hand-o. Steven, maybe we can just spend a little time on the executive summary because I think it gives a good overview of how we organized the whole thing.

Steven Lane
Please do.

Review of Draft Report (00:05:59)

Arien Malec
So, in general, the transmittal has the front matter and the introduction, which is really focused on our charge. So, the way that we have organized the transmittal in consultation with ONC is to separate the transmittal into three parts. The first two parts really are responsive to the ISA charge proper. The first set of recommendations address the process and structure of the ISA, and so, these are the pieces of feedback that we have heard along the way about areas where the ISA as a concept and the ISA in practice can be made more effective to stakeholders: Our reflections on the cross-cutting concerns and being able to pull out use cases that cut across different areas of the ISA section, how we coordinate with the USCDI, how we align with federal programs, and then, in particular, our comments on how to better keep the ISA in track with the work of accelerators and improve the overall usability of the ISA. So, that is Section 1.

Section 2 is really the meat of the formal response to our charge, which is our specific updates for the ISA in the areas below, but this is where we track all of the information about making sure the ISA reflects Standard X, Standard Y, Use Case Z, etc. And then, we formatted the lab and order recommendations as a major section focused on how we better expand the use of ISA name standards in almost all of the cases beyond the ISA. Each of the standards that we name in that section are actually tracked in the ISA, and it is just a reflection that despite that tracking, we have the opportunity to make major advancements in this area with a careful set of policy coordination, and we make recommendations relative to the policy coordination that we believe ONC could take relative to those areas. So, if you are confused by the structure of the recommendations transmittal, hopefully this provides a little bit of an explanatory framework for how to read through the recommendations transmittal.

Steven Lane
Any questions on that? Great. Again, we did have a number of you go through this in detail and provide helpful editorial comments, most of which we just reviewed and accepted because they were perfect recommendations. So, if you read through this last night, you may notice a little change in commas, or spacing, or slight changes in wording, all of which was very much in concert with the direction we were going and did not really warrant the detailed review by the group. There are a couple of comments that are in the document at this point that I think do warrant discussion, so what I would like to do, if we can, is go through those as a starting place and address those with the group as a whole, and then allow people to raise their hands as they trip upon other things during the meeting. So, with that, and with no hands up, I would suggest that we scroll down to the first comment, which is Grace's, which is on Page 13, and it has to do with our Recommendation No. 9 regarding the HIPAA right to request corrections to one's medical records. Grace, did you want to comment on that?

Grace Cordovano

Yes, and I was just going to try to pull up the policy levers. As I was reviewing this, I was just curious. I notice that the corresponding policy levers that were in the workgroup's workbook were not included. Would it be helpful to pull that up and pop that in?

Steven Lane

That would be what is included in the worksheet Item 12, and the policy levers that you captured there really were ONC correction principle of 2008, the HIPAA privacy rule, the HIT policy meeting from 2011, and the 2015 edition of health IT certification. I do not think we need all of that. I think as we looked at policy levers, it was interesting. Arien, you can add color here, but as we have done this in the past, we have really looked at what policies ONC would be leveraging, so this is different than background material. Is there a CMS policy, an ONC policy, a CDC policy, or what have you that ONC could work with to try to bring this about? So, in a sense, the HIPAA privacy rule is a policy of sorts, as are the certification criteria, so those could certainly be added. I think meetings that occurred 11 years ago are less policy-related. Arien, what do you think about this?

Arien Malec

Grace, I think when we looked at it, it felt more like policy background than prospective policy levers, and it may be worthwhile putting back in as a preamble… So, in some cases, we have put in the transmittal a findings or preamble to the recommendations. It may be worthwhile taking that material and putting it as a background preamble noting that there is a HIPAA right to correction and noting that we have had previous work in this area with consistent recommendations. It might be a good piece of background information to the actual recommendations that we are making. Does that make sense?

Grace Cordovano

I think what I would like to emphasize from what has been placed in the workbook is the fact that this has been discussed and there are policies in place, and it is still not working in the real world in 2022, so I think that is what I want to emphasize.

Arien Malec

That is right. So, to our comments, I think that goes more in the way of a preamble to the recommendations than it goes in the realm of prospective policy levers, so maybe we can go offline and suggest a set of preamble text to the recommendations.

Steven Lane

So, Arien, you are suggesting that that would be sort of a preamble sentence or paragraph at the top of that ISA content section as opposed to a background paragraph at the bottom of this particular recommendation?

Arien Malec

That is right. So, what we would do is, under the heading text "corrections to medical record," we would put a preamble section, as we have done in a couple other areas where it is important to have some context for the recommendations…

Steven Lane

So, Arien, I think I actually moved all of those down below the recommendations and called them background, just for ordering's sake. So, Grace, I just added that background section there. Why don't you take a few minutes and copy/paste polish up whatever couple of sentences you think are appropriate there, and then we can come back to that when we finish with the other comments, okay?

Grace Cordovano
Will do, thank you.

Steven Lane
All right. Next was a comment by Ike, I believe. Yes, we are on Page 19 now.

Mark Savage
Steven?

Steven Lane
Mark, your hand is up.

Mark Savage
Sorry, I have had a hand up. The one thing I wanted to flag, if memory serves, is in the 2011 recommendation from the policy committee, there was a certification recommendation that a correction be passed on to others who had received the information. That strikes me as being important. I do not see it written out in the recommendations here, but I have just flagged for Grace's and your consideration whether that particular point is worth somehow getting back on the current playing field.

Steven Lane
Why don't we see if Grace finds a way to incorporate that? I think it is worth noting, thank you.

Mark Savage
Sure.

Steven Lane
All right, any other hands? Seeing none, let's go back to Ike's comment. Where was it, Ike?

Steven Eichner
Nineteen.

Steven Lane
Nineteen, yes indeed. So, this was in Recommendation 16 regarding lab orders and results, specifically the Sub-recommendation 16A recommending that ONC, in conjunction with partners, create and support a policy framework that encourages closed-loop order-to-result communications and multilateral distribution of results, especially including to public health, using standards and comprehensive implementation guidance. So, you had a comment there at the bottom.

Arien Malec

No, Ike is exactly right, so we probably should update this to note. So, the comment is meaningful use promoting interoperability measures relating to electronic receipt of results were topped out. The ELR requirements are still there. So, we should make this text a little more precise.

Steven Eichner
To clarify, reporting to public health versus…

Arien Malec
Right.

Steven Lane
So, how are we going to fix that? I think we have time to just fix it here.

Arien Malec
Yeah. So, I think what we say is "While the associated meaningful use/promoting interoperability measures for incorporation of electronic results were determined to be topped out, and therefore removed from the incentive program…"

Steven Eichner
"…ELR reporting to public health still remains" or something like that.

Arien Malec
So, the first fix narrows the statement. Let's figure out how to put ELR back in. Maybe just a parenthesis.

Steven Eichner
I think you just put a period after "topped out" and just add a second sentence that says "ELR reporting to public health still remains as a measure."

Arien Malec
Well, structurally, you have got a "while," so the "while" wants to…

Steven Eichner
Right.

Arien Malec
So, maybe we just remove the "while."

Steven Lane
Wait. See if you like it now.

Arien Malec
No, it still does not work because of the "while." "While" wants to have a clause that counterbalances the "while."

Steven Lane

Isn't that the "ELR is still included"?

Arien Malec
Well, the original intent of the sentence was "While it was topped out, we still do not have broad deployment of tightly constrained implementation guides." So, maybe what we do is remove the "while" in the… Yeah, it is still…

Steven Lane
No, I got it. I will just pull this out.

Hans Buitendijk
I have a suggestion on the first part to help set up ELR more. The incorporation of the initial electronic results reporting to the ordering provider was determined to be topped out, not the ELR.

Arien Malec
Yeah, or "incorporation of electronic results to the ordering provider."

Hans Buitendijk
Correct.

Arien Malec
I like it. Michelle has a comment here.

Michelle Schreiber
I have been trying to figure out exactly what it is you want us to do, since we have the meaningful use program.

Arien Malec
Yeah. So, we are not making any recommendations in this transmittal for CMS. We are going to be super precise. The first part of this recommends that ONC, in conjunction with other federal partners, which obviously would include CMS, create a policy framework that encourages, incentivizes, requires, or otherwise enables closed-loop result communication and multilateral distribution of results. Structurally, if you look at the CMS programs, the topping-out requirements were in the day when the CMS programs were focused on provider physician behavior, and there was a CMS measure about incorporation of results into the electronic health record, and CMS, I think very rightly, has removed all of the measures that basically define clinical practice or physician practice in favor of measures that improved interoperability.

And then, the second part of this is because we removed all the certification criteria that were not directly tied to CMS measures, and again, in isolation, both of those decisions make total sense, and now we are in a place where we do not have any certification requirements for results and we do not have any interoperability requirements related to any of the programmatics, including promoting interoperability, MIPS, ACO measures, etc., and so, there is little incentive for labs and for EHRs to use the LRI and LOI implementation guides, except as it is convenient in the moment for their use. And so, I think our general reflection is we are in a position where we have reasonable adoption of electronic results, non-standards-

based or partially standards-based, poor adoption of orders, and a fair amount of friction in the system because of the need for cross-mapping at the LIS as well as at the EHR.

So, I want to be super precise that in this transmittal, we are not making recommendations to CMS directly, we are making recommendations to ONC to work on a policy framework. One of the ways that one could enable policy would be to tie certification requirements to interoperability as opposed to physician behavior, and then, the other corresponding way one might do this from CMS is to think about the CLIA requirements on lab, and in our previous 2018 report, we made a much more specific set of recommendations on policy levers. Here, we are carefully staying away from what policy levers one could use and making more of a general recommendation to ONC to create a framework. Michelle, does that help?

Michelle Schreiber
That is helpful, thank you.

Steven Lane
So, Arien, look at the text there. Are you happy with that?

Arien Malec
I love it.

Steven Lane
Okay. Hans, I got your space up above.

Steven Eichner
Steve, in that hospital point, ELR **[inaudible] [00:23:28]** measure, why don't we just add "public health reporting measure and PI"?

Steven Lane
Okay. All right, are we happy? No hands? All right. Scrolling down to the next Ike comment, it is on Page 21. I thought this was reasonable, but thought it was just a little bit of a bridge too far for me to just accept without running it by the group.

Steven Eichner
The reason I suggested the text addition was so that we have weighted recodes throughout the system so that as we are adopting LOINC and relevant coding as early as possible in the process and maintaining that usage throughout, it recodes.

Arien Malec
I think that is right. Hans, what is your take, or Hung?

Hans Buitendijk
I think I agree with the intent. The term "usage" could be stated that it must be used everywhere, which is not necessarily right, but we want to maintain that coded data. It keeps on going along with the result or the order, whatever it is, so that it can be used by the next party as well. There are internal purposes where

you want to use the internal code because that is the one that really tells you a bit more than the industry code. That is why I am concerned with what "usage" means.

Steven Lane
How about this, Hans? I just updated it. Sorry, I do not think we are displaying. We should be displaying down on 22. There we go, thanks. Do you like that better?

Hans Buitendijk
Yeah, I am more comfortable with that, because then it is available, and it needs to be persistent throughout the chain, but not always required to be used.

Steven Lane
All right. No hands? Ike, are you comfortable with that?

Steven Eichner
Yes, absolutely.

Steven Lane
Perfect. All right then, I think you had a couple more at the very end, Ike. We are down on Page 26 here. And, in this edition, I was not quite sure about the "unless" phrase. I thought that might restrict us a little too far because certainly, the lab might be asked to pass on data that they did receive, even though it should not be the bulk of it. It just seemed like it might be too tight a constraint, so I just wanted to bring that forward.

Steven Eichner
Right. I think the concern here is that there are some situations where a patient may be interacting directly with the laboratory for submitting a sample, and there may be a relevant question that is related to the time at which the sample is being collected that is not necessarily relevant to the processing of the sample, but is still relevant from a public health perspective. So, if that information is not collected at the point the sample is taken, what happens? An example is pregnancy as a status. You may have a lab order. The physician tells you on Tuesday to go get a lab test. You do not go until Thursday. You did not have a positive pregnancy test when you saw the physician. You got one over the weekend. You are now pregnant at the point the test was actually conducted.

Steven Lane
So, Hans, this was your recommendation initially. Do you want to comment on this?

Hans Buitendijk
Yeah. I would agree that if the lab does not report it and does not have it available, then the question becomes if we should pass it. Clearly, if they have collected it, they do not need to pass it. If the patient is a walk-on into the lab, then they are likely responsible to do that nowadays, but the question here is if there are other paths to get it to public health other than through lab reporting, and I think that is what we are trying to address here, that we should explore other pathways so that data that is otherwise not needed for the performance of the lab test is not required at that point once I have that alternative path to go through

the **[inaudible] [00:28:10]**, and I think in that sense, we are in sync. I am still looking at the text where it updates.

Arien Malec
So, if I am tracking all of this well, Hans, what we are asking for is as we have broad adoption of ECR in areas where ECR provides the clinical context for the result, we want ELR to focus on the transmittal of the result itself. I think Ike's comments are that there are cases where the lab is collecting contextual information relevant to the lab, the order, and the result itself, and in those cases, we clearly should be transmitting that relevant contextual information.

Hans Buitendijk
Yup.

Arien Malec
So, now we just need to make the words on paper say what we just said and agree on them.

Steven Eichner
Thank you for that, Arien.

Steven Lane
So, how do you like the text as it stands now, guys?

Hans Buitendijk
The word "unless" is tripping me. That is what is happening.

Steven Lane
Yeah, that was what I got stuck on too.

Arien Malec
Maybe we should strike the "unless" and say as a third sentence that these recommendations would not apply when the lab is the entity directly collecting contextual information relevant to the result.

Hans Buitendijk
Or, when ECR can and has taken care of it. If there is no ECR and the lab is not collecting it, then it is the only path that can be **[inaudible – crosstalk] [00:30:05]**.

Arien Malec
That is right.

Hans Buitendijk
What I am trying to say is ECR can be, and only labs themselves collect the data because the patient shows up never having been to a doctor.

Steven Lane
Arien, why don't you take a stab at it? I am getting a little discombobulated here.

Arien Malec
Sure.

Steven Lane
While you are working on that sentence or those sentences, Steve, the other thing that you included here, the last sentence, "Information necessarily for actively matching submissions must be included in all relevant messaging," kind of goes without saying, but I also think it goes beyond the initial intent of Hans's recommendation, which really had to do with separating out and drawing a brighter line between ELR and ECR. So, how attached are you to that sentence?

Steven Eichner
I think the challenge from the public health end of it is that we are interested in both the lab report and the case report data, and if they get separated, we need to confirm that there is an easy way of linking them back together.

Hans Buitendijk
Agreed.

Steven Lane
Okay, if Hans likes it, I like it.

Steven Eichner
That is so that we are not to a point where we have a patient name and address and we are making another guess about entering the record.

Hans Buitendijk
Yeah, it goes to how you need patient identifier/matching. We have to figure out a way that the records can be linked up. I completely agree. It is not easy, but it needs to happen.

Steven Lane
Okay. Arien is still in his workshop working on that red text, so perhaps we will come back to that and scroll back up to Grace's work. It looks like you got it all there, Grace. That is certainly not going to fit into our slides.

Grace Cordovano
Yeah. I do not know what to remove, so I put it in, but I am happy to remove whatever needs to be removed. I do not even know if we need the reference links in there.

Steven Lane
Yeah, we do have some reference links, actually, in some others.

Grace Cordovano
I noticed that.

Steven Lane

This is rich. I do not think it is going to make the slide deck, and that is okay. When we get to this point, we can voice over that there is a lot of background work that has been done here, and it is all in the document.

Grace Cordovano

I have to say I do not know if I feel comfortable removing all of it. I would like some reference to something. As you said, it is rich, and I feel that from the patient and care partner perspective, a lot of this is frequently glossed over, so I do not want it to be glossed over, I want it to be historically captured that there is this presence of information, and that it does not get lost in translation.

Steven Lane

And then, do you have these in roughly chronological order?

Grace Cordovano

They are in chronological order. The only one is the last bullet. I was asking Mark. Here is his link. So, that is July 25th, 2011. I can move that one around. I guess that would be after the third bullet.

Steven Lane

Yeah, why don't we put them in chronological order, clearly identify the dates associated with each, and then, in the slides, perhaps have at least two slides on these four sub-recommendations? So, probably, there will be the first recommendation, the next three, and then the background, so I am picturing three slides for this recommendation.

Grace Cordovano

Thank you.

Steven Lane

Anyone have any thoughts about that approach? So, we are going to update this. Arien, are you going to be back with us soon with that sentence?

Arien Malec

Still working.

Steven Lane

Right on, man. Okay. All right, that actually does bring us to the last of the submitted comments in the document. Oh, you are working away. I see that. Okay, good. We will come back to you. As you have been listening to this discussion and hopefully perusing the document on your other screen, does anybody have any general or specific comments that they would like to propose? Anyone on the workgroup, anyone in the public? Remember, you are all welcome to chime in. This is your great chance. All right, hearing none, we are going to leave Arien to his toil, and if you do not object, Arien, I am going to invite Ram to present his walk-on suggestion.

Arien Malec

I think it would just be worthwhile to do a last call to the workgroup to note that we are down at the bitter end. As you noted, it would be useful to either cancel the next workgroup meeting or to focus the workgroup

meeting on the accompanying slideware that will accompany the transmittal. This is the opportunity to have your last say. Otherwise, this is the copy that we intend to carry forward to the full HITAC.

Steven Lane

And, I will also note in that context that we have a really good track record. The HITAC has liked our recommendations, and Micky has liked the HITAC recommendations thus far, so this is as close as one gets to a direct route to the ONC's ear.

Arien Malec

By the way, I am done with the draft text.

Steven Lane

Terrific, okay. So, for the display here, we will drop down to 26 again and try to tackle that. All right, we will just continue to look for hands. So, now, do you want to walk us through this, Arien?

Arien Malec

Sure. Two main changes. No. 1, as our context, is "Where is ECR is adopted, laboratories should not be encumbered," yada yada yada, and the second is the inclusion of this "for clarity" sentence. "These recommendations would not apply where an ECR is not available, or where the laboratory itself is a source of contextual information." We give a couple examples of direct-to-consumer or information collected at the specimen collection itself.

Hans Buitendijk

Thumbs up.

Arien Malec

Ike?

Steven Lane

Are you good with this, Ike?

Arien Malec

Is this responsive to your comments?

Steven Eichner

I think we are there.

Arien Malec

Good.

Steven Lane

Going once, going twice? All right, we are going to change the text color. Go crazy. All right. ONC team, are you guys comfortable with everything we are doing, with our process, etc. up to this point? Any concerns?

Michael Berry
No concerns.

Steven Lane
Wonderful, all right. Grace, thank you for doing your reordering there. I appreciate that. Okay, good, and we will figure out how to move that into slide format. Ram, let's pop over to the spreadsheet, if we can do that. You will all notice, if you want to pull up the spreadsheet yourself, that we have hidden the rows of the items that we incorporated elsewhere or decided not to address, so in the spreadsheet now, we are just displaying all of the purple, which has been incorporated into our report, except for this Item No. 36, regarding EHR decision rationale, which Ram raised just recently. Do you want to walk us through that, Ram? I hope you are still with us. There you are. You might be double muted.

Ram Sriram
Can you hear me now?

Steven Lane
Now we got you. Go ahead.

Ram Sriram
For some reason, it randomly took me to somewhere else. Again, this is Ram here, from NIST, and my comment is more about the future of what is going to happen for EHRs because people are talking a lot about AI and those types of things, but what we have actually been doing so far is mostly in terms of the past and present, what has already been done, and we are trying to incorporate that and see how this could be interoperated, at least at a syntactic level. Interoperation has both syntactic and semantic kinds of things involved in it, and some of the things that we have put in there also have semantics associated, but in the future, when the AI systems are helping EHR to make certain decisions.

For example, with ulcerative colitis, the GI person comes up with a particular diagnosis and wants to send that particular information to the internist. How does one go about doing that? How does one go about recording that in the EHR, and how can you transmit that, communicate it both syntactically and semantically, to the internist with the EHR? To do so, we have to incorporate this whole concept of design **[inaudible] [00:41:10]** rational, and that is what I was proposing on. That is all.

Steven Lane
We are having a little trouble with the display, Ram, so I took and copied your draft recommendation from the spreadsheet into the public chat so people can see it there. So, you included a little background text, very brief. Let me fix this. Oh boy, sorry. I am losing it here. And, that recommendation… So, again, this is an 11th-hour suggestion to add this.

Ram Sriram
But, as I mentioned, it is something to think about for the future. We will not be able to do it right now.

Steven Lane
Right, right. This is really the notion that in the ISA, ONC would track this as a use case.

Ram Sriram

Yeah, that is all. Nothing more than that. I have been working in AI for about 40 years or so, this is based on some of the background. Especially with what is happening in the AI world right now, I think explanations are going to be extremely important in the medical field, especially if you want to increase trust in the decision making. If you do that, then you want to relay to the proper stakeholders why a certain decision has been made, and then you can track the decision making and all kinds of things. That is just a comment about the **[inaudible – crosstalk] [00:42:50]** of the AI.

Steven Lane

Arien?

Arien Malec

I am struggling right now with how we format this as a… So, we have a set of recommendations structurally where we want to list in the ISA a use case, and/or that we want to track a use case to a standard. So, those are the easiest recommendations for us to add. Are we recommending that ONC track a use case in the ISA, and are there standards that we want to name in the ISA? So, in the area of decision support broadly, we do have CDS Hooks and other means for incorporating the results of decision support, whether through traditional means or through AI, into the EHR. We also have ISA standards for data extract and data availability to feed AI/ML models. The area that seems to be missing in the AI space is ethical use or ethical guidelines for creation of AI/ML models, but it is not clear to me if that is an ISA standards add. It feels more like a policy add. So, that is where I am getting stuck here. I agree with the sentiments, I am just stuck with how we format this in the transmittal as a request to ONC to track something in the ISA. Grace, you have your hand up, and Hans has his hand up.

Grace Cordovano

I have to gently disagree. This is not necessarily new. We have touched on this in previous discussions, also in the USCDI Taskforce work. This is something that was submitted in ONDEC, and I did post a link to it and it is at comment level, that technically, if the output from any AI/ML/MLP-powered predictive analytics that are considered clinical decision support tools at point of care is used to guide decision making about an individual's care and coordination, it should fall under all EHI, and I have spoken to ONC numerous times about this. I have not really gotten clarification, but it it if is being used to guide patient care, it seems that it would be part of the designated record set, and it certainly could be information that could be exchanged.

Arien Malec

Yeah. I would absolutely agree with you that because the DRS includes anything that is patient-specific that is used to guide care, then the conclusion would be if the output of an AI model is patient-specific and used to guide care as part of the DRS, that is a policy recommendation. I am going super narrow and policy focused. We are making a set of recommendations relative to the ISA, and so, with the exception of our free-range **[inaudible] [00:46:27]** orders results, which we spent a lot of time trying to figure out how to format and make as extensions of the ISA, I am trying to figure out how to make that comment an ISA-related comment because I agree with the sentiment and I agree with the perspective. It does not feel like it is the place of this workgroup to make those recommendations. Hans, maybe you or David can rescue us and put together a policy framework where we can fit this in.

Hans Buitendijk

I like the intent behind this to have clarity on that, and if so, how one would document it, but I think more discussion is needed. For example, is it only decisions that were suggested by AI that are then documented further on how they were done, or is it any decision by a clinician? What is actually the scope? Because the current language that is suggested could include all decisions that are made by clinicians to provide encoding of the decision rationale that they use. So, I think there is a bit more work to be done, and then, the question is where was the AI, MLP, or otherwise invoked medically, and where were they actually decision support tools based upon which clinicians make decisions? So, I think there is a lot to be worked through. I am not disagreeing that once you have that information associated directly to a patient, it is highly likely that it becomes EPHI.

Arien Malec

Hans, I think I am now vectoring in the right way. The specific request is to make sure that the output… We have a CDS Hooks or other mechanism for incorporating decision support into the EHR. We need a corresponding mechanism, and maybe David will tell us this is already part of CDS Hooks, and I believe it is because you get cards which can be incorporated into the EHR. We need a clear standards mechanism by which the output of decision support, that is, the tailoring of the decision support algorithm to the patient, can be incorporated back into the EHR. First of all, Ram, is that the framework that we should be thinking about your recommendations in?

Ram Sriram

I mentioned that the recommendation is not so much at the present because there is a lot of work which already needs to be done, as you can see, so we do not know how ONC is going to deal with this. We are to prepare them for the future. That is what I am looking at, and following Hans's comments, this involves all decision making there, and I used AI as an example there. So, that means it is a lot of work that someone has to put in. Someone has to come up with this entire recommendation scheme, and nothing is out there, except in bits and pieces. So, my intent is not so much to say that you have to put this in this particular document, it is more that you have to put it on the table to discuss it.

Arien Malec

Okay. David is going to have the magical solution for us.

Steven Lane

Sorry, in the display, can we pop back to the document on Page 18, where I have been trying to capture some of this? Maybe we can work there. First, I think we have to make the decision whether we attempt to add this at the 11th hour, and if so, what does it say?

Arien Malec

My take as a fellow cochair would be if we add it, we add it relative to tracking standards for encoding the output of decision support, including decision support that uses AI and ML, where that output includes the rationale for the recommendations.

Ram Sriram

Arien, I think that should be good.

David McCallie

This is David. The way I am thinking about this is in whichever section of the ISA documents clinical support standards, there is an emerging use case for tracking and standardizing the explainability, which I think is the term that is being used in the AI community, of AI-recommended decisions. So, you have increasingly got black boxes, and a clinician or a patient might wish to know why the black box recommended that they receive treatment or not, and I think the research is still quite young and quite active, so there are not emergent standards that I am aware of, but in the long run, there will need to be ways to explain and track the explainability of a particular decision recommendation. So, I think it is for the future. Arien, if you want to turf it to the next instance of the ISA, we have done that in the past, tracking things for the future.

Arien Malec

I think this is good. I think this recommendation is narrow, targeted, and it feels like something that ONC can make action on. There is an existing standard to provide access to appropriate use criteria in the ISA that refers to CDS Hooks already, so it feels like a natural extension to the existing CDS content structure recommendations in the ISA.

David McCallie

Right. Yeah, there are a number of clinical decision support standards tracked in the ISA, not just CDS Hooks, which is really more of a delivery mechanism. So, I am happy with this language. I think it is just a placeholder for work that will emerge in the future, and that is not a bad thing to put in the ISA, so someone who is trying to get up to speed on what is going on in clinical decision support would be aware that there is an emerging recognition for the need of explainability.

Steven Lane

How about the language? Does anybody want to take a stab at that, if they need to?

Arien Malec

It looks good to me.

David McCallie

My only concern is the rationale for recommendation. It is really the rationale behind the recommendation. It is not whether you should make this recommendation, it is why you made this recommendation.

Steven Lane

So, have at it, David. Which bullet are you on?

David McCallie

I am at "This should include the ability to standardize, document, and display the rationale behind recommendations generated by…"

Ram Sriram

Ram here. So, one comment that was made is this should be for both AI and human decision making. Arien, did you make that comment on that? Even for human decision making, how do you know why they made the particular decision?

Arien Malec

So, traditionally, decision support has been through encoded rules, and then, increasingly, decision support is via AI/ML algorithms. In each of those cases, not just the recommendation, but also what we are calling the rationale or the explainability of the recommendation should be included, and I think what we are calling for is making sure that we track the need for incorporation of both back into the EHR.

Steven Lane

And certainly, when you think about human decision making, clinicians who make decisions are already trained to document as part of their clinical documentation. Their decision-making process is required for certain billing and coding, so I do not think we need to track that in the ISA per se.

Arien Malec

That is right. It is areas where we have rule sets that are encoded by humans based on evidence-based guidelines where those rule sets need to include not just the decision, but also the rationale, and typically, you do this in e-prescribing, you do this in appropriateness of use criteria, you do this by providing evidence for the specific decision. Grace has a comment.

Grace Cordovano

I just have a question and would like to clarify. There are a number of comments too, and the understanding is that the information is already there, but when we talk about "there," it is not patient-facing, it is not individual-facing. This is all internal information that is available at point of care, mostly to physicians. It is not readily available to patients. So, I think that is another piece. Is that something that is relevant to emphasize here, that it needs to become patient-facing, transparent information?

Arien Malec

Grace, I think we can get that by encoding, communicating, and documenting because, to your point, when the output is documented and charted, which it needs to be because it is part of the DRS, then you have the policy hook to be able to provide it back to the patient as well.

Steven Lane

I added a sentence at the end here, trying to capture some of that.

David McCallie

I see this as upstream of the decision on how to use this data. Can we state that we expect black box decision support to be able to offer an explanation for the recommendation? I think that is the best policy.

Arien Malec

Right, and again, not to over-constrain how you would do this, but the output of a CDS Hooks process includes a set of cards. Those cards can and should include not just the recommendation, but also the explanation for the recommendation, and those cards can and should be incorporated into the EHR.

Hans Buitendijk

And Arien, where CDS Hooks are used, those are capabilities, but this area of decision-making supports, etc. will not be limited to the use of CDS Hooks. There will be many other places where there are capabilities

that are being used that generate orders, diagnoses, plans, suggestions, and otherwise. How did you come about those that I might have invoked in many different ways?

Arien Malec
No doubt, and again, where I am trying to get this down to is recommendations that go into the ISA, where you want to name a use case, and then you want to name standards and implementation guidance that are associated with that use case.

Hans Buitendijk
In that context, I put in the chat that I think we need to look a little bit further, but evidence reports and one other variable in FHIR might be standards to reference as well to say that there might be something that needs to be followed up on to see if they are indeed applicable.

Arien Malec
Okay, cool. Steven is walking on a tightrope wire now.

Steven Lane
I am doing the best I can here. Okay, how do you like that? How do you like them apples?

Arien Malec
Yup.

David McCallie
I like it.

Hans Buitendijk
Yeah.

Steven Lane
Okay. "…are existing standards." Better still. Okay, let's see. John Kilbourne, you have been commenting. Are you comfortable?

John Kilbourne
Yes, I am comfortable.

Steven Lane
Wonderful. And Andrew, you have been chiming in also from the ONC perspective. Do you have any concerns about this? Thanks, Raj.

Andrew
No concerns at the moment, thanks.

Steven Lane
Awesome. Anybody else? Hands?

Hans Buitendijk

Yeah, Steven. One thing is where it says there are existing standards, maybe we should clarify a little bit further there with "There are already some existing standards" because it is not complete. So, there is something emerging there we want to look at.

Steven Lane

Okay, good. Well, Ram, thank you for your willingness to bring forward this topic as you have.

Ram Sriram

Thank you.

Steven Lane

All right. Have we anything else from the things we have touched on? I am looking up above. Oh, Christina. We got some more spacing and wordsmithing. Thank you very much for going through those. I do not think we need to discuss those. We will just accept your changes. Looking up further, I do not see any other recommendations in the document. Let me get some font color here. All right, this is looking pretty good. I want to specifically and directly thank Arien for a lot of hard work on the background and executive summary and pulling that organization together. That was very helpful, I think.

Arien Malec

That is how the sausage is made.

Steven Lane

Indeed. You can work in my butcher shop anytime. All right, Hans needs to jump. I think we may be finishing early today, which is totally fine. We will be working with the ONC team to turn this into slides. Does anybody feel a deep and abiding need for us to meet next week, or can we work on these slides through the next 48 to 72 hours, and then get these out to all of you for review and try to manage that electronically if we can through the end of this week and over the weekend, and then only meet as necessary, with the caveat that I may miss next week, even if you do meet, because I will be at my daughter's wedding?

Arien Malec

First of all, congratulations. Secondly, I would encourage the workgroup to do one last read of the document with a critical eye. I am sure there are typos. And, I think we can send the transmittal accompanying PowerPoint deck via email for the workgroup's review. If there is a substantial demand to meet next week, I am more than happy to conduct that session and walk the workgroup through the accompanying PowerPoint deck, but really at the workgroup's discretion. But, hearing no pleas for meeting, I would propose that we just do this via email and offline review.

Steven Lane

I will also remind everyone that you are more than welcome and invited to join the HITAC presentation discussion of this on the 16th of June. Like these meetings, I think there is a public chat on the HITAC. Mike, correct me if I am wrong.

Michael Berry

Yes, there is a public chat, and there is also a formal public comment period similar to this.

Steven Lane
So, lots of opportunity for engagement.

Michael Berry
Arien, if this helps, the way I heard Steven's comment was to leave it on the calendar, but only have it if needed, rather than to cut it off the calendar right now.

Arien Malec
Works for me. We will leave it on the calendar and cancel it on Monday unless there is a substantial call to meet.

Steven Lane
All right. And, just FYI for the group, we have had input from various group members who have and have not been able to participate in expressing their support and enthusiasm for the work that is going on. Clem in particular sends his regards and has been tracking our work from afar. All right, with that, why don't we close the meeting? ONC team, why don't we all plan to have our follow-up meeting now to get that done instead of waiting another half hour? Is that okay with you guys?

Arien Malec
Public comment?

Steven Lane
Oh, we have public comment! My bad. Yes, public comment.

Public Comment (01:04:59)

Michael Berry
All right, 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 are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. And, let's see if we have any public comments. Not seeing any, I will turn it back to our cochairs.

Steven Lane
All right. Again, thank you to the various members of the public who have been here and have been listening and following along. We appreciate your participation. And, thank you all to the workgroup members. This might be our last meeting. I believe we do not have a plan, as far as I know, to meet after the HITAC meeting. Do we, guys?

Arien Malec
I do not believe so.

Steven Lane
Okay. So, again, if this is indeed the end of our time together, a huge thanks again for everybody's time and participation. I think we did our work, I think we have come up with a really nice set of recommendations, and I will be proud to join Arien in presenting them to the HITAC next week.

Arien Malec

Thanks, everybody, and please do tune in to hear the festivities. Hopefully, we just overwhelm everybody with the elegance of our recommendations, and we have no debate and comment.

Steven Eichner

Arien, Steven, this is Steve Eichner. Thank you so much for your leadership for the workgroup's activities. I think we really produced some good work.

Arien Malec

Absolutely. I think it is a testimony to the group, and to all the fantastic input, and also to Steven Lane's amazing stone soup method for crowdsourcing recommendations.

Steven Lane

Everybody have a great day, and Arien, let's you and I jump over and meet with the ONC now.

Arien Malec

Good.

Steven Lane

All righty. Bye-bye.

Adjourn (01:06:37)