Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 3: ONC HEALTH IT CERTIFICATION PROGRAM UPDATES – INSIGHTS CONDITION, STANDARDS UPDATES, AND RFIS

May 18, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Hung S. Luu	**Children's Health**	**Group Lead**
Hans Buitendijk	Oracle Health	Member
Clem McDonald	National Library of Medicine	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Dustin Charles	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Carmela Couderc	Office of the National Coordinator for Health Information Technology	Presenter
Riki Merrick	Association of Public Health Laboratories	Presenter
Craig Newman	Altarum	Presenter
Eric Crugnale	Sonic Healthcare	Presenter
Erin Holt	TN Department of Health	Discussant

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

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Mike Berry with ONC, and I would like to thank you for joining us today. We do have several guest presenters with us today, and I would like to thank them in advance for their participation. All of our Task Force meetings are open the public and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled toward the end of our meeting this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate that you are here, and I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning, and welcome.

Michael Berry
Hung Luu is not able to join us today. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
I am not sure if Elaine Johanson or Meg Marshall is with us today, so I will move on to Clem McDonald. Naresh Sundar Rajan? Naresh may be running a little bit late today. He may be joining us later. Fil Southerland? All right, thank you so much, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:13)

Steven Lane
Thank you so much, Mike, and welcome, everybody. We are happy to be here again with you. Hung Luu, who normally leads this… Wait, is this Group 3? I think it is. Hung, who normally leads this Group 3 session, was unable to join today, which is unfortunate because we are talking about a topic that is near and dear to his heart, I know, which is laboratory data, but we are going to have a number of subject matter expert presentations after Carmela walks us through the RFI related to lab data interoperability, so we are very, very excited for this. I will be primarily leading the discussion, and Ike will be watching for the hand raising and taking notes in the spreadsheet as we go. I also want to thank all of you who joined us yesterday at the HITAC meeting. I think we had a good discussion, the presentation was well received by the HITAC with some interesting questions that arose, and we did have a chance to raise some of the key issues that have been coming up in our discussions in anticipation of our future presentation next month with our recommendations.

I also want to point out that your cochairs have been hard at work trying to keep up with meeting notes from our past meetings, and the ONC team gets those posted to the website. You can get to those through the HITAC calendar, and I invite those of you with the time and interest… We do not bring meeting minutes back here for review and approval in a formal way, but they are posted to the website, and I invite anybody to go and review them. That is the documentation of our deliberations, separate from the final recommendations that we come up with, so if people have time to review those and point out any opportunities to make them better, I think that would be more than welcome.

So, with that introduction, anything else, Ike? If not, why don't we go ahead and dive in? I think the next slide will give us a chance to review our charge, or charges, as it were. So, this is the full Task Force charge, as we have seen many times. Drop down again. Here, the highlight is on the specific charge that we are looking at today, looking at the request for information on program standards, certification criteria, and information blocking, so this is more on the program standard side, and perhaps certification criteria, though we will clarify as we go along. Next slide.

All right, we are digging into the request for information. This is the last bullet on our Group 3 to-do list. Next slide. Again, we are starting with laboratory data interoperability RFI, and Carmela, you are here to clarify for us just what is being requested as part of the NPRM, and then we will hear from subject matter experts and then discuss whether there are opportunities for us to provide specific recommendations in response. Good morning, Fil. Thank you for joining us.

Steven Eichner
Steven, I just wanted to add that we do have the chat that is open for contributions, both from Task Force members and the public. Task Force members, you can select your audience. Everyone will be included as part of the official notes and resources for the meeting. Things that are to staff or private messages to other participants are not. We will address comments from the public during the meeting itself or during the public comment period that comes toward the end of the meeting. We do strongly encourage public comment. It is really important for the Task Force to get input from the public. It will really help us form our recommendations to HITAC and then on to ONC.

Steven Lane
Thank you for that, Ike, and I will add my welcome to the members of the public. There are 10 of you out there at this moment. Many of you have been attending regularly. Some of you are here specifically with expertise in this domain, so we really appreciate participation. We had a little bit of confusion in the last couple of meetings around hand raising by the public. The preference is to have the public hold their hand raising until we go to public comment at 10 minutes before the end of the meeting, but feel free, as we have said, to participate in the chat, directing your chat comments to everyone. We will make them part of the public record. All right, with that, Carmela, do you want to start, and then we will work through our outside experts?

Laboratory Data Interoperability Request for Information (00:06:53)

Carmela Couderc
Sure. Good morning, everybody. Advance a slide, please. So, we had an RFI, a request for information, related to lab interoperability in HTI-1. So, as a little bit of background for folks, in the 2015 edition proposed

rule, ONC proposed to adopt certification criteria related to laboratory ordering that included some HL7 specifications, 2.5.1 Lab Order Interface, commonly known as LOI Release 2, also Electronic Directory of Services, eDOS, and Lab Results Interface Release 2, commonly known as LRI. So, these are all HL7 Version 2 implementation guides. However, we received public comments on the proposal, and based on those comments, ONC did not adopt them in the 2015 edition rule.

Now, fast forward a few years, and Section 2213B of the Consolidated Appropriations Act of 2023 included a provision directing ONC to conduct a study on the use of standards for electronic ordering and reporting of lab test results. So, it specifies that ONC shall conduct a study and determine the extent to which clinical labs are using standards for electronic ordering and reporting of lab results and to assess different trends in laboratory compliance with such standards and their effect on the interoperability of lab data in public health data systems, also to identify challenges related to collecting and reporting demographic and other data with respect to laboratory test results, as we think sometimes of ask at order entry, identify other challenges using or complying with standards and reporting lab test results with data elements that have been identified in the standards, and just to review other relevant areas determined as appropriate by ONC.

So, that was in the Appropriations Act, and in the RFI in HTI-1, ONC seeks comment on topics such as the use of health IT standards by clinical laboratories, the use of such standards by those labs, and their effect on interoperability of lab data with public health systems and any of the challenges that we list above. Now, specifically, the RFI has five questions. The first is which implementation guides or other standards should ONC adopt in certification criteria for health IT, pointing transmittal and receipt of lab orders, results, and directory of services?

The second one is that ONC is interested in the utility and maturity of existing HL7 Version 2 and C-CDA standards supporting lab interoperability and the impact of moving to FHIR-based lab data exchange. The next one is what barriers would additional health IT certification criteria for lab interoperability create for developers and other interested parties, and how might this impact adoption and use of technology? The next question is would developers of lab information systems or IVD systems that have not traditionally submitted products for certification under the program seek out and benefit from certification criteria relevant to the products? And then, the last specific question is are there any steps that ONC and HHS should consider taking to advance lab data interoperability? So, with that, we open it up to discussion.

Steven Lane

Thank you so much, Carmela. I think that is really a great set of questions, and I am looking forward to digging into them. Just to provide a little bit of clinical context to this, obviously, laboratory data plays a central role in clinical care and decision making. The ability to both be able to order and receive results of labs, but also to be able to gain access to a patient's history of laboratory test information is critical for decision making, both at the individual and at the population level. We have all obviously been embroiled in a pandemic, where lab result data was particularly important, so it is striking, I think, that Congress said that it was really time to focus in on this, even though we were unable to adopt specific standards back in the 2015 rule, as you said. So, this is a great opportunity with pushback from Congress, kind of like we saw with the 21st Century CURES Act itself, like "Industry has not gotten here fast enough; we now need to put a little bit of muscle behind that," so I am glad that we are here discussing this.

Steven Eichner

And to add onto that, I think that there are a wide range of parties that are very interested in laboratory data and laboratory information exchange, not only looking at exchange within a single hospital or hospital system between the ELIM system and a larger EHR system, but also in support of exchange between hospitals, laboratories, and public health to support public health reporting, disease investigation, and disease control.

Steven Lane
And, of course, individuals.

Steven Eichner
Absolutely.

Steven Lane
Individuals desire and should have the ability to access their complete laboratory data and to utilize that in their own decision making. Carmela, we have a question from a member of the public. Our friend Susan Clark asks, "Is this RFI inclusive of genetic and genomic lab data?" When I have received this question in the past, I have always said that is just another kind of lab data. There is microbiology, there is chemistry, there is hematology, and there is genomics. It is just all lab data. Would you agree, or does the ONC have a different perspective?

Carmela Couderc
I would agree with that.

Steven Lane
Wonderful. There is your answer, Susan. All right, seeing no other hands, why don't we go ahead to Riki's presentation? Riki, would you like to introduce yourself as well?

Riki Merrick
Sure. My name is Riki Merrick. I am on the staff at the Association of Public Health Laboratories. I have been working in electronic lab data exchange, specifically to public health, but also helping public health laboratories, since 2006. I am also the cochair of the Orders and Observations Workgroup at HL7 and a cochair of the IHE Pathology and Laboratory Domain at IHE, so I do a lot of work on the standard development side, and also helping public health labs and public health agencies implement respective standards. Next slide.

For most of the content on these slides, we had a working group meeting at HL7 last week, and we spent a border talking about this, so most of this came into my brain from that session and is lifted off some of those minutes, so some of you may have seen this already. Carmela read the questions, and I have structured these slides for each question with the thought process, so for laboratory orders, No. 1 has three different sections, so I am going to focus on laboratory orders first as a subsection, and have structured this to highlight the available standards that I am aware of, and then the consideration.

So, for lab orders, Carmela already mentioned that in 2015, we were talking about LOI R.2. We are now at LOI R.4. It is Version 2.5.1-based. We have the eDOS, which was split into two parts. It has the specification about how to exchange directory of services, and I am going to talk about that part later, but it also includes

a list of commonly asked ask-at-order-entry questions, so those are questions that are originally intended to be things the laboratory needs to know to do their work in order to interpret the result for the test that is being ordered, but over time, and because ELR, electronic lab reporting, to public health has been pretty successfully implemented and has been a good way for public health agencies to get information, some of that data that is really important for public health to prioritize their case investigation, to better understand the emergency situation and situational awareness, those were also added, so there are some of those type of questions in this document as well.

So, that is a list of how to code these commonly asked ask-at-order-entry questions and, if they have coded answers, how to code those answers. Right now, that is focused on V.2, so it is talking in V.2 data types, for example, as response types. There is a project at HL7, which is kind of on hold because we do not have a project champion for it, to broaden that aspect of this document to also describe what the data type would be in FHIR and in CDA, but again, that is a future project, maybe. And then, for LOI, LRI, and eDOS as a lab domain area, we have a guide for all the related vocabularies called the Value Sets for IG, which gets published separately so you can make updates to the value sets without having to update the actual specification. And then, on the FHIR side of things, we are working on a FHIR order entry IG for any order workflow in the U.S., but that is in the development stage, so, maybe in the future, and while CDA could capture the document of the laboratory order, it is not designed to deal with the workflow of ordering, so I have not included anything here.

So, considerations around laboratory orders: There are a lot of existing V.2 interfaces out in the world. Most of them use ORM because they are older than when we had OML, but some may be using custom OML. I personally think use of LRI R.4 would be good because it would enable consistent order content use and describe exactly the elements that are required by CLIA because that was one of the things we did when we wrote LRI and LOI to ensure that all the CLIA-required elements are covered. It does already provide guidance on how to use AOEs and how to identify them as such, and it includes profile components so that you can say you are using the base profile of an LOI, but you are also supporting public health, for example, so there is a public health lab profile component you can declare conformance to, and that includes those additional elements that are important for public health. So, those are the things that LOI provides. Next slide.

So, on laboratory orders, there is more, so I have two slides for that. The first slide concentrates on the available standards in the U.S. realm. I have not included what is available internationally because that is a lot more. So, for results to providers, LRI R.4, and for results to public health, there are several options. One is the ELR R.1, which is in certification and is highly implemented everywhere, but then, LRI, like LOI, also has a profile that has a public health component, and that is basically the newer version of ELR R.1 so both of those would cover the use case of reporting results to public health, and again, the vocabulary that goes along with it.

In CDA, I am not that familiar with it for results exchange for providers because I am on the lab side. I think a lot of HIEs or providers use C-CDA-based document exchange and associated template IGs. There may also be some V.2 exchanges when HIEs are used. And then, in FHIR, there is no explicit IG, but, of course, US CORE. Because some lab elements are in USCDI, US CORE has built a diagnostic report profile for laboratory result reporting and a US CORE laboratory result observation profile. Next slide.

So, for the considerations, I have already said LRI has those specific lab use cases, so that includes clinical genomics, that includes newborn screening, public health reporting, emergency preparedness, and some other specific things so that you have rules around how to report these more complex situations, and it would be really helpful if more people would use it to be more consistent across the different use cases, and then, the nice thing about LRI is that it has those identifiable profile components, and those profile components could be pre-adopted into older result messages. Then, I already mentioned the latest version of ELR really is the public health component in LRI R.4, and so, maybe we can update to the latter through SVAP, which might help a common base for others to move to LRI and also align the public health reporting with the clinical reporting stream and data elements.

And then, the US CORE profiles currently do not cover all CLIA elements, so, from a perspective of exchanging laboratory results from the labs with ordering providers under CLIA, they would need to be updated to cover that use case. And then, from my perspective, having results as FHIR resources available for access in other settings, so, outside the lab-to-provider use case might be a good initial use case for FHIR use. Next slide.

So, for the directory of services, there are two standards available. One is eDOS, which would be a 2.5.1-based spec. The other one is a catalog IG based on FHIR. So, eDOS, unlike LOI and LRI, is not as well established using V.2 exchanges. It is part of the lab domain, but it is outside of the workflow between providers and LISes. It is more for the LIS to let the EHR system that the provider uses know what tests can be ordered, in what format the results can be expected, and things like that, so it is used when setting up new communication partners or when updates to the catalog happen, but it is still somewhat removed from the configuration workflow of the orders interface that the physician uses because the EHR has to align multiple different incoming catalogs with what the physician can order from.

So, from an HL7 workgroup perspective, we were talking about not being sure how much of an ROI it is to push for that, but we would not propose the V.2 version of eDOS because it is very complex and complicated, but using the FHIR catalogue may be an option, but, as I am showing, it is to be published soon, so it is not that mature, but the benefit is that the generic paradigm of FHIR, which is that you go look for something when you need it, is helpful, for example, when you want to verify that the catalogue is still up to date, or in a case where you might want to shop for the right lab to order the test from when price transparency becomes more important. So, that is my feedback on the first question. Next slide.

So, maturity of existing standards versus FHIR: For provider laboratory interactions, V.2 is it. It has been used for a long, long time, but it is not consistent because a lot of the V.2 interfaces have been around for a long time or are built based off the base standards, and each partner-to-partner interchange set it up slightly differently, but they are well established. It is a lot of work to update them due to CLIA requirements, so there needs to be ROI for upgrading to later and newer versions, potentially when new data elements need to be added or a larger use case that needs support is updated. That might be a good reason to push for that.

I am not as familiar with provider-provider. I guess payer exchange uses C-CDA as well as V.2 messages, but in the working group, we were talking about when we think FHIR would be a good idea. So, for ordering workflows, that work is in progress at HL7, so we have not really figured that out, so it is probably not immediately available. For C-CDA documents moving to FHIR documents and collections, that might be a

good opportunity to migrate because really, they are static things where you do not have to deal with workflow elements, and that is pretty well defined. And then, we are thinking that over time, we will have fewer and fewer people that have expertise in V.2 and more and more people that have expertise in FHIR, so once we get to that decrease in V.2 knowledge and increase in FHIR knowledge, that might be the timeframe to switch, though if it is just adding one or two new data elements, adding those to an existing V.2 feed might still be more efficient than switching to FHIR. Next slide.

Additionally, we were thinking to use FHIR mainly in greenfield topics, so, stuff that V.2 has not covered very well, for example, genomic data sharing, durable medical equipment orders where you have to have more data for prior authorization, and there is an IG and STU out there for that already. We were thinking orders might be useful to incorporate into the workflow where you have the situation that a provider says, "You are going to have this test done, and maybe you get a QR code or something as a patient," and then, when the patient walks into the lab of their choice, that lab can scan the QR code and retrieve the order, which may be a FHIR resource or may be a V.2 message, whatever that partner supports at the time. So, that was one place we thought FHIR might be really helpful for ordering. And then, there more complicated use cases like genomics or anatomic pathology where we do not have good, structured data in V.2. For public access to results, like for the provider-patient or outside the ordering provider, patients, public health, or research might be a good approach. So, that is our answer to No. 2. Next slide.

In No. 3, we talked about LOI and LRI supporting the use of AOE data. Sorry I had a typo in there. So, as I said, there are two types of AOE. One is the AOE that the lab needs, and they are included in the catalogue, and if you do not answer those, the lab is going to call you and say, "Hey, I need the answer to this because otherwise, I cannot give you the right interpretation for the test you want this result for." And then, there are the other ones that are important for public health, so the question there is now that electronic case reporting becomes more and more established and the source system for that kind of data really is the EHR, wouldn't it be better to make sure we have a good way of linking ELR and ECR, so, the lab result and the case report on the public health side, so that we do not have to keep stuffing things into LIS systems that they do not really need to care about? And then, we could update LOI and LRI specifically to focus more on the AOEs that go through that.

We did talk about the fact that there are sometimes labs that care for walk-in patients, like clinics, for example, that have laboratories associated with them, so they manage more of that patient information, so they have the need to capture some more of that data that is relevant to public health within their system, and so, maybe they should support ECR to report their results to public health, and there is some research that needs to happen, whether… I know there are different reporting requirements when it is a provider reporting versus when it is a lab reporting, so we would need to make sure that those triggers are the same and none of the lab reportables would be missed if the lab used ECR to report to public health.

So, the other thing we were talking about is when you have data exchange between two systems, if only one of the systems is certified, that is still not as helpful as if both are certified, but if you are looking at only certifying one, it should be the source system because if the source system can generate the data in the expected certified way, then the receiver at least has the opportunity to get the data in that format. So, ideally, both systems should be certified. Next.

Another thing we were talking about was separating semantics from syntax aspects. So, maybe it is not important whether we structure the data in V.2 or FHIR resources, but what we want to really focus on is identifying the right semantic data, so, right code systems to use, the right code to value set rule, so that systems that use older syntax and different formats can still have better-quality data transmitted through those different formats. I skipped the first one, focusing on options. So, rather than saying I certify LOI, maybe I can make sure I certify to this profile component alone, because then I can still use my old V.2, 3, or whatever profile as long as I can support everything that the public health component supports, in my older message, I can pre-adopt that profile component, and then I can still have better unstructured data than I would otherwise. And then, another thing we were discussing was differentiating between having certification requirements for the system and the tooling to test those systems from enforcing or incentivizing users to actually do this. Next slide.

So, we did not really get to discuss this one in the working group, so these are my own thoughts. From a vendor perspective, if I can sell a certified product that has benefits to the user of the product because the users can much more clearly see what features the product has, that would hopefully be a motivation to participate, and one of those things is evidenced by what IHE does. They have connectathons where product vendors can participate, and when they successfully pass a connectathon, then they can post an integration statement saying, “Hey, I am supporting this IG profile,” so that could also provide such an avenue. Next slide.

We did spend a little bit of time talking about other steps to consider, and so, with my SHIELD hat on, which stands for Systemic Harmonization and Interoperability Enhancement for Laboratory Data, we are doing a lot of work and we have a community roadmap that has been approved by the steering committee, which will be published once we find the official link to where we can officially publish it, that calls out four different strategies to improve lab data overall within the entire healthcare ecosystem, but as part of that, one of the standards that we are encouraging for use is the LOINC-to-IVD test specification, also known as LIVD, as a FHIR IG, because it can help exchange some of the data that we hope to provide in what we call the laboratory interoperability data repository, so that is a place, like a library, where you could go and say, “I am looking for this particular IVD test because I want to set it up,” and I can get all the attributes that I need to set it up, including correct coding in my system.

Maybe I have received a result from this IVD test and I need to look at some other attributes like positive predictive value or compare the cross-reactivity with other viruses or maybe an antigen test, so some of that metadata that will help people use results better should be made available through that, so we think that might be helpful to consider. And then, personally, I think it is important to not just certify the product, but maybe also do some testing of the site-specific implementation of those certified products because it is one thing to have a certified product, but is another to not customize away the certified aspects of the product in a site-specific implementation. I think that is all I have.

Steven Lane
Thank you so much, Riki. That was a tour de force, I must say. I do not see any hands up with comments. I am also sensitive to the fact that we have a number of additional presenters. Did anybody want to ask any questions of Riki? Hans has bene including some helpful commentary in the chat from his perspective. We do have some questions that came from the public, though I am not sure they apply directly here. Luis

Palacios's is a separate question that we can come to toward the end if we have time. Hans, did you have anything you wanted to add here?

Hans Buitendijk
Not at the moment. I would like to hear the others as well and then, at the end, summarize it into what might be a focus for HITAC. Rather than jumping in right now, I am providing some thoughts in the chat for additional backdrop to help clarify the suggestion that I already put in the spreadsheet.

Steven Lane
Perfect, okay. Riki, I presume that APHL will be submitting all of this as public comment. Is that accurate?

Riki Merrick
I think a lot of this will be submitted through HL7, but APHL is also planning on submitting comments, so it may be similar, yes.

Steven Lane
Great. As I pointed out in the chat, our role here is to see what we can additionally add, or if there is any contradiction to any of this that we might want to submit as opposed to just reiterating what we hear from our subject matter experts. All right, let's go on to the next presentation. Thank you so much, Riki. Next presentation.

Michael Berry
Steven, I do not think we have any more presentations, but we do have guest presenters that could offer their perspective verbally.

Steven Lane
Well then, let's do that. Let's go to our guest presenters. So, who would like to go next? Who would like to jump in here?

Craig Newman
This is Craig Newman. If you do not mind, I will go first. I think it will be relatively brief.

Steven Lane
Perfect. Thank you, Craig.

Craig Newman
All right, I am Craig Newman with Altarum. We are a nonprofit organization. In my little section of it, we try to work with public health agencies to improve their interoperability, including in the orders and the results space. Like Riki, I have been involved in this area for quite some time, probably going back to about the same 2006 timeframe that Riki mentioned. I am currently a cochair of the HL7 Public Health Workgroup, as well as a cochair of the HL7 V.2 Management Group, which Riki is as well, but I think omitted from her own introduction. So, I will admit that my background is largely V.2-focused, particularly in terms of the creation of the LOI and LRI specs way back in the day, so I do not have a specific presentation. Riki, as you mentioned, did a fantastic job. I did want to just reinforce a couple of points for the committee to hear.

I do agree that the focus on orders and results and perhaps a little bit less on direct resurfaces makes sense. I think it is the orders and results that we are hearing as being the priority in many public health scenarios, so I do agree with that. I also very much agree with the idea that these implementation guides are broken down into profiles, and any regulation or certification requirements must be very specific on the functionality that systems are expected to be meet. We know from past experience in the immunization world that when an IG is very broad and covers a number of scenarios, when the certification requirements are not clearly defined, it leads to confusion as to what systems are expected to support, and that leads to confusion in the implementation space in the real world, and so, we definitely would encourage ONC to be as specific as they can when they put forth requirements for systems and for implementations.

I will also agree that the V.2 standard really is the workhorse standard for orders and results today, and we do not see anything in public health and more generally that says that that is likely to change. I think Riki brought up some good points on when FHIR may become more relevant as the community becomes more familiar with it, it becomes more widespread, and the knowledge of V.2 starts to decline, as it eventually will. So, we think focusing particularly in the short term on the V.2 specifications makes a lot of sense.

I would raise some concern over the idea of the ORM versus OML message types. I think it is very practical that the older message types will remain in use in circulation for a good long time, but we do also have to consider that any time that there are multiple ways of doing things, that means somebody has to support always, otherwise you get disconnects, and so, while I agree the ORMs are established, I think as we look forward, we may want to provide requirements that, as much as possible, provide a single approach that everyone can implement, and we do not have multiple ways of potentially doing the same thing.

I know that brings, to my mind anyway, discussions that we had back in the early stages of Meaningful Use in certification and attestation about whether or not existing, established, real-world implementations and integrations need to meet new requirements as products become certified and whether or not there is a role for, for lack of a better term, grandfathering in things that exist and making the requirements apply going forward, and so, I would encourage ONC, I think, to think about what the impact of requiring LOI or profiles in LOI as part of certification and other incentive programs means for existing integrations and be very clear one way or the other about how those requirements apply to how data is flowing the real world today. I think that is mostly it.

I guess I will speak generally from the public health side. At least in my experience, they are still very much learning about FHIR and about what it offers. They are steeped in V.2, as it has been a focus in public health reporting for quite a while now, and I would again encourage folks to think about that as they think about, at least, the near-term future and any requirements that are established. We want to make sure we have practical expectations for vendors, for implementors, for healthcare organizations, and for public health, and today, a lot of that expertise is focused in the V.2 domain, and so, I think that should continue to be the core of any recommendations or requirements that are put forward. I think I will leave it there. I am happy to also answer any questions as part of the larger discussion if there are any from the group, so I will pass it back to you, Steven.

Steven Lane
Thank you so much, Craig, for taking the time to show up and share all of that with us. Riki, you have included some information in the chat. Did you want to respond to Craig?

Riki Merrick
No, I agree with what Craig is saying. I was just writing it out in the back.

Steven Lane
That is perfect, thank you. All right, so we also have Erin Holt and Eric Crugnale here to offer their perspectives. I think Crugnale comes before Holt in the alphabet, so I will just pick on Eric first, unless you would rather have Erin go first.

Eric Crugnale
No, that is fine. Can you guys hear me?

Steven Lane
Yes, and we can see you, thank you, Eric.

Eric Crugnale
Okay, good. So, I am Eric Crugnale with Sonic Healthcare. We are a laboratory company globally, but I work for the U.S. operation and have been supporting our lab interoperability and connectivity efforts for quite a few years. We are commercial laboratories, so I am representing those interests. I am the cochair of the American Clinical Lab Association's IT committee, and I am also on the SHIELD steering committee. I think this is a great opportunity, obviously, to respond to the RFI and kind of move lab interoperability ahead. I think that is absolutely needed, having lived in the trenches for the past 10-15 years. Just a brief history from the commercial lab perspective, while Meaningful Use and the certification requirements, as Riki mentioned, the lab standards were not necessarily adopted or were partially adopted, that did not eliminate the demand for lab interoperability between commercial labs and eligible providers, let's say, that were implementing EHRs and attesting to meaningful use in different ways. Lab connectivity was a must for them, and labs had to make significant investments to implement orders and results interfaces, and again, the standards that were used were HL7 2.x, most commonly, not the LOI or LRI standards.

The other piece of it is since labs were not eligible providers, LIS systems did not need to meet certification requirements. Again, many of the underlying systems still would not meet those requirements, and let's just call them legacy systems. They would need some work in order to be able to support some of the… One of our biggest challenges is supporting some of the data elements. I see this in real-world situations. In many lab systems, you are lucky if you have a place to store a LOINC code against a result, let alone against an order code, or to map SNOMED into your lab results.

So, those would be like examples of investments that have to be made into those systems to support some of that, or you wind up what we end up doing today, which is dealing with it externally to the system, in your interface engine or in an external application that is providing that functionality. So, with LIS, I do support some level of certification, but in addition to that on the LIS side, going back to, say, Meaningful Use, there were also incentives on the provider side to adopt and use the certified technology in a meaningful way. So, in some way, I think to incentivize the laboratories to adopt these systems and make the investments in the technology that is necessary to support the interoperability is important as well.

With regard to standards, I would agree with what Riki and Craig said, and again, there are just thousands of these legacy connections in place, and what would be the cost-benefit of upgrading or replacing them? I think looking at that closely where there is value to it would be important. I also do feel like the eDOS use case, which I think was probably promoted through the efforts of the commercial labs more than anything, has not been adopted. I think it would have huge benefits to those commercial labs. We have tens of thousands, if not hundreds of thousands, of point-to-point order/result connections. We have tens of thousands of compendiums loaded in various EHRs that are very difficult, cumbersome, and burdensome to maintain, to update, to deprecate codes that are no longer in use, so the thought of some sort of a solution for that, even to implement new interfaces, is a burden, and I think FHIR potentially is probably the way to go there because eDOS just has not been adopted or implemented, and I think that is something that could be very valuable to the commercial labs. Let me see what other notes I have here.

I think the other thing I just wanted to mention was labs continue to make significant investments in continuing to perpetuate this very basic nonstandard connectivity between providers, whether that could be lab to lab or lab to referring provider. How much more can labs invest in this area? The sooner we can figure out where we want to go, and I think it is great to comment on these things, and then provide the appropriate incentives and appropriate targets for improving this, I think it would be really beneficial. There was one other thing I wanted to mention about use cases and workflows. One workflow to also consider on the order side is where we have orders at the time of referral, let's say, in the EHR, there are aspects of that order that are not known. We do not have a collection date. There may be other AOEs and things that need to be collected at the point of care or the point of collection, whichever you want to call it, so that is just another point where that order flows from an EHR to the collection management system in the lab and then is completed there.

So, there may be things that cannot be completed in that first step of that workflow. That was just one specific thing. One other specific thing, back to the limitations on the current LISes, is that examples of that which I have seen as being challenging is having enough detail about specimen information to have a valid SPM segment, and also, as we mentioned anatomic pathology, microbiology is another area. We deal with this in public health a lot. Again, the LIS systems are not necessarily equipped to provide the discrete and codified data that is required for ELR or for some of these other standards. So, I think that was all I was going to comment on at this point, but I appreciate the opportunity. Thank you.

Steven Lane
Thank you so much, Eric, and I just wanted to raise the issue… We were talking about workflows and specifically where FHIR can valuably play a role. As a clinician, one of the challenges that I face is getting comprehensive lab history data from labs. It is great when I order a test and am either the ordering provider or CC provider and I get that result via V.2. It is nice when I can request CCDs from other providers and get some subset of lab data, whatever the source system decides to send me with a given C-CDA document, but truly, what I want to be able to do is just ping all the labs and say, "Send me all the data this patient has ever had so that I can construct or access a comprehensive history of their lab results." Where do you see that on our roadmap, and will FHIR specifically make that possible where V.2 and C-CDA are really not designed to give a full lab history download?

Eric Crugnale

That is an interesting use case. We have definitely seen that type of a request, but more so where making the results available via, say, a portal or user interface versus electronically… Practically, to this point, that has either been through some sort of a portal where rights can be granted and the permitted use of that data is treatment-related. I have seen that made available by labs. The other thing would be certainly through a health exchange, but I could see that FHIR use case, FHIR being beneficial for that specific use case, again, when it is appropriate to be able to share that information or service that type of a request.

Steven Lane
Yes, that makes a lot of sense. Again, labs, of course, are providers under the information-sharing requirements, so they should be fully able to participate and respond with data in the format requested. So, as a provider, I very much want to be able to send a query to Sonic and just download all the labs from my patient, so I think we need to work toward that to avoid any appearances of information blocking.

Eric Crugnale
Yes, and again, I think FHIR fits that because, again, it is routing that to either an existing interface, or maybe there is not even an interface with that provider, a point-to-point.

Steven Lane
Right, why bother building an interface, right?

Eric Crugnale
Exactly.

Steven Lane
Hans, your hand was up briefly. Did you want to add anything?

Hans Buitendijk
Not yet. I was not sure whether there was a queue building for the end or not.

Steven Lane
Well, we have Erin yet to go.

Hans Buitendijk
Yes, and then I will raise my hand.

Steven Lane
Erin?

Erin Holt
Hey, everybody. Just to sound check, can you hear me?

Steven Lane
Yes.

Erin Holt

Thank you. So, my name is Erin Holt Coyne. I am the Chief Public Health Informatics Officer at the Tennessee Department of Health. I am also a cochair of the HL7 Public Health Workgroup. I have been involved in public health informatics since probably around 2006-2007 timeframe and participating in standards development for public health since about 2011. Our agency, the Tennessee Department of Health, obviously operates a public health lab as well as other traditional surveillance and other public health programs. We also operate 56 primary care clinics, 16 of which are FQHCs, so we operate an electronic health record in addition to a LIMS, as well as surveillance and other public health data systems, and we are currently working through implementation of LOI/LRI R.3 in addition to supporting our usual ELR, as well as implementation of the LRI public health profile, specifically for electronic laboratory result reporting.

So, the perspective that I am bringing is not only from our traditional public health side of things, but also from some of the clinical care and associated implementation that we have been working through, and I have to make the statement that making the case for supporting lab-related standards-based interoperability is just critical. Besides reducing some obvious burden, I think it allows us to build that infrastructure due to better alignment of the implementation across the standards and the actors that can be leveraged in times of emergency, frankly, that we were able to leverage to some capacity during COVID, but probably not to the extent that we should have been able to, and reducing the variation and the ambiguity to allow us to raise the bar for quality information available to all actors in the information chain when they need it is critical.

So, I would like to run through a couple specific points. Regarding data availability and quality, discrepancies in interoperability can really lead to missing data, and we have seen that firsthand. We have a situation we are working through now where we have a misalignment of understanding of parent-child relationships within the lab result message where we might be using or a lab might be using parent-child relationships to return results associated with reflex testing, and they are being automatically considered as micro, therefore not having necessarily susceptibilities, and for some reason, because of that, results are actually being resulted as text and not actual coded, discrete data. That is a huge problem for many different reasons. Information captured as text or using inconsistent, nonstandard coding can lead to inability to trend, certainly without special effort, and they result in data not being available for reporting, like federal reporting like UDS reporting, which is something that we are working through right now.

It is also hard to have the data needed to meet the obligations around laboratory result reporting to public health without that data coming in the order message, particularly in regard to some specific patient-related data, information like race and ethnicity and contact information. There has been a lot of conversation about the need for patient address for jurisdiction assignment. When that information is not given, jurisdiction is assigned based on the facility or the provider, which can cause delays in initiating that investigation and transmission mitigation. There is also a need to be able to document in a standard way confidentiality around a patient or a visit, which can impact the information communicated to a lab for billing, so that has bene critical to us.

And then, lab-specific, going back to some of the conversation about an ORM, the general order message, versus the OML, the lab order message, we are seeing this right now where we have requirements to receive specific information regarding specimens, and our own lab orders may be being sent as a general ORM message, not including specimens. That burden is then put on our clinical care to do ask-at-order-

entry questions to collect that additional specimen information to be able to send to the lab. So, that is a place where reaching some agreement and creating some alignment on the standards for what is needed now could be really beneficial. Also, this notion of handling preliminary finaled and corrected results in a standard way to maintain fidelity and confidence of information is also really critical, not only for our public health programs, but also in building that confidence and reliability in our clinical care usage of that information.

Talking a little bit about data usability and readiness, I kind of alluded to the ability to be able to scale and leverage daily operations for orders and results for emergent situations, like for COVID or Mpox. I think that is critical. There really should be infrastructure in place with a process to maintain and update vocabulary, including in emergent situations, so, not just one time or biannual, but allowing for more frequent or more emergent needs of maintaining that vocabulary, and so, I think we oftentimes focus a lot on the syntax, but I will echo Riki in this that there also needs to be some focus on semantics in the content, the value sets, and the data types for this information. Lastly, I just wanted to note that the HITAC Public Health Data System Task Force recommendations really laid out a number of recommendations in this space, including transmission and receipt of orderables and results sufficient to trigger reporting criteria for ECR, electronic case reporting, ELR, and transition to cancer registries.

Having that LOINC and SNOMED coding in place not only is great for computable semantic interoperability of laboratory data, but it is also going to allow the use of the trigger codes and having the trigger codes actually available to trigger the case report, so it kills a couple birds with one stone. So, again, comprehensive use and normalization at the source of key terminologies, including LOINC, SNOMED, UCUM, and others, and then, specifically, adoption of the LOI and LRI implementation guides. In addition to that, the recommendations also specifically talked about needing to be able to support modular certification, advancing syntax and semantic certification criteria, but also provide a path from the current baseline state to a target state. So, what can we do now to help improve the current situation, and what steps can we take to work towards a target state? So, I think that is something for this group to also consider.

Lastly, there were a couple other recommendations that I think also applied to this. The inclusion of newborn blood spot screening was one, establishing real-world post-implementation testing, which I think could be critical, particularly in the lab realm, the need to harmonize with other public health workflows, where I think there is sometimes a lot of confusion between electronic case reporting and electronic lab reporting, and they are definitely related, but they are not the same. Information is collected at different points in the clinical workflow, and to Riki's point, it is not always appropriate to expect the lab to carry the burden of communicating certain information that really is captured elsewhere in the workflow that should be coming from another part of the system's workflow, possibly in a case report. And then, again, there were several recommendations around being able to leverage standard codes and syntax that might be able to be referenced for this group.

Steven Lane
Thank you, Erin. Hans?

Hans Buitendijk
Thank you, Steven, and I really appreciate all the updates and perspectives. This is a very complex area because, in part, what are standards able to do, what are they capable of supporting, could certification be

done against the standards versus what is the right time to actually consider certification against what? I really appreciate Erin's last comments on what we can do now and what we can do over time to get somewhere, and I think that is at the heart of some of the comments that I wanted to share on where the HITAC may want to focus, and that is looking at the proliferation of connections that are there. We can all argue that they are not necessarily ideal, they are varied, but they get data across, and when we look at going back to LRI, having been in certification, the uptake was limited, so there was a lot of work done to certify, but the actual use of it was very limited. That goes back to some of the comments that Eric made as well, that effectively, not directly, perhaps, the focus was on the EHRs, not as much on the lab systems' lack of incentive or otherwise to provide that uptake.

So, I think there are a couple of different dynamics that we have to keep in mind that drive us to what we can focus on now, what we should focus on later, and what we should perhaps drive in other ways. Taking that perspective, when we certify, particularly workflows, not queries, though the principle is effectively the same, we need to look at both parts or all parts of the workflow, in this case to the provider or ordering provider and the lab, mostly, because they are both the source of some of the information: The initial order, where we ask if that is going out and can be shared with anybody, and the result, where we ask if that can be shared with anybody and if it is consistent, and if we only look at one side and not the other, then that is not going to help in order to move forward. We do not see the uptake that we need.

The second question is what we should focus on when we do it, and in this area, where, really, are the biggest challenges? Is it that data does not come across, is it that data are in different syntaxes, or is it the quality of the data, and what can we do there? Mostly, it seems at this point in time, though not exclusively, the challenges are around consistent use of LOINC, SNOMED, and UCUM. Are we interpreting vocabulary correctly, etc.? So, should we really focus on that part more so than the syntax? Because the question that comes up is that there is an effort investment to be done from what we currently have into the new format, but how much are we actually getting out of that in terms of the value that we get? Format is not necessarily driving some of the data quality issues that we are facing.

So, can we focus on vocabulary, which means how can we get what SHIELD is also looking at, encouragement that the right language, the right SNOMED/LOINC/UCUM is used from the get-go from the devices, to the lab, onto EHRs and others? Are we putting enough effort there, and should that really be where the key focus should be? I would suggest yes, that is where it should be, based on our discussions. The other part is realization and implementation base there. We are not working with a greenfield, so how can we meet everybody where we are and grow that in the direction that we do?

So, if we are looking at that, can we take advantage of these profiles within the guides, not necessarily the guides in total, but the capabilities that they point out, be it how to communicate devices consistently, how to communicate newborn blood spot, genomic data, etc., so that they can be expanded to that may lead some to adopt everything because they might do it, but at least adopt those capabilities, the additional data for pandemic responses, etc.? So, focus on target areas because a wholesale replacement just to move from one format to the latest format is a substantial amount of effort, but the question is are we getting as much benefit out of it as we need to if we focus differently?

Lastly, yes, the workhorse, as Craig also indicated, is HL7 V.2. FHIR is very useful in a number of areas as it is expanding, but it is not ready. It also provides some other capabilities, such as that certification of, let's

say, catalogue and LIVD. On the EHR side, what does that mean? Do you really need to do that, or is it more about making the data available in similar fashions as LOINC is doing with its vocabulary, that it is available at time of configuration, but does data really need to be "pushed out" or made available directly inside an EHR or other HIT as well? So, I think we have not really settled on what is really sufficient and good to support that challenge, and therefore, I believe jumping into considering certification or considering, at this point in time, for those areas, besides the fact that the guides are not ready, would be substantially premature.

There is a lot that we need to learn in that space as to what is the right place to really make that data available, while, at the same point in time, FHIR US CORE enabling labs to expose data using the same FHIR APIs as others would be tremendously valuable, where it could be used because of the nature of the data and C-CDA. So, I put some comments in the spreadsheet, but they focus around if we do workflow, focus on everybody participating in the workflow, not only one side. That is not going to be sufficient. Focus on the key quality issues that are in play, and take advantage of the fact that there are profiles within the guides to help advance that, and then build our progress forward rather than one big wholesale switchover, where that is a lot of effort that could have been streamlined quite a bit more.

Steven Lane
Thank you, Hans. Ike?

Steven Eichner
Thank you so much. I have three points to make. No. 1, thinking about FHIR and laboratory data, it may not be useful at the moment to use FHIR for all laboratory-related or laboratory-results-related functionality. However, we have included in USCDI some components of elements that are related to laboratory results, so one of the things we may want to use to address is what is the relationship between the two? Are we going to support, or should we look at supporting laboratory results data access through certified technology, through USCDI, or certified systems there? Do we treat LIMS systems differently, and if so, how would that actually work?

No. 2, we have not talked today, and I just want to make sure we have a placeholder for it, about patient access to laboratory results and the like. One of the things that makes that perhaps a little bit more complicated is a network of state laws that impact how and when patients may have access to their laboratory results data, in some cases, embargoing it for several days with the healthcare provider that ordered the test getting some early access to help interpret the data, and if we are looking at, again, providing access to test results, how do we incorporate enough information about those results so that the patients can begin to understand what they are seeing? Thirdly, looking at the relationship between electronic case reporting and electronic laboratory results reporting, I am hoping that Erin can provide a little example as to where they are different, just so there is a clear understanding of "Hey, these are really different and it does make a difference, they should not be considered the same, and they are not interchangeable." Erin, can you provide a little example?

Erin Holt
Yes. I think generally, the intent of the case report is to provide notification to public health of a potential suspect, not reporting of a case, even though the name might suggest that. It is a heads up. So, depending upon the condition, we might get that so much earlier in the workflow, based on maybe even an order that

was placed, or something in the problem list, or… Lab information may not necessarily be available, and in certain situations for certain conditions, we may need to act before the lab information is available, so waiting for labs, or just relying on a lab, or waiting for the lab information to send the case report is not always going to be where we need to be. There is also information that may not necessarily be needed as part of the laboratory workflow, but is documented elsewhere in the clinical or administrative workflow, and it may not be appropriate, then, to force laboratories to receive the document, to carry, and to push, and we have certainly seen that with some of the COVID-related ask-at-order-entry questions and maybe some of the additional patient demographic information.

We also have conditions that might only be laboratory reportable or specific organisms only reportable from a laboratory versus diagnoses or clinical suspicions that are reported from clinical care, and we may have situations where there is no lab report even sent, for example, with some of our overdose reporting. So, there are reasons why the case report and the lab report are used, and together, they tell a story that aids public health in making certain decisions at certain times, not only to determine case status, but also to initiate surveillance investigation, transmission mitigation, and patient care, like whether or not somebody is released from isolation/quarantine, that sort of thing.

Steven Eichner
Thanks so much. I have one additional issue.

Steven Lane
Ike, we need to cut to public comment. Let's go to public comment.

Public Comment (01:20:38)

Michael Berry
All right, thank you, Steven. We will return to our conversation shortly, but we are going to open up our meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment to see if any members of the public raise their hand.

Steven Lane
Luis Palacios, I know you had a number of questions early on. This would be a good time to raise them, if you want. If not, we can see if we have a moment to get back to them.

Michael Berry
All right, we see Luis Palacios. You have three minutes. Go ahead, Luis. You might be muted.

Steven Lane
You might be double muted.

Luis Palacios
I am double muted, thank you for that. First-time caller, as they say. I have to go back to the question itself because I think that part of it was answered, but at the same time, as a newbie, I am going to say that I deal with multiple specialties, and I am sorry for rambling, but I am just a little nervous, and I have radiology.

From a certain standpoint, radiology could not care less about what comes from a laboratory standpoint, but yet, C-CDA and USCDI force the issue for the importation of this information, and radiologists have the challenge of saying, "Do I need to pass this information forward or not?", and I cannot find a conclusive responsibility if this is required or not, so I am just hoping that this body can tell me conclusively what that responsibility is. Let me just stop there and not ramble.

Steven Lane
Luis, maybe you should restate the core of the question.

Luis Palacios
Okay. When I receive information from another entity, do I need to echo the information forward? Because I am not responsible for the information wholesale. Does that make more sense?

Steven Lane
Yes, I think it is the core question of when you, as an information holder, are asked to release information, do you also release information that was generated elsewhere that you have received? That is an open question in our industry, that people define their designated record set as they do, and some of them include information received from elsewhere, and some of them do not, but thanks for the question. You might want to submit it as a public comment also.

Luis Palacios
Okay, thank you.

Steven Lane
I do not see any other hands up from the public, so let's cut back to our spreadsheet for the last five minutes. Ike, you said you got your questions answered, so we will go to Eric.

Eric Crugnale
Yes. Just real quick, as Hans was making his last comment, what really connected with me is that the greatest incentive, let's say, and benefit would be to get to that point where we have achieved a much greater level of interoperability, and I think Riki was mentioning specific use cases, and Steven, we discussed that need to just be able to query for lab results, but to get to this point where we are not needing these point-to-point V.2 interfaces for certain workflows. So, if you look from a commercial lab perspective, instead of saying, "Oh, you have to upgrade these to 2.5.1 and support these standards," it would be like, "Hey, we are going to get to a point where you do not need that anymore," where we can potentially use FHIR to support that, and what I am going to call an interface list or an API-driven level of interoperability. That was just a comment I wanted to make.

The other thing I wanted to add is from a vendor perspective, I am sure we are all aware that these are revenue-generating activities for these vendors in many cases, and again, labs are spending large amounts of money to pay for the licenses for this or pay for transaction charges associated with this connectivity, so that might be something else that has to be addressed. If some of that goes away or those revenue opportunities go away for these vendors, how receptive are they going to be and how would they be able to continue to support it?

Steven Lane
Sorry, Eric, just so I am clear on your comment, are you saying that vendors are making money off of requiring their customers to build and maintain interfaces?

Eric Crugnale
Correct.

Steven Lane
All right, so they are not just making money off of providing laboratory services, they are making money off of providing interface services, and to lose that would cut into their bottom line.

Eric Crugnale
Yes, and it is not that the labs are paying those charges. The labs are not collecting that revenue, the EHR vendor is collecting that revenue, or there are third parties that sit in the middle there that kind of collect that revenue.

Steven Lane
Hans?

Hans Buitendijk
I would agree generally that it is going to be a balance between what standards and what capabilities are needed. Interfaces are a form of APIs, it is just a different form, a more classic form, but it is still an API. It is all about sharing data. What is the best method? If you have a simple query, today, FHIR is very well suited for that. If you have a complex workflow, of which the lab is one of the simpler complex workflows, that requires a level of interaction that FHIR may or may not yet be able to support or the guidance is not yet there. So, I think it is always an ongoing evolution, and in that progression, what is then the right progression to wholesale change if you do a certification program rather than targeted advances as new capabilities become available?

So, I think that is the balancing act, and so far, we have seen that certification of a V.2 guide LRI for general lab results reporting focusing on EHR has not achieved that, so I think we need to keep that in mind, that a wholesale approach is not necessarily the best thing to do. I think we are all trying to get to integration/interoperability without special effort, so the more that is plug and play, the less there is custom, that is good. So, focusing on new capabilities, ETOR or otherwise, where these new guys can be inserted would be excellent opportunities. Does that require certification? Not necessarily, because the levers that are in play to support an ETOR, public health or otherwise, may already be sufficient to align with the right guides that do not necessarily need certification. I think the context here is what should be considered for nationwide, across-the-board certification versus where do we promote the use of new standards? I think that is not always the same answer.

Steven Lane
Thank you, Hans. I think you got the last word in. We are at time. I want to again encourage workgroup members to enter your thoughts into the spreadsheet. Fil, thank you for that. Hans, you have a number of ideas there. We will be coming back to evaluate these recommendations in detail. We really appreciate all of our discussants and presenters today. Thank you so much, it was very valuable, and have a great day.

Hans Buitendijk
Thank you. Take care.

Michael Berry
Thank you.

Adjourn (01:29:10)