



Transcript

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

May 31, 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

And, good morning, everyone, and thank you for joining the Interoperability Standards Workgroup. I am Mike Berry with ONC, and we are always happy that you could be with us. 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, let's begin roll call of our workgroup members, and when I call your name, please indicate you are here. 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?

Hans Buitendijk

Good morning.

Michael Berry

Thomas Cantilina? Christina Caraballo? Grace Cordovano?

Grace Cordovano

Good morning.

Michael Berry

Steven Eichner?

Steven Eichner

Good morning.

Michael Berry

Adi Gundlapalli or Sanjeev Tandon? Raj Godavarthi?





Rajesh Godavarthi

Good morning.

Michael Berry

Jim Jirjis? Ken Kawamoto? John Kilbourne?

John Kilbourne

Good morning.

Michael Berry

Leslie Lenert? Hung Luu is going to be absent today. David McCallie?

David McCallie

Good morning.

Michael Berry

Clem McDonald? Mark Savage?

Mark Savage

Good morning.

Michael Berry

Michelle Schreiber? Abby Sears?

Abby Sears

Good morning.

Michael Berry

And, Ram Sriram?

Ram Sriram

Good morning.

Michael Berry

Good morning to all, and thank you, and please join me in welcoming Steven and Arien for their opening remarks.

Co-Chair Remarks (00:01:55)

Steven Lane

Well, good morning, everyone. Once again, we are here at what we hope to be our final working group for finalizing recommendations that we will be sending on to the HITAC now in a week from Thursday. It will still be next month. And so, we are very excited to be here to try to move through these as quickly as possible. We did just hear this morning that our first set of recommendations, our Task 1 recommendations, that were presented to HITAC, approved unanimously, and transmitted to the national coordinator have





been approved and received by the national coordinator in their entirety and without editing, so those have now been made part of the official public records. You guys can all feel very proud of the work that you are doing and the fact that it is being well received by the folks downstream of us. Arien, do you want to add anything?

Arien Malec

No, just to remark, as usual, that we have made a huge amount of progress to date, but our June meeting is rapidly approaching where we have to finalize all of these recommendations. We have a lot of work to do today. Let's dive into it.

Review of Recommendations (00:03:11)

Steven Lane

And, just a reminder to members of the public who may be joining us that we welcome your input. You can use the public chat during the course of the meeting, and we have reserved the last five minutes of our time for public comment verbally. If there are a number of people who want to make public comments, please raise your hands early on, let us know, and we can move to public comment early as necessary. So, we have a number of recommendations that we want to work through today, essentially cleaning out as much as possible those that people have worked so hard on. As you heard, Dr. Luu cannot join us this morning, but Hans has worked closely with him in the development or finalization of the lab recommendations. We will be starting with whoever is presenting on Row 41, Item 33A.

Arien Malec

Just as a reminder, last time, we got through the resulting set of recommendations, and now we are starting in on the ordering set of recommendations, just to situate people appropriately.

Steven Lane

And, what I am going to do again is sort of monkey with the display of the document so that we can see as much as possible on the screen so we can have our font size as large as possible, and as soon as you guys can get us to Item 33A, while it is coming, I will get you started, Hans. This is a recommendation, and again, it has to do with lab orders specifically. So, the recommendation is that ONC, in conjunction with other federal partners, SDOs, and industry partners create and support a policy framework that encourages, incentivizes, requires, or otherwise enables by and multilateral, including public health, closed-loop order-to-result communication using standards and comprehensive implementation guidance.

Now, I will just set you up, Hans, by reminding you all that this is not an ISA-specific recommendation. We are not making a comment or suggestion here about either the structure, or the content, or the process of the ISA itself, but it is certainly related to ISA standards, and our plan is to separate out these related recommendations into a separate section and present them to the HITAC after our ISA-specific recommendations, but we all feel and we have gotten reassurance from the folks at ONC that this is within our scope, so we will be proceeding in this way.

Arien Malec

Or, at least scope-adjacent. I think the way I would put this is that we have the specific task to make recommendations for updating the ISA. At the same time, we have noticed that there are elements in the ISA where the standards are fit for purpose, but universal adoption is not yet received, and so, those are





the areas where we are weeding in to look at specific work that is required to get to for, in this case, end-to-end order-to-resulting.

Steven Lane

And, there we are. Wendy, go ahead and increase that size display so that we can see more of it here. Hans?

Hans Buitendijk

All right, thank you, and as Steven indicated, Hung is not available today, but I will try to do my best to help provide the context behind this and how it fits. As Steven also indicated, on this first one on Line 41, it is about a policy, not about the guide itself, but as a side note, an awareness that both the LRI and the LOI are about to go through what is called in HL7 a peer review with the latest updates that will also include the latest approaches that we are learning from COVID and that are widely distributed as guidance, as well as work on the SOGI in progress. So, if we want to provide a heads-up, although ONC already is most likely aware of it, that there are new versions coming out, we could add it as well, but that is not the main focus here.

So, the first one is very clear. We talked a little bit before about the closed loop from ordering to results with LIVED enhancing the encoding of the results coming back because not all devices can accept LOINC contacts and not all orders contain LOINC contacts. We want to move forward with that and make sure that it comes back. ELR was called out in the notes there as well because LRI is not only about lab results generally, but it is also specifically providing guidance on lab reporting for public health. And, if we can do more to help ensure that all parties, not only the ones sending the order or receiving the result, but everybody in the chain can contribute to that, and the policies would be focusing on that entire set, hence the reference to closed-loop, and not only on one side of the equation. So, I could move forward, but I will pause for a moment and see whether there are any questions or comments.

Arien Malec

Ike has a question. Go ahead, Ike.

Steven Eichner

It is not a process question, just a language piece. Maybe we can clarify a little bit the closed-loop and multilateral, just to clarify that there are two slightly different purposes, with closed-loop applying, but not necessarily the same standard coming back on the multilateral in terms of closing a multilateral, if that makes any sense.

Hans Buitendijk

Ike, if I hear you correctly, that would mean clarifying more that the order out and the result in are not necessarily the same standard, though they are related. Is that what you mean with bilateral and multilateral?

Steven Eichner

Maybe the same standard, but it is a slightly different process. In other words, the closed loop is order to result back to the ordering entity, and the multilateral is obviously not based on the order. Does that make sense?





Arien Malec

This one was one where we tried to be deliberate in wordsmithing. The intent is that we go from order to result, where that result is returned back to the ordering provider and also provided onto other key actors, most especially including public health. That is the intent of a very shortly, precisely worded statement. I am very happy to explore other ways of saying the same thing, but I think it says what we intended to say. If there is a specific wordsmithing that you think would improve the readability, I am definitely open to it.

Steven Eichner

Contrariwise, looking at a multilateral closed loop, I am trying to envision what that looks like.

Hans Buitendijk

Ike, I just jotted down a note on the side not to be included yet, but I get the sense that multilateral is more that we want to include terminology to emphasize that all actors, such as the ordering provider, the lab, etc., are engaged to cover the closed loop from order to result and back.

Steven Eichner

Right. I am not questioning the idea of multilateral routing. It is more looking at the idea of a closed loop. Usually, in this context, it is a single order with the result being sent back to the entity that ordered, and then, multilateral distribution is a secondary or a second component of results reporting.

Arien Malec

Okay, cool. So, if we modified this to say that it enables closed-loop result-to-order communication and multilateral distribution, including public health, that would... Hans, why don't you continue? Let me do some work on some wordsmithing, and I will post it to the chat.

Steven Eichner

I think that it is exactly it. It is simultaneously multilateral. It is not that it is a separate process, it is just clarifying what the intent is, which I agree with completely.

Hans Buitendijk

Do you want me to go to the next one, then?

Steven Lane

Yes, please.

Hans Buitendijk

So, the next one that is up is now looking more at the same starting of the recommendation to ONC, "In conjunction with federal partners," but to really focus on the most common important orderable tests and panels for each order type, including the orders that link to prioritized results. A lot of work has already happened, but let's make sure that that continues so that the library of standards vocabulary is expanding and is more widely used so that it not only exists, but is used in that closed loop through all the different steps where it becomes relevant.





So, examples are listed below: Harmonization, advancement, consensus of standards-based catalogs. The laboratory and radiology tests are using, for example, LOINC universal lab orders. In that sense, it also goes beyond LRI and LOI in that radiology tests are not covered under LRI and LOI, but they are covered here, so we need to keep that in mind as well, that this is extending across any kind of orders effectively, not just lab. And, when the custom non-panel LOINC codes for the individual tests can be used, they should be made available with mapping provided there as well, which ties back to some of the other things.

We talked before about lab order details such as frequency, priority, and timing, and they are addressed as well. And, for radiology orders and order details such as imaging modalities, anatomic location, etc., those data elements should be part of it as well. Again, just to clarify, the radiology orders are not covered under LRI/LOI. They would be currently addressed effectively in anybody's interpretation of Version 2 from IHE standards that are available, so that is a much bigger mixed bag at this point in time.

Steven Lane

So, Hans, I will just make a friendly amendment here. We have been discussing this in various settings for a number of years now, and it goes beyond lab and radiology, of course, so I think this need for identifying the most common and important orderables and results and supporting those at a national level through the A prioritization schema is really important, so I would just make this one suggestion, if that is okay with you.

Hans Buitendijk

No concerns here.

Steven Lane

All right. Arien, do you want to back up?

Arien Malec

Yeah. David has a question first, and then maybe we can back up on the language and just see if we have consent on the language.

David McCallie

Yeah, on what I would have called a standardized order catalog, this 33B, do we have some notion of what the point of it would be? Is it just that there would be some unstated incentive to use it as opposed to what you are currently using?

Steven Lane

I can answer that when this came up some years back, and David, I think you were there in our Interoperability Standards Taskforce, where we were dealing with the challenge of mapping and the fact that we needed for these orders and results to move effectively between ordering provider, resulting agency, downstream users, that we really needed everyone to be on the same page, and if we could identify the top 20, top 100, or top 500 orders and everyone could do whatever mapping, testing, etc. to make sure that those worked well, that that got us a long way down the line with the traditional 80/20 rule. So, I think that is the purpose here, to identify the priorities such as the likely hemoglobin, the INR, the PSA, the chest CT scan for the lung cancer screening, you name it. There are commonly used tests for population health management, for health maintenance, for quality reporting, etc., and the idea was to capture those.





Arien Malec

The answer to David's question is yes. The intent is to create a standard catalog of orderables.

David McCallie

Yeah, and I have obviously pushed for that for more than a decade. I am just now wondering what the impact of it is, who is going to make it happen, why they would make it happen...

Arien Malec

Look at 33D in terms of the recommendations, and look at 33C. Those two really get at the... Cool. And also, if we could have ONC work on a policy framework that includes submission of self-developed tests for assignment of standard codes and assure the harmonization of multiple existing code sets for orderable tests, that is really where we would get at actually using the orderable catalog. But, in general, the framework would be making sure that we have the standards for order-to-result, to public health, and to ordering providers, as well as referring providers, etc., making sure that in the order, we have a standard orderables catalog that can be used, and then, it would be pretty cool if the receiving labs could actually receive the orderables catalog. But yes, this is why it is a complex space, because you actually need multiple actors to collaborate on multiple elements of the standard space.

David McCallie

Yeah. So, as you know, the problem has always been not that we did not know what our common orders were, but that there was no reason to change your order catalog to map to the common order catalog.

Arien Malec

Yeah, in the same way that there was no reason to use LOI or LRI.

David McCallie

Well, there were. There were specific incentives for those two that have topped out, so that is kind of what I am getting at: What is the incentive? But anyway, you have answered the question that you have got additional recommendations that are pushing in that direction, and that sounds good.

Arien Malec

Yeah, and we have been asked by ONC to be careful about how we articulate specific incentives. I think there is a policy framework that ONC could put together with other federal actors that would create a meaningful policy framework that encourages adoption, but we have been asked not to weigh into the policy programmatic.

Hans Buitendijk

On that note, though, Arien, would it still fit in light of the other places that we indicated here, "encourages," "incentivizes," etc.? Would we use those terms to also indicate that ONC looks at approaches on how to encourage and incentivize the adoption of it? Because just creating the catalog does not necessarily mean that we...

Arien Malec

Should we say "prioritize and adopt"?





Hans Buitendijk

Correct.

Arien Malec

Yeah. Again, let me do the same offline magic on wordsmithing.

Hans Buitendijk

I think the intended goal is that where there is communication across parties, rather than it only including a local code, it already would include, depending on the circumstances, in addition to or just the LOINC, SNOMED, or whatever the appropriate code is for the test or the result value, that it already includes that as much as possible. It does not mean that locally, you could still do some mapping where it is not available, but what would it take to not only have this catalog, but also that it is being increasingly used consistently?

Steven Lane

So, let's scroll back up to 33A. I would like to finalize these as we go. I have captured the text that Arien suggested, just separating the bilateral closed-loop order-to-result communication and the multilateral distribution. Any questions or concerns about that new language?

Hans Buitendijk

Perhaps on the multilateral distribution of the results, maybe just make it explicit.

Steven Lane

Perfect, got it. Any hands up? Any comments? I want to acknowledge a number of you who came a little late and introduced yourselves in the chat. Thank you for that. All right, if there is no objection, we will consider this one to be completed, and similarly, we discussed 33B. Any questions or concerns with that one?

Arien Malec

In purple.

Hans Buitendijk

Arien, I think you were still trying to do "prioritize and adopt,"

Arien Malec

Yeah, "prioritize or incent the adoption of the most common."

Hans Buitendijk

Yeah, we are still wordsmithing.

Arien Malec

Steven, I will take care of...

Steven Lane

Popping that in?





Arien Malec

Yeah.

Steven Lane

Okay, good, but otherwise, we will consider 33B acceptable to the group. Great, turn it purple when you are done. We made mention of 33C. This was incentivizing laboratories to submit self-developed tests to LOINC for assignment of standard codes. This is kind of part of the puzzle that will make this work. Any questions or concerns on that one? 33D is also mentioned in this state.

David McCallie

Steven?

Steven Lane

Yes, David?

David McCallie

On 33C, the IVD developers submit their tests to FDA, and then indirectly to SHIELD. Is LOINC the right target for this?

Hans Buitendijk

The IVD tests are being mapped, or guidance for most appropriate mapping based on content is provided by the manufacturer as to what LOINC code for the tests and what LOINC or SNOMED codes for the result values that they generate.

Arien Malec

Yeah. So, we already have recommendations up in 32 on the LIVD/IVD mapping process. This is for the order, and making sure that self-developed tests have an orderable code that is mapped into LOINC.

David McCallie

Well then you should clarify that because a self-developed test sounds like an IVD to me, if by that, you mean somebody doing some chemistry to get a result.

Arien Malec

Yeah, it is a different regulatory scheme, unfortunately. So, we have a set of regulatory schemes that are under FDA for mass-developed IVDs, and then, a different regulatory scheme for self-developed tests.

Hans Buitendijk

Do we want to clarify to make sure?

Arien Malec

I think we should make an assignment of standard orderable codes. I will make the edit.

Hans Buitendijk

But, would it also help to say that this is not about manufacturer IVD tests?





David McCallie

I am not concerned about that so much as whether we are channeling the same advice in completely different directions, and as a clarification, is this about the orderable side? That helps.

Arien Malec

Good, okay. I will make it purple.

Hans Buitendijk

Arien, in the other cases, I think we have used the term “test codes” instead of “orderable.”

Steven Eichner

This is Steve Eichner. Real fast, don't you also want the same LOINC code to be used on a result that is provided?

Arien Malec

Yeah, we already covered that one above.

Steven Eichner

Okay.

Steven Lane

Display, please scroll up to 33B just so that we can clarify the language that was added in response to comments. Any concerns about the final language?

Steven Eichner

I would put “incentivize” instead of “incent” in the second line, just underneath “partners.”

Arien Malec

Okay, “incentivize.”

Steven Eichner

Sorry, in 33B.

Arien Malec

I got it. All right, good. Done. In 33C, we have got a little bit of a language change there. Anyone have any concerns with that? Steve, your hand is still up.

Hans Buitendijk

Perhaps one comment, but this might be cutting it a little too fine. Not all tests are orderable. They are indirectly being performed, but not necessarily orderable. I am just wondering if by having the term “orderable” in here that we are effectively aiming at too small a set of test codes. “Test codes” would be all, “orderable” would be a subset, and I think we want them all.

Steven Lane





So, standard...?

Hans Buitendijk

Test codes.

Steven Lane

Test codes, all right.

Hans Buitendijk

Because “orderable” is a subset of it.

Steven Lane

Arien, I think you are in there.

Hans Buitendijk

Arien, are you okay with that?

Arien Malec

I did it already.

Steven Lane

Okay, do you want to turn it purple for us?

Arien Malec

I will turn it purple.

Steven Lane

Terrific. All right, next up, 33D.

Hans Buitendijk

So, in 33D, harmonization of multiple existing code sets for orderable tests, it references SNOMED, CPT, and HCPCS across the different areas, whether you are in a clinical or an administrative/financial, shifting around between code sets, and as a result, that can get confusing, as they are not necessarily at the same level of granularity. So, the intent here is to encourage that as much and wherever possible that that is aligned so that we have one consistent set whenever possible. That is, in itself, probably a very large discussion based on some areas where perhaps there is more granularity needed for one purpose or another, but the more it is aligned, the sense and belief is that that would also enhance clarity and consistency, reduce documentation burden by having to know different kinds, etc., so, trying to get to a more common set rather than multiple.

Steven Lane

And really, identifying LOINC as the hub here, the idealized hub for this work at this time. John Kilbourne?

John Kilbourne





Yeah, I think the more we can specify or crispify the purpose of this, the better because “harmonize” means a 10-year-long discussion of things that does not always end up landing somewhere. I am being a little facetious there, but the more we can focus what we want to have happen, we want these test scheme/code schemes to do what? To come together, for people to use a common set? Maybe I am the only one, but I do not really know what we mean by “harmonize” in this context, and I have been at a lot of harmonizing discussions in the last 10 or 15 years. I do not really know what we mean here, and maybe somebody else might not know exactly what we are trying to accomplish by harmonizing.

Arien Malec

These are not radically different worlds, like the DOD and the VA. Sorry, that was a really bad joke.

John Kilbourne

No, I am with you there.

Arien Malec

No, I agree. So, Hans, I think the intent is we should be using LOINC for orderables, right?

Hans Buitendijk

Yup.

Arien Malec

I think John has got exactly the right point. Should we say we should be using LOINC?

Hans Buitendijk

And, I think we can make that explicit. There is one set that is used, and from there, everything is derived and pulled.

Arien Malec

“The standardization of orderable test code sets to LOINC.”

David McCallie

I think maybe “cross-mapping” is the word you are looking for, instead of “harmonize.”

Arien Malec

I do not think so. I will let Hans comment on that, but I think right now, for orderables, LOINC catalogs are probably the most common. There are some people who, given the same set of information, pick CPT for reasonable reasons, and then, there are other folks, long-tail off the list, who pick a different terminology set for an orderable catalog, and I think what we are saying is darn it, just use LOINC as the orderable catalog. Hans?

Hans Buitendijk

Yeah, but to one thing that Dave mentioned, there is a part of cross-mapping and there is a part of alignment on the singular one in that they are probably both happening at the same time. Even if we arrive at LOINC as the set, those other code sets might still be appropriate to be used, and that is what we need cross-mapping for, or we are not fully there yet, and we need cross-mapping. So, I would agree with David that





there are two elements to it: Cross-mapping and alignment, and getting us to a singular set for orderable. That does not mean that there might not be purposes for other sets for other purposes.

David McCallie

Yeah, people use HCPCS and CPT for very specific reasons: They like to get paid. They are not just going to switch to LOINC unless that continues to happen. That is why I am saying at a minimum, it is a cross-map. If you force them to use LOINC, they need to be able to go back and say, "What is that equivalent CPT or HCPCS?"

Hans Buitendijk

So, I would put the clarification that it indicates that, that it is both. We are aiming for LOINC, and we need cross-mapping to get there and to keep connection with the other code sets as well, but we still need them.

Arien Malec

How about that?

David McCallie

I like that. David says yes.

Hans Buitendijk

Yup.

Arien Malec

Let's let it be, and we will turn it purple.

Steven Lane

And, I want to remind people that this is really down-in-the-weeds work. People have been trying to clarify these recommendations for years, and of course, the environment in which we are functioning is changing. I have to tell you, for those of you who are uninitiated, if Hans, Arien, and David agree on something, it is almost certainly spot on. I have come to learn this. I did add a policy lever up in 43J regarding our Recommendation 33C. Thank you, Sylvia, for that. All right, shall we go on to Recommendation 34?

Hans Buitendijk

Let's see. We have talked so far about the provider, the clinician perspective, and the closed loop there to order and result on the test. This one is shifting the focus to the patient, and to get to a point where we have names of tests, results values, and otherwise, that are easy to understand and patient-friendly as well, so that these items are being displayed and used elsewhere in consumer-focused communication such as apps, portals, etc., that they become better and easier to understand and work with for the consumer. So, that is the focus of this one, to say that we should not only focus on what is appropriate for clinicians and providers, but also on what is appropriate and friendly towards the patient, so, order and result display names for patients.

Arien Malec

Hans and Steven, I think this work is in process and originally referenced a larger piece of context that, when we de-referenced the links, turned out not to be in progress. Should we just delete that sentence?





Steven Lane

That is fine. I believe there is still some work going on on this, but the key really is to keep this moving.

Hans Buitendijk

Is there a document, even if it is a small set, that is actually already in play that the ISA should reference as a work in progress, that we should add?

Arien Malec

So, Hung had a link to an organization that was looking at patient-friendly display names, but when I de-referenced the link, it did not exist. It had moved on, which was telling.

Steven Lane

Ike?

Steven Eichner

Just a minor wordsmith. I think probably distinguishing looking at using display names and displaying the names for patients could probably be reworded really quickly. I can take a shot at it online.

Steven Lane

Sure. If you think there is clearer language, take a shot at it, put it in red, and we will come back. Hans? Any other hands up? David, your hand is up.

David McCallie

Yeah. There is a certain complexity that cannot be elided away by a friendly name, and I would consider that something more valuable would be a standard explanation with a link. That is not to say that friendly naming is not important, but this stuff is complicated.

Steven Lane

That is a bigger kettle of fish, and there are a number of third-party vendors that have tried to develop some clarification on lab and other testing. I certainly point my patients to various references at different times. I do not know that that is necessarily something we are going to be able to tackle nationally, but it is an interesting point.

Hans Buitendijk

Is there an opportunity? For example, as part of certification, there has been the info button capability that was used to point to different knowledge sources, and it did not try to establish any particular one, but there was the ability to then reach out to that in a more standard fashion.

Arien Malec

I am going to request in this area that we stay pretty firmly in our lane. So, maybe the call here is for names and explanatory comment, or again, is that just straying too far?

David McCallie





Well, that was certainly what I was thinking, names and explanatory comments, or links and explanatory comments, or something, but Steven, I understand the point that the scope of that gets way big. But, somebody coming up with a simple, friendly name to explain some incredibly complex antigen test is going to be in explaining mode pretty quickly.

Hans Buitendijk

But, perhaps if we indicate an ability to link to it, as in David's example.

David McCallie

There you go. That is good. That is an implementation thing, but that captures what I am worried about, that the name itself is not sufficient, so do not spend a ton of money getting friendly names and then discover you still have no idea what the test means.

Steven Lane

All right. So, who is in that cell at the moment?

Steven Eichner

I am not.

Steven Lane

Arien is. Arien, do you want to add that?

Arien Malec

Sure. So, what we are asking for is display names and content links?

David McCallie

The ability to link to explanatory content.

Steven Lane

And, I did find the page on LOINC talking about the consumer names, which is where I got that phrase. We used to refer to these as patient-friendly names. They added that terminology. We could reference that when I said this work is in progress, but as we learned, there really is not a lot of work being done with that at the moment.

Arien Malec

So, I am actually struggling with where to put this and make the sentence actually read without a lot of surgery. "Patient-friendly..." Anyway, if somebody can help me, I would greatly appreciate it, because I do not think it is an easy add.

Hans Buitendijk

I can come back after the last one and then give it a whirl if you want to.

Steven Lane

All right, let's do the last one, Hans, because that was yours originally.





Hans Buitendijk

So, the last one is a bridge between ordering results on the lab side and the case reporting on the other side, where we see increasing overlap, that some data is being added to ELR that perhaps could be part, and then, a number of cases that could or should be part of case reporting. So, this is indicating that ONC, with other federal partners, particularly CDC and public health jurisdictions, should revisit the variety of requirements that are being put on ELR and find a better balance with the use of ECR to enhance and right-size those data flows. That is the intent behind that.

Steven Lane

So, basically, skinning down ELR because ECR should carry the water for some of these data.

Hans Buitendijk

Correct. Keep it focused on its intent, and then let ECR pick up on the rest of the contacts that it needs to convey.

Arien Malec

As an editorial comment, I think we have heard from public health that when ECR is broadly deployed, public health often gets the case report via ECR faster than it gets the actual lab result.

Hans Buitendijk

Clearly, ECRs are not required in all circumstances necessarily when there is a lab result, but many, but we can look at that as well to really get the improved data flow there, and the appropriate size of the data set as needed.

Steven Lane

Any questions on that one? And, Arien, I also tried a little wordsmithing on 34 and could not figure out how to fit in David's novel idea. So, I don't know, David. I think we may need to come back at that one, because it just muddies this water a bit.

Steven Eichner

This is Steve. I think looking at Line 35, are we referring to the performance of the laboratory test or the results of the laboratory test? In other words, I am concerned more about the results than the performance metrics around the test.

Arien Malec

Yeah, I think what Hans is saying is that in some cases, ELR is overloaded with a case reporting function, and in a world where we have broader adoption of ECR, we can lean more heavily on ECR as the case reporting function and keep ELR focused on providing public health the relevant result data.

Steven Eichner

Right, I thoroughly understand that. I was just looking at the word "performance," in other words, looking at the goal here being the test results reporting, not the statistical factors relating to the laboratory test unto itself. Does that make sense?

Arien Malec





Oh, when you say it is not relevant to the performance of the laboratory test, you are looking at that word “performance” there.

Steven Eichner

Right. I wholeheartedly agree that it focuses on results.

Arien Malec

Got it. So, you would move the word “performance” to “resulting” in that sense. Got it. Any objection?

Hans Buitendijk

Nope.

Steven Lane

All right. Any further thoughts on either 34 or 35?

David McCallie

I like the change on 34. This is David.

Steven Lane

Thank you, David. I am not sure who made the bulk of that change, but it is lovely. All right, let's consider both of those finalized, if we can. All right, and then, let's also move on. So, thank you for that, Hans, for taking us through that. Next up on our agenda is SDOH standards, CDC race/ethnicity vocabulary subset, per Mark.

Arien Malec

Easy for you to say, Steven.

Steven Lane

Right. And, I think we are going back up to the top of the document, and it is No. 7.

Mark Savage

Are you ready for me to go?

Steven Lane

Please.

Arien Malec

Go for it.

Mark Savage

Okay. So, I added a little bit over the weekend just for background that the workgroup has already heard. In the background and observations is the federal preference for self-reporting/self-identification for race and ethnicity, with a link to the standards policy back from 1997. The observation is that despite the preference, it often does not happen that way, and hence, the Gravity Project made the recommendation to add to ISA some work that the Gravity Project is doing. It is draft in STU2 for the implementation guide





to identify the source and method of collecting the value for race and to identify the source and method of collecting the value for ethnicity.

So, I have pasted the recommendation from the Gravity Project presentation succinctly right there on Column F about how to amend the ISA to include those things with a note that while we were charged with looking at this for race and ethnicity, this point about including source and method would be applicable to some other self-reported personal characteristics as well, and indeed, the Gravity Project is testing it for some other personal characteristics beyond race and ethnicity, if that is helpful.

Arien Malec

When we are thinking about the ISA, I am confused what standard or implementation guidance we are pointing to. Is this about making sure that in communication of race or ethnicity data via an ADT, for example, that the implementation guidance for the standards be updated to include the source in all cases? I am having a hard time taking this recommendation and mapping it to the change of the ISA update.

Mark Savage

Okay. I think at a conceptual level, we are noting the importance, and that is the outline format there, and then, the link that goes underneath that for ISA would be, at the least, STU2, which is in ballot and close to being finished, where the approach for that is being laid out, and that can be a reference standard. Does that answer your question, Arien?

Arien Malec

STU2 of what?

Mark Savage

Of the SDOH clinical care implementation guide. STU1 is already a part of the SDOH data elements that are in USCDI Version 2, so we are now going through a second iteration of that ballot, and part of that STU2 is includes a draft specification...

Arien Malec

Is it FHIR?

Mark Savage

Yes.

Arien Malec

This is a FHIR implementation guide?

Mark Savage

Correct.

Arien Malec

Okay, got it. So, we probably want to name in this recommendation the FHIR IG. And then, Hans, how does this sit relative to the general comment that we need to update consolidated CDA, FHIR US CORE, and





other standards to... This feels like a specific instance of a general problem of updating the implementation guidance to USCDI V.2 and V.3.

Hans Buitendijk

Yeah, the three areas within HL7 where this plays is that it would be SOGI data, so it would be more than race and ethnicity, and race and ethnicity have been addressed more already in the three guides. It is more the SOGI that is not fully agreed to yet on how to best communicate in the different areas. So, in that sense, I think they can coexist next to each other, but once you start to go to the note, then you have gotten more into the SOGI part that the current updates are looking at. So, I would keep them separate, in a way, if you just look at which ones need standards updates more and which ones need more attention in the way outlined here.

Arien Malec

Okay. Mark, can I ask you to go back with this recommendation and put in the pointers to the FHIR content, and then, any time we are talking about FHIR, are we doing the same thing for consolidated CDA or ADT guides? But, if we have more specific recommendations here in terms of IGs, I think it would be better to name them.

Steven Lane

And, those would go into the recommendation itself, correct?

Hans Buitendijk

Yeah.

Arien Malec

Those would go into the recommendation itself, yeah.

Steven Lane

Abby, your hand is up.

Abby Sears

Yeah. I just was curious, Mark. I would like to better understand why we are looking for the information on the source and the method. The reason I am asking is in my head, I am both managing the additional information and the work required to actually get that information and how accurate it will actually be if we do get it.

Mark Savage

What I am told in the column of identifying reports from the field is that there will be a significant number of instances where you do not know from what is in the EHR whether it is self-reported, whether it is a clinical observation, or whether it is from a batch file, and that is significant information to know, whether the individual was the source of it and how that was collected.

Abby Sears

Did they give you any idea why that mattered so much?





Mark Savage

No, I did not ask that question to the people that I was talking to internal to clinical settings. I know from my own work, and, for example, the federal standard, which specified a preference for self-reporting, that it is important to know that, and it is important to people who go into the clinical setting and say, “But wait, you have this for me, and that is not true.” One example that was given to me was a person from the Dominican Republic being classified as African-American instead of Latino, or the other way around. I have forgotten which it was. And, with his particular health issues, that had some significant implications for the algorithms for hypertension. So, it actually has clinical implications as well to make sure that you get that right. That also connects to what we have been talking about with the patient’s ability to correct errors in the medical records in order to preserve patient safety and better care.

Steven Lane

Are you okay with that, Abby?

Abby Sears

I do not know. Sure. I just think about the complexity of collecting that and the complexity of adding that level of information. I do not think there is anything bad with it, it is probably really good, I am just concerned about whether it will really happen, and what that looks like in the workflow of collecting it, but it is probably good to have it in the standards and to talk about it so that if people can collect it and do it well, we have a good way of actually standardizing it.

Steven Lane

Actually, I think you are channeling Clem, who had to leave us early, with the notion of trying to avoid the added burden of data collection on end users, and it certainly is as important for the folks who are capturing this data as it is for the folks who are capturing clinical data, so I think we should a comment that it should be exchanged if known, but that adding this to the standard does not introduce a requirement to collect this. So, Mark, you are going to work on this wording a little bit, it sounds like, and then we will scroll back to you.

Mark Savage

Yes.

Steven Lane

Make changes in red if you can. Hans, your hand is still up.

Hans Buitendijk

I put a note in the chat, and I think that was received by Arien, so I will lower it again.

Steven Lane

Perfect. All right, great. Let’s scroll down to Item 10 and go through that as quickly as we can. Steve Eichner, I assume that was you who was adding alternative language in this recommendation. I incorporated those recommendations. So, this is a recommendation, again, that we have talked about in other taskforces before. It is not an ISA-specific recommendation, so it would be outside of that, but certainly adjacent to our work, recommending that ONC, in coordination, explore the development of a certification program and associated funding to facilitate compliance for public health information systems to establish minimum





technical and functional standards in support of bidirectional health data interoperability with exchange partners, including providers and individuals. Go ahead, Arien.

Arien Malec

Yeah, I wonder whether, in light of where we sit, whether we want instead or in addition to recommend that the ISA be updated to include the definitive set of public health standards that could be used in policy and programmatic. I think this is consistent with our other recommendations on priority use cases or use cases.

Steven Eichner

This is Steve. I think you can do that at the national level, but I am not sure you can do that at the state level. There may be other reporting requirements.

Arien Malec

No doubt, STLTS will be STLTS. I am thinking about ONC's request to us to be, wherever possible, responsive to the ISA update, and it feels like at least one thing that we could do that is in line with our ISA update is to make recommendations on pulling in the ISA a common subset of public health standards, applicable both to reporting systems like EHRs and public health data systems.

Steven Eichner

Very much agreed. A secondary component here is it is great to have adopted standards. One of the things that we have noticed after working with a variety providers over a variety of years on ELRs, ECRs, and on down the line is that sometimes, although the technology itself may be certified, one of the things that seems to happen after market is providers then do some localized changes to their information systems, things like adding additional fields to maybe replicate an existing standardized field, and then it results in the standardized messages not being complete or accurate from a semantic and a syntactic perspective. It affects public health certification in an indirect way [inaudible – crosstalk] [00:55:42].

Arien Malec

I think we have lost Ike. David, while Ike works his audio, let me get to you.

Steven Lane

Arien, actually, it is your audio.

Arien Malec

Me? I got it.

Steven Eichner

It is great to be able to catch the ball, and that is fantastic. If somehow the ball gets altered in flight, it creates a problem.

Steven Lane

So, Arien, I do not know if you are coming and going. There you are, you are moving. Arien, I tried to capture what you were just saying. Does that get at it?

Arien Malec





Let me just move my screen around. Yes.

Steven Lane

David, your hand is up.

David McCallie

Yeah. I think I sort of answered what my question was, which is basically what problem are we trying to solve with an expensive and complicated certification program? And, I guess the corollary is is that the best way to solve said problem? I live in that world and I do not, but certification programs are big, complicated, and expensive.

Arien Malec

David, I think the problem that we are trying to solve is the one that we faced in meaningful use stage two, which is that we had a lot of EHRs that were adopting common standards for public health data without the state means or the STLT means to accept the data using the standards provided.

David McCallie

So, Arien, that is a good point. Let me then put a notion out that instead of certifying... Well, maybe we would want to talk about certification of their APIs or their interfaces, in other words, a testing, a workbench, like you can demonstrate that you successfully handle ECR submissions that are properly formatted, etc. It is really the APIs that we want to certify the data.

Steven Eichner

Thank you for that. And, the other piece of that one, as I said earlier, is it is great to be able to catch a message that is meeting the certification standards, but if it is not being sent with accurate and complete data in a semantic manner, that also creates a problem. One thing we found looking back at stage two was while a cancer message, as an example, frequently met the structure requirements that we expected, the way that the message was populated did not result in useful information being submitted. It was not really public health's inability to catch a certified message, it was the content of the message once it was in production, in many cases, not all, that the content was not useful. So, a secondary piece probably needs to be on the actual transmission of a message in a production environment, not just on the test bed. Same thing on receiving it, too, for that matter. It can work in bench, but if public health does a bunch of modification once we get it turned over from the vendor and we mess stuff up on our side, that is a problem as well. It is not in a single player's court.

David McCallie

So, that is more of a real-world data assessment than what I think certification typically means. Certifications are static. It is just that it is a big, complicated space, and I certainly think public health could benefit from improvements of interoperability, but I do not know that we are capturing a recommendation here that has much chance of being implemented.

Arien Malec

I think there is a broader set of funding mechanisms and other things at play that would accompany the requirement with the funding. Hans, you have your hand up.





Hans Buitendijk

Yeah. The way I understand the ISA, by referencing the different standards, that already has effectively pulled the minimum data elements inside those standards. Whether they are APIs, messaging, documents, or whatever, they are effectively already there at a much more granular level than we would see in the USCDI, which is fine. In the standards, you would actually see what you really needed in order to do interoperability, and USCDI is more a general library of concepts and general data elements. So, I am not convinced about the first one being needed because that is already there. The question is what is it in addition to that? Are there use cases missing that need to be covered because those are not yet in play, and from the ISA, it can go into certification or not? I think we need to keep certification separate from ISA. Not everything in ISA needs to be certified.

Arien Malec

That is right. So, Hans, let me ask the first bullet question this way. Is it currently possible in the ISA to look at the comprehensive set of public health standards and implementation guides that are the latest and greatest and the most reasonable to adopt in order to achieve public health data interoperability?

Hans Buitendijk

Yeah. When you go to the ISA listing, there is a section on public health. I am trying to see whether I can get the link in the chat. Now, we might [inaudible] [01:01:51] but it is complete, which is fine. Then, we can add the ones that are not there. I think that most of them are up to date, but there are a couple of them that are probably not, but that is the place where everything should be. And, I am still navigating.

Arien Malec

Yeah, still navigating.

Steven Eichner

One of the other differences in large part between public health's typical approach for information systems and EHRs is that many public health information systems are very much more segregated or separated than a single integrated application, that we have a separate system for immunization forwarding and a separate system for disease investigation. They may share a common interface as a third-party standard tool as an interface engine, but the background systems may be very different, and a lot of them, particularly for larger organizations, are really customized solutions. They might have at started with a core, commercial, off-the-shelf system but are rapidly so highly customized as you are really looking at an individual certification if you are looking at functional certification. Now, there has been some work done on voluntary certification, particularly around immunization reporting and the work that ERA has done, and I think that has been largely successful and commendable as an example of something that has worked.

Steven Lane

Ike, I am going to break in here. I just realized that I took us off topic and off of our schedule. This was a nonprioritized item that I inadvertently raised because I was just working my way down the list. I think we need to shelve this one for now and go back through our agenda to get to our prioritized items. I sincerely apologize. We were supposed to go to communications and referrals between providers and community-based social care providers, which is lower down in the list, and I apologize for that. Is that okay, Arien, as cochair? Are you with me?





David McCallie

We cannot hear you, Arien.

Arien Malec

If you can hear me, I am good.

Steven Lane

Good, and again, I wanted to apologize. We were trying to go in an order here. So, the next one, which we did not end up having in the list, was No. 21, and the recommendation is that ONC track in the ISA standards and implementation guides needed to support the use case of bidirectional communications in closed-loop referrals between community-based social service providers and other healthcare stakeholders, including individuals, patients, clinicians, payers, and public health. And, our workgroup prioritized that highly, and therefore I wanted us to get through that. David?

David McCallie

I obviously like the spirit of this. I am thinking about the notion of bidirectional communication, which sounds like peer-to-peer rather than a shared chat or discussion. I do not think that is necessarily what you intended. In other words, it seems to me it is not a problem for direct to solve, although that may obviously play a role, it is the need for some way to have almost a scratch pad of communication around management of a case that allows everybody to participate in the discussion.

Steven Lane

I think that is very similar to Mark's earlier recommendation around the shared care plan. This does not get so specific so much as to keep a focus on the use case, but yes, it is bidirectional communications and closed-loop referrals.

Steven Eichner

This is Steve Eichner.

Steven Lane

Steve, go ahead and use the hand-raising feature, just so we can make sure that we are getting everybody in order. Hans, your hand was up next.

Hans Buitendijk

Just a quick question. In the ISA, there is already the closed-loop referrals. There is also the Gravity, and I am pretty sure that BSeR was in there as well, so I am trying to understand what is the additional thing that we feel is missing. It sounds like it is very general, which I am not disagreeing with, but I am trying to understand what it is we believe is missing that needs to be added because some of the...

Arien Malec

Hans, I was trying to find it. I went to the content structure care coordination for referral, and then you have referral for acute care. Is this referral to extraclinical services?

Hans Buitendijk

Let me find that.





Arien Malec

Yes, BSeR. So, I think Hans is right, that the...

Steven Lane

That it is already there?

Arien Malec

That it is already there

Steven Lane

Terrific. If that is the case and we feel comfortable... lke, sorry. Do you want to throw your comment in here now?

Steven Eichner

Sure, sorry about that. I was just going to suggest that the referral is likely to start with a healthcare provider, and the way it is currently worded and the way it is usually interpreted, the referral would start with a social service provider.

Steven Lane

It actually can go either way, right? A social service provider can identify the need for healthcare or other services, and vice versa. Yeah, this was not meant to be directional.

Arien Malec

Hans, am I looking at this right? "Referral to extraclinical services," which I find a confusing name.

Hans Buitendijk

Yeah, I got the same reaction, which I was just typing in the chat, if that would have been called community and social...

Arien Malec

"Community-based organizations and other extraclinical services" would be clearer.

Hans Buitendijk

Yeah, and Gravity should be listed there as well in that context because Gravity is addressing a variety of social services, SDOH-related and otherwise, and BSeR is addressing more community, and there are some discussions going on in alignment between those two, but that is where it would fit.

Arien Malec

Okay. So, Steven, maybe we reword this recommendation to say we recommend that the ISA clarify the language to include referral to CBOs as a use case and track gravity standards in addition to the standards currently listed.

Hans Buitendijk

Yup.





Steven Lane

All right. Let me simply make some notes here so we can come back to that. The challenge in any coming back at this point is having the time to come back insofar as this is our last day.

Arien Malec

Steven, I will take the mission of making the suggested edit, and we can loop back in line if we have time, which we do.

Steven Lane

Okay, great, super. Then, next up on the agenda is FHIR endpoints from David McCallie, which is just the next one down, 24, I believe.

David McCallie

So, there is a set of several items here that are somewhat related. I did an email survey of colleagues that are still actively working on various consumer access projects and asked them for areas that they thought should be in the ISA that might not be there, and so, that is where these several focused areas come from. The starting point is this notion of a FHIR endpoint standard so that consumers can quickly identify the API address for their data. Hans, I will ask you. I think you said that this was already being tracked in an accelerator, in which case this may be redundant to specifically talk about it here.

Hans Buitendijk

Yeah, there is a combination of things there. FAST has moved from an ONC sponsor initiative to a FHIR accelerator, and that is where directories are a key element for that infrastructure that are in play. The other part is that as part of certification that has its current-phase deadline by the end of this year, not precisely, but in the next couple months, endpoint listings are becoming a requirement to be certified to certain FHIR APIs, so there are a number of things that are already addressed. The question is if we are looking at a particular aspect of it that we need to clarify more.

David McCallie

Yeah, I do not have anything specific, other than the broad notion that it is a problem that needs to be solved. It may be, Steven, that we can just drop this one because I think we have made the broad connection to the accelerators, and certainly, ONC is well aware of FAST and that they have got it started.

Steven Lane

So, are you saying 22 through 24?

David McCallie

No, 24 in specific.

Steven Lane

Twenty-four in particular, okay.

David McCallie

Yeah, 22 and 23 are specific use cases that are not currently covered.





Steven Lane

Okay, and those are lower priorities, so we will come back to those.

David McCallie

Yeah, lower priority.

Steven Lane

So, we are withdrawing 24.

David McCallie

Yes. I am okay with that because I think it is covered elsewhere.

Hans Buitendijk

May I make one consideration around that? The challenge, probably, with the endpoints is perhaps not as much the technology part of it, but there is the need for vendors to publish endpoints. There is NPASS, but our endpoints being enabled and accessible in all the natural places, like networks, providers, and otherwise, depending on your use case, it is easier to go in nationally, by vendor, by provider, or by network. That aspect of endpoint libraries and directories is not yet at an optimum point.

David McCallie

Yeah. I think clearly, there is a technical problem that is fairly straightforward. How do you capture and represent sufficient information? That is step one, and step two, which is much harder, is what is the business case for managing and maintaining these directories, but I do not think that is in our scope here.

Steven Lane

So, we are going to withdraw this one?

David McCallie

Yeah, I am okay with that. I think it is covered elsewhere.

Steven Lane

All right.

Arien Malec

I made the edit to 21 if we want to look at it.

Steven Lane

Good, let's go back there. You made the edit. Where did you make it?

Arien Malec

In the recommendation.

Steven Lane





Okay. “Recommend that ONC update the use case label from the current referral text for particular services to referral to community-based organizations and other extraclinical services in the ISA and track Gravity...” Love it. Anyone have any thoughts on that one?

Unknown Speaker

Love it.

Arien Malec

Let it be purple.

Steven Lane

Mark, you did an update up above.

Mark Savage

Yes, Item 7. It is a blend of what was said on the call with what I observed in the chat, so I hope I got it correct. There seemed to be some chat conversation about the reference to ADT.

Arien Malec

Hans and I were going back and forth on the general topic that as we go from USCDI V.1 to V.2 and V.3, there is work to update the US CORE standards for consolidated CDA and FHIR, but we are noting that you also need to do the same modifications for V.2, NCPDP, and other standards that are non-CDA and FHIR. So, our comments were more of a cross-cutting comment.

Mark Savage

Steven, I think the use of the word “include” there opens up to anything else that might come in, and it just says “for example.”

Steven Lane

All right. Is this feeling comfortable with the folks, No. 7? All right, let’s go ahead and finalize that. And, next up on our agenda is non-prioritized ISA topics. David, you have two of these. These are the use cases you were mentioning, downloading DICOM images and genomic variant data, so that was back to Nos. 22 and 23, correct?

David McCallie

Yeah. SO, the problem being solved here is that the existing FHIR APIs often fail when you are going for data that is not directly managed by the EHR, as is often the case with images, which typically are managed in separate systems, so work was done in the Sync for Science program with Josh Mandel’s team to come up with a standard for allowing the EHR to transfer the request to the PAC system containing the consumer’s authorization for access to the record in a technically clean and secure way, and to my searching, I could not find that use case being tracked anywhere, so the proposal here is simply to add this use case to the ISA, and in the case of this one in particular, I think a link could be made to the Sync for Science proposal that is out on GitHub. I had that in the original spreadsheet, but I see the link is gone now.

Steven Lane

No, I may just be hiding the column, sorry.





David McCallie

It is okay. I do not think we have to solve that, it is just the notion that it is a use case that needs to be tracked.

Steven Lane

You do have that link over there in the background.

David McCallie

Good. And then, on 23, it is essentially the same concept, that there is no easy way to get and download your genetic variant data if you have had a whole-genome or whole-exome study done, and the person who recommended that we track this said that there is some early work in HL7's genomics group on FHIR extensions to do this, but it has not been tracked at this point. So, this is the notion that you get a whole-exome study, and you want to look at that data on your own and submit it to other services for evaluation. There is no good standards-based way to do that yet, and there should be.

Steven Lane

Any comments, questions, or concerns about us including these as recommendations for use case tracking? Hans?

Hans Buitendijk

Not a concern overall, but perhaps that we could add some wording that it is not only about downloading DICOM, but that it is also about referencing DICOM, so we do not need to send everything over the wire always.

Arien Malec

Yeah, it is about image view and download.

Hans Buitendijk

And sharing.

Arien Malec

Thank you, that is right. View, download, and share consumer- and diagnostic-quality images.

Hans Buitendijk

Yeah.

David McCallie

The broad issue is that some of these more complex and technically different sources of data that the consumer has a right to access are not in the EHR, and therefore you need some way to transfer your authorization to the system that does manage it, so I think that is the broad problem, for which there are good technical standards that just have to be profiled, documented, and tracked.

Steven Lane

How is that language?





Arien Malec

I think it is good. I think rather than saying “DICOM and other high-quality images,” we want to say “both consumer- and diagnostic-quality” because DICOM is a standard, but because it is DICOM does not mean that the image is diagnostic-quality.

David McCallie

Yeah, and that is why I said “and other high-quality images,” but I will accept that we do not need to specifically reference DICOM, although it clarifies for the technical audience the area that you are focused on is PAC systems.

Steven Lane

How is that?

David McCallie

Yup, that is good.

Steven Lane

Anything on 23? There was not a similar reference for this one, correct, David?

David McCallie

I was not able to find it. There is an HL7 genomics workgroup that has been developing FHIR extensions to handle VCF, so they probably have notions about how to do this, but I was not aware of it, and my source was not either.

Steven Lane

All right. Our time is tight. Actually, Clem had an item that he is not here to represent, but I think it is pretty straightforward. This was down toward the bottom, No. 25. You got it, thank you. Clem suggested that ONC develop and support the implementation of a methodology to assess and monitor the actual delivery of standard codes in real-world laboratory messages. We made a lot of recommendations about how this should be done, and Clem’s point here is that this should be monitored and incentivized. This seems to me like a supplement to some of the earlier recommendations we discussed. I am curious whether people are comfortable with this, since Clem is not here to represent it.

David McCallie

You are missing an “of” there, “implementation of a methodology.”

Steven Lane

Ah, thank you. I was trying to improve on Clem’s language as best I could. Any concerns? Does anybody feel uncomfortable adding this to our list of recommendations?

Arien Malec

And, Steven, this would go in our extracurricular or curricular-adjacent recommendations.

Steven Lane





Yes, indeed. We will definitely be separating these out.

Hans Buitendijk

Separating them completely differently, or still in context of related [inaudible] [01:23:00]?

Arien Malec

We would jump this into our curriculum-adjacent recommendations to labs.

Steven Lane

Yeah, that is to say it would go with the other lab recommendations.

Hans Buitendijk

Got it.

Steven Lane

David McCallie, your hand is up.

David McCallie

If Clem wrote this, I am surprised that the word “transparency” did not enter into his recommendation because I thought that was his key point, to allow people to assess. Maybe it is covered in “a methodology to assess and monitor.” Maybe that is the transparency, although it is not how I think of transparency.

Arien Malec

I am tracking the through line on Clem comments here. It is “Hey, we think that LOINC transmittal is getting better, but we do not have any mechanisms right now to track the real-world adoption of laboratory codes in practice that would give us the instrument flight deck for how we are doing on LOINC standardization.”

David McCallie

Right, and Dr. Luu has shared with me a recent study, just out in *JMEA*, assessing the accuracy of mapping, and I think 40% were inaccurately mapped. We discussed at great length that in some cases, the data is not being made available, and in some cases, it is being mismapped, and Clem suggested that was transparency, but I suspect that is what he means by “methodology to assess and monitor.” Since he is not here to change the words, let’s just live with what he suggested.

Steven Lane

All right. Let’s pause there and cut to public comment. I do not see any hands up, but let’s go through the verbal here. ONC, do you want to take us there?

Public Comment (01:25:11)

Michael Berry

Sure thing. Thanks, Steven. We are now going to open up our meeting to public comment. If you are on Zoom and would like to make a comment, please use the hand raise function at the bottom of your screen on the Zoom toolbar. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute or unmute your line. We will pause and keep watch to see if anyone raises their hand.





Steven Lane

And, I will just acknowledge that the people who join us from the public are really doing a great service in watching over this work and contributing as you do. I recognize most of the names on the list, so thank you all for coming. All right, if we have no public comments, let's just return to Item 25, Clem's. So, David, at the end there, I think you were saying you felt comfortable with the language as it is in the spreadsheet at the moment. Did anyone have any concerns about that?

Arien Malec

No. Hey, Steven, I just want to raise a process question. I think we are going to talk about it in just a bit in our offline chat, but I think we are pretty close to needing to work off the recommendations transmittal itself as opposed to this spreadsheet, so this is really by way of a call to all of the workgroup members to look at anything that is not in purple, and if you feel very strongly that it needs to be in the transmittal, please work with us offline, and in next week's meeting, we will do the transition to primarily work off of the transmittal, but also review a parsimonious set of items in the spreadsheet that want to be in the transmittal. So, this is really last call for comments.

Steven Lane

Thank you, Arien. I think we have a moment to return to Item 10 and see if that is going to be dropped, or kept, or modified. Again, I took that out of order. Previously, it was the last thing we were going to try to cover today, and if we could display Item 10, that would be awesome, but this was, again, public health interoperability. First, now there is a listing for updating the ISA to identify and specify the minimum data elements, APIs, and other standards and implementation guides to support use cases related to data exchange between public health and other stakeholders. The argument was whether or not it is needed.

Arien Malec

Maybe we can look at our other recommendation offline about the priority use case page.

Steven Lane

Maybe that is enough there.

Arien Malec

Maybe that is enough.

Steven Lane

Okay. And then, the other one had to do with exploring the development of a certification program, and maybe that is too much. So, does anybody want to speak for or against us having recommendations? It sounds like we are talking about dropping this one.

Steven Eichner

This is Steve. Maybe not necessarily in terms of looking at a certification piece, but maybe we can charge with better ways of looking at confirming and, in production environments, working on those data quality issues to be identified as being potentially the problem, and then figuring out what potential solutions are.

Steven Lane





I think that in reality, there are so many people working on this right now and thinking through the challenges and opportunities, and unless our workgroup has something novel to recommend into that dialog, I am not sure it is worth us adding this to our recommendations. Abby, did you have something you wanted to say?

Abby Sears

Well, I do not know. I think it is just a really important thing. Without some sort of certification process, we are rounding the lack of standardization and mapping issues, but what I am hearing you say is that it is being worked on and that you think it is going to happen, and if we think it is going to happen, then I can live with taking this off. Otherwise, it is really important from our standpoint.

Arien Malec

Yeah. So, I am looking at Recommendation No. 18, which calls for the use case section to be expanded, and then we reference in a bullet somewhere down the term “disaster preparedness and pandemic response.” I think what we should do is add the words “public health, disaster preparedness, and pandemic response.”

Abby Sears

I just think it is a little bit different than that.

Arien Malec

No, I agree with you. I think listing standards is insufficient for ensuring that standards are adopted and used, and that public health is funded to adopt standards. I think to Steven’s point, there is a lot of work that is going on in this area, and it is probably best for us to confine our comments in this area to the ISA.

Steven Lane

All right, and we are over time. Mark, you are going to have the last word.

Mark Savage

I am sort of in the same space that Abby is, that this is important, and even just adding our imprimatur to certification in order to have some sort of structure across the ecosystem is a small but worthy add.

Steven Lane

So, exploring the development of a certification program does not seem like too big an ask. We have more hands up, and we are over time. Christina?

Christina Caraballo

I put mine in the chat.

Steven Eichner

This is Steve. If you are going to say “certification,” there has to be funding attached to it, because otherwise, we cannot get very far.

Steven Lane

Okay. We will take all this under advisement as we craft our transmittal. I am not sure what we are doing with No. 10. We will talk about that in our next meeting, Arien. Thank you, everyone. I apologize for going





a couple minutes over, and Christina, we will look at the bullet that we modified with public health below.
Thank you.

Adjourn (01:32:00)

