Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

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

April 19, 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
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
Riki Merrick	Association of Public Health Laboratories	Presenter
Andrew Northrup	Office of the National Coordinator for Health Information Technology	Presenter

Gregory Pappas	Office of the National Coordinator for Health Information Technology	Presenter

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 glad that you could be with us, and I would also like to welcome our guest presenters today, who you will meet momentarily. As a reminder, your feedback is always 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 for about 11:55 Eastern Time this morning. I am going to begin roll call of our workgroup members, so when I call your name, please indicate that you are with us. And, I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Kelly Aldrich?

Kelly Aldrich
Hi, everyone.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Thomas Cantilina or Jeff Ford? Christina Caraballo?

Christina Caraballo
Good morning.

Michael Berry
Grace Cordovano?

Grace Cordovano

Good morning.

Michael Berry
Steven Eichner?

Steven Eichner
Good morning.

Michael Berry
Sanjeev Tandon?

Sanjeev Tandon
Good morning.

Michael Berry
Raj Godavarthi?

Raj Godavarthi
Good morning.

Michael Berry
Jim Jirjis? Ken Kawamoto? Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
David McCallie?

David McCallie
Good morning.

Michael Berry
Clem McDonald? Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber is not able to join us today. Abby Sears? And, Ram Sriram?

Ram Sriram
Good morning.

Michael Berry

Good morning, everyone, and thank you. And now, please join me in welcoming Steven and Arien for their opening remarks.

Co-Chair Remarks (00:02:05)

Steven Lane
Thank you so much, Mike. We really appreciate everybody's time and attention this morning. I am sorry, I will be on video momentarily here, but I really did want to take this opportunity to set us up a little bit for this discussion. Let me just transition my…

Michael Berry
You just went on mute, Steven.

Arien Malec
There we go. Are you back, Steven?

Steven Lane
I believe so.

Arien Malec
You have an echo.

Steven Lane
No, I have got it fixed. What I was going to say was that this is a challenge that we have been struggling with in health IT for years, and I can tell you as a clinician, as an informaticist, and as a member of the national health IT community, this is a challenge that I deal with every single day as I take care of patients, as we manage our health IT systems at my organization, and as we all work together in workgroups like this and in taskforces throughout the industry. The need to be able to exchange discrete laboratory data in such a way that it can go easily into workflow and really be put to work by the relevant individual, stakeholder, or process has been a challenge from the beginning.

As I think back over 20 years ago to when we were setting up our first electronic medical record, the first true interoperability that we attended to was our interfaces with our external lab systems, where we sent the labs out and got the results back, and we know that we can do that. We know that we can order and receive test results in a way that goes right into workflow. And then, when we started interoperating between organizations, this appeared immediately as a critical need, and we have made some progress in certain situations. In COVID, certainly, in the context of the pandemic, we were able to do a lot of early work to be able to get test results, and subsequently antibody results, to move back and forth between systems, but it was a very limited use case, and of course, laboratory data is so extensive, and there are so many use cases where it is critical to be able to understand what is going on, whether it is at the level of the individual, the provider, or the organization, or the country, or the world.

And, we also know that the standards exist. You can write an HL7 V.2 interface and bring across all of the data that you need in order to integrate, and we know also that FHIR is working, that patients, individuals, have the ability to point their app to the national labs and bring down the data that they need, but as a clinician, I cannot point to the patient's FHIR app. I cannot point to the lab to just randomly say, "Send me

all the results you have" or "Send me a subset of the results you have on this patient," and a lot of very smart people have struggled with this mightily over the past few years, and a number of them are on the phone with us today. We have invited a number of people who are trying to do this to join us.

But, what we have found is today, if you are an organization that is focusing on how to interoperate discrete test results with other organizations that you end up dedicating human resources to setting up and maintaining mapping at a level that is simply not scalable, so we do not have the solution in place to solve this, and we have talked about this within prior iterations of the Interoperability Standards Priorities Taskforce, we have talked about it within the Care Quality Commonweal, and Joint Document Content Workgroup. Today, this is being discussed within Sequoia.

A lot of groups have worked on this, and a number of the people who worked on it are here today to talk to us, and what we are going to see is a lot of very complex flow diagrams of how this data is moving today, but what we need, really, is a national solution that is scalable, that does not resign us to having tens or hundreds of mappers sitting in every single organization to maintain this flow of data. So, really, I want to thank the people who have joined us today to present and a number of folks who have joined us today to listen to this presentation because this is really important work, and we have to figure it out. Thanks for indulging that, Arien.

Arien Malec
No problem. It was very impassioned, and I would only add to that that the last time we brought this band together for the incarnation of the Interoperability Standards Priorities Taskforce in 2018 or 2019, we concluded at the time that there were zero interoperability barriers to complete transmission of orders and results. We had implementation guidance in the LOI and LRI guides, we had good work from LOINC on mapping to standard compendia, there was good work on ask-it over entry questions. There were zero structural, "You just cannot do this" barriers to interoperability of lab data, and yet, when COVID hit us, we had massive problems getting the demographic information that was associated with a lab result over to public health because in most cases, when the lab order went electronically, it was only set up to transmit insurance information.

So, making progress on bilateral workflow, order-to-result, and back to the ordering provider, as well as onto public health is pretty clearly a national priority. We have all the technical means to do that, and we should. But, back in that report, if you go back and look at it, we suggested to ONC that ONC convene FDA, CMS, and other regulatory agencies to look at the mapping between what we called analyte machines at the day and LOINC to be able to preserve the semantic content of a lab all the way from analyte machine, from IVD, all the way to clinical result, and lo and behold, many other people had this fantastic idea. We are here to hear from a number of them. I take this as a sign of giddy optimism that we know what we need to do, and all we need to do is accelerate the work that is on the ground and put the appropriate policy levers in place.

So, with all of that, we have a fantastic presentation where we are going to hear about SHIELD, we are going to hear about LIVD, and then, maybe the ONC team can correct us, but I believe we are going to hear from ONC about some of the coordination that they have done. I am not sure that is reflected here on the agenda slide. Mike, can you confirm whether we have a member from ONC to do a presentation? If not, we will roll straight into Riki from APHL to give us a view of SHIELD.

ISA - Lab Data (00:10:12)

Riki Merrick
Hi, everybody. Can you hear this?

Arien Malec
We got you.

Riki Merrick
All right. So, thank you for letting me introduce you to SHIELD's strategic plan for improving laboratory data interoperability, and Steven and Arien already took a little bit of my thunder, but we will get you through this anyway. The next slide is the obligatory disclosure. So, this strategic plan is going through consensus in the SHIELD group, but the SHIELD is a consortium of stakeholders, so there is no official signoff, and so, it does not represent anybody's specific policy or position, so that is a nice disclaimer.

The next slide gives you a little bit of the outline of what I was going to talk to you about. I am going to introduce you to the strategic plan and give you a little bit of background about SHIELD. SHIELD has been around about six or seven years now, so we have been working on this a long time. It is a slow-moving thing, as everybody pointed out. And, we will talk about the business cases and the current state, and then we will focus mainly on the first stage of the strategic plan and go from there.

The next slide gives you the introduction to SHIELD. It is a public-private collaborative with a mission to describe the same tests the same way anywhere in the healthcare ecosystem. So, that is a big mission. As Steven pointed out, we are having trouble with that. So, this consortium has been put together of stakeholders in the blue blocks on the right. We think we have pretty much everybody covered. And, we have been pretty successful in building consensus about what the nature of the problem is, identifying specific issues that we can improve, and the pandemic, of course, highlighted the issues that we are having even more and pushed SHIELD to actually work on a strategic plan. So, we formed a couple of committees and tried to come up with a solution.

But, SHIELD worked with the IVD manufacturers to provide the most granular coding at the source of the data. Thinking the manufacturers know their tests best, they should be able to properly codify them. So, the IVD Industry Connectivity Consortium, or IICC, developed the version 2.51-based instrument interface standard at IHE, called the Laboratory Analytical Workflow, and that has been tested in connectathons, and it is part of the technical framework at IHE. And then, they set out to work on the LOINC-to-IVD mapping standard, which Hans will talk about. But, throughout this whole work, we really realized that there is not a single terminology that is able to encode all the information that we need around laboratory data, so one size will not fit all. We will need a group approach. Next slide.

So, we have broken the strategic plan up into two stages. Stage 1 is the pilot. It is the first thing we need to do. We need to harmonize the coding of lab data and create an authoritative source that can be used nationally by all lab data users. We need to build the infrastructure to move the data between stakeholders without any loss of fidelity in meaning and provide tooling to make that process as easy and automated as possible. And, part of the infrastructure that SHIELD is thinking about building is an IVD data hub to provide

real-world evidence to IVD manufacturers and other stakeholders, and that is build as an incentive for IVE manufacturers to participate.

And then, hopefully, with having built all this infrastructure, we are ready for Stage 2, to roll it out to the over 300,000 labs and their partners across the U.S., and this will need a series of sticks and carrots to move this forward, and we certainly want to use the lessons learned from the pilot and improve upon it. So, this will not be easy by any means, and will take many years, and both of those will need very close collaboration between public and private sector. Next slide.

So, I am going to set the stage a little bit here to understand how lab data moves around the system. There are many places where we use paper, so that is another thing we need to address, but in this diagram, you will see those red bursts, and those are places in the current state where data is manipulated, where that mapping is happening that Steven was talking about, which takes resources and provides opportunity for introduction of error. So, Healthcare Provider No. 1 orders their test from their in-house lab and No. 2 uses a reference laboratory, as an example. The lab performs the test, and if the instruments are not interfaced, then that is a manual step to make that data electronic into their LIS, so that is why there is a burst on the left side. Next.

The lab provides the results back to the provider, and even with an in-house lab, depending on the size of the healthcare system, the data may need adjustment, but when you need to integrate data from the outside labs, you need to have even more information. Next. Provider No. 1 is now asking for another test from a reference lab as a follow-up. Next. When the result gets back, they need to understand if the result is considered equivalent to in-house result and can be used in the patient flow sheet or for decision support. For example, during the early days of COVID, when a patient had an existing COVID test, it could be used to triage for provider PPE and patient handling if the test was considered equivalent, but if you did not have enough information, preferably to the level of the test kit, the instrument used, and the specimen type specifically, then you would have to just assume it is not equivalent, and you would have to redo the test. Next.

We currently have quite a bit of standards defined to support reporting to public health, but not all the labs encode the tests the same way, so the public health agency also has to curate data. Next. Lab results may also be used for research and clinical trials, but the requirements there differ from study to study, making the lab data not comparable across studies, or sometimes not even within the same study. Next. We are all familiar with exchanging data between providers, either directly or via HIEs, but that is also not super standardized. So, you see a lot of red bursts, and we have a lot of problems. Next slide.

That brings us to the business cases. So, for laboratories and healthcare providers, obviously, there are a lot of resources that are used to codify and curate the data which require specific skill sets that are not easily found, and even when you have highly skilled people, there is still a high level of variability in the mapping outcome, and of course, maintenance is never-ending. On the IVD manufacturer side, they have to support a multitude of different interfaces with each LIS, which takes a lot of resources on their end for maintenance that otherwise could be used for research and development. In addition, they must provide costly studies for post-market data to the FDA so that their test can remain on the market, so we hope to make both those things easier with SHIELD's strategic plan.

Information system vendors have created their own data models and local coding to support their clients because that is more flexible and faster for each individual implementation, but it certainly creates some data siloes and hinders data exchange between different vendor systems. So, supporting proper exchange, again, requires a lot of resources, which drives up user cost. And, last but not least, and most importantly, the clinicians are dealing with a lack of interoperability and loss of meaning when they are merging lab data from different sources, either risking patient wellbeing or redoing tests to avoid that. Next slide.

So, here is where the strategic plan comes in. So, for the majority of the presentation, I am going to talk about Stage 1 of the strategic plan, which is establishing the authoritative source for the codification of data,

which we call the Laboratory Interoperability Data Repository, or LIDR, and the related infrastructure, and then, ensuring the flow of the knowledge throughout the healthcare system and providing tooling to share that knowledge and create the IVD data hub to make that knowledge accessible on the individual level. Over all of those strategies, we need to make sure we have a feedback loop where we have processes to identify errors that can improve the data quality that feed back into the pilot and so on, so it **[inaudible] [00:20:07]**.

The next slide shows where we are today, or what we envision it to be after SHIELD. Next. Providers will still order a test, and the new test comes on the market, the IVD manufacturers provide a lot of data to the FDA, and a UDI can be assigned to the test, and that data can be submitted by the manufacturer to LIDR. Next. And, it can then be potentially curated, and the mapping can be verified, but it will include all the metadata that is needed to properly identify the test and the related elements around it using standard terminologies, like in SNOMED. Next. SHIELD will provide the tooling for labs to use LIDR to properly set up the new test in their LIS system, and they can also use the IHE LAW standards for instrument interfacing in their labs, which will report themselves back to the LIS. Next.

If we are using SHIELD standards, for example, LOI and LRI, for the ordering and result reporting back, those standards already support all the required elements by CLIA, as well as additional demographic elements, because both of those have public health **[inaudible] [00:21:56]** component so that those data elements that are important for public health can be exchanged if we need to get them through the lab. There is a whole other discussion that we should have about getting demographic data and some other data that the lab does not need for interpretation of their lab results directly from providers to public health through case reporting rather than shoving them through the lab flow, but that is a story or discussion for another day. Next.

LRIs will send the data back, retaining the properly coded test results, including identifying the test kit used so that the healthcare provider can determine equivalence of the results. Next. SHIELD will build that IVD data hub for real-world evidence for post-market studies. Next. The labs can still report directly for public health and research, but hopefully with a higher level of standardization. Next. But, they could also use the hub to get their data from that. Next. So, well-curated data in both providers' EHRs can then be exchanged with a lower loss of data fidelity. Next. One more.

So, for all of this, we will use the feedback loop, and we have come up with some key performance indicators to improve any data quality. Next. I will walk you through some action steps. We have to identify all the data elements that are needed to ensure that a test result is sufficiently described to enable clinical interoperability. We need to define whether those elements need to be traveling with each patient's result, so, having to go be an LOI and LRI, versus whether they can be looked up in LIDR, for example, at a later point in time. So, once we have completed that analysis for the different use cases, we need to work with information system vendors like LIS, EHR, and middleware vendors to make sure they all support those required elements. Next.

We suspect that in the process, we will identify elements that are not currently covered by the standards specifications we have proposed for use. Until then, we will work with standards development organizations to identify any gaps and remedy those. Next. We need to build the first prototype of LIDR in the IVD data hub, as well as associated tooling to support upload, review, and publication of its content. For that, we need to complete requirements gathering, define proper governance processes and decision-making practices, and create those feedback mechanisms during review and after publication, and LIDR will need ongoing support, for sure. Next.

For the pilot, we will decide what we want in the minimal viable product for LIDR and the IVD data hub, and for that, we want to identify either high-impact tests that have IVD vendors that want to participate in this process. And then, we need to obviously populate LIDR with the uploads and start sending data through the system. Next. So, an important thing that we have not done yet is we will need to build governance for longevity specifically for LIDR because that is kind of the Rosetta Stone of the common model of meaning

around lab data, and so, it needs to be curated and supported indefinitely because lab methods evolve and new use cases of lab data show up every day. So, we need to make sure that we have input from all the data creators as well as all the data users so that we do not leave anybody out.

The next thing for SHIELD is to socialize the strategic plan, which we are doing, and reorganizing SHIELD a little bit to work more on the implementation side of the strategic plan and continue ensuring participation for all stakeholders. Some of those things in the SHIELD strategic plan, like the IVD data hub and LIDR, will need funding sources, and we will need to figure out how to get that still. And, that is my end. The next couple slides just have some acronyms explained.

Arien Malec
So, we are going to do joint questions at the end, but can you define LIDR, L-I-D-R?

Riki Merrick
Yeah, that is the Laboratory Interoperability Data Repository, so that where we are envisioning to have the information that Hans is talking about in LIVD and any other metadata about the tasks be available for query.

Arien Malec
Perfect. Thank you so much. So, Riki, that was fantastic and truly amazing. So, we do actually have folks from the ONC. Andrew Northrup is going to talk about the ISA currently, and Greg Pappas is originally from FDA, on loan to ONC and really serving as the ONC leader for SHIELD, so, Greg, do you want to give a brief intro before we go to Andrew's section on the existing standards in the ISA?

Gregory Pappas
Thanks a lot. Riki did a fantastic job. I just want to make a little bit of a nuanced point that Riki said SHIELD will do this and that. Actually, it is the SHIELD plan calling for this and that. SHIELD is an outstanding group of volunteers and champions from many organizations, including the government, that has put together this plan. As Riki said, we came together, identified the right partners to do this work, came to consensus of the nature of the problem, and then did the strategic planning process. It is not binding on the government. We are not proposing that. We are proposing as a group of experts that we think this is a way forward. Pending any other brilliant ideas that come from other people, this seems to be the way forward, and we are hoping that government agencies and private sector agencies will come together and fund this activity and do this activity. SHIELD is not the implementing body per se, so I just wanted to make that little bit of a correction for some of the statements that Riki made. She was doing it for ease of presentation, but I just wanted to point that out. Thank you.

Arien Malec
Thank you, and again, profound thanks to Riki. All right, Andrew, why don't you lead us through what we currently have in the ISA? And, you are mute. Double mute.

Andrew Northrup
All right. What about now?

Arien Malec
There we go, perfect.

Andrew Northrup
All right, thanks. My name is Andrew Northrup. I am the Laboratory Data Class Lead. I sit in the Terminology Content and Care Delivery branch of the Standards Division in ONC's Office of Technology. Like Arien said, I will be walking us through the ISA pages pertaining to laboratory interoperability today. So, as you see here, we are at the ISA landing page, the ISA main page, where the relevant pages we are looking at are located are in the ISA content page in the banner up here, so I am going to click on that. Now, this brings us to the main ISA table of contents. There are going to be two tabs in here where the laboratory

pages are going to be located. The first one we are going to go into is the content and structure tab, so I am going to click on that, and then scroll down here to laboratory. I am going to click the little plus sign to expand this menu here, and in here is where we start to see the substantive areas.

So, the first one I am going to click on is exchanging in vitro diagnostics, IVD test orders and results. I am going to expand that into a new page. And, you see here these are the standards that are associated with exchanging IVD test orders and results. So, HL7 FHIR implementation guide for LOINC IVD mapping, which is LIVD. Some of you are familiar with that. We also have CLSI Model 16, the next-generation in vitro diagnostic interface for physicians. The next one is the IHE LAW, Laboratory Analytical Workflow profile, and the final one, LIVD, digital format for publication of LOINC to vendor IVD test results.

I am going to go back now, go back to my content and structure, go back to my laboratory. Next up is ordering laboratory test results for patients. Now, here, there is one specification listed. This is HL7 Version 2.5.1, implementation guide, laboratory orders from EHR, also known as LOI, Release 1. And then, moving back to where we were, going to the next area, under laboratory, received electronic laboratory test results, and here, we have one implementation specification, and then an emerging specification as well. So, the first one is HL7 Version 2.5.1, implementation guide S&I framework, lab results interface, Release 1, and the other one, the emerging specification, is implementation guide to lab results interface, which many of you know as LRI.

Moving back, the last item under the main laboratory area is for supporting the transition of a laboratory's directory of services to provide us health IT or EHR systems, and now, here, in this list, we have one implementation specification, EDOS, the S&I framework laboratory test compendium framework Release 2. As I said, this is what we are calling EDOS, electronic directory of service. And then, two merging specifications, one related to EDOS and one related to another laboratory services directory, HL7 FHIR, or a catalogue implementation guide, Laboratory Services 0.1.1.

And, I am going to move back to the main content structure. There is also a laboratory-related item under this area, public health reporting, if you can see my cursor, so I am going to expand that, scroll all the way down, and the laboratory-related area here is this one, electronic transition of reportable laboratory results to public health agencies, so you give that a click, and here, we see a few different specifications. One is HL7 Version 2.5.1, implementation guide, electronic laboratory reporting to public health. Some might know this as ELR. And then, down here, these are all related to electronic reporting to public health.

Just going back here, we have now covered the lab pages related to content and structure. We are now going to move into the ISA pages related to lab vocabulary and terminology. So, I click on this. Very similar, but not the same layout as the content and structure page, but a lot of similarities here. So, scrolling down to laboratory, expanding, and then, the first item here is representing laboratory tests ordered. When I click on that, these are the terminology standards relating to representation of laboratory tests ordered. So, there is a standard for observations, LOINC, and also a standard listed here, CPT, current procedural terminology.

Going back to this main listing, we have covered tests ordered. Now, we are going to go into representing tests performed, and here, there is one standard listed, LOINC. Going back into this page, we have the final area, representing laboratory test values. So, we have had tests ordered, tests performed, and now, these are the values and results. And so, for representing laboratory values and results, we have both LOINC and SNOMED CT. And then, just moving back, the one final area in ISA related to laboratory data interoperability is here similar to the previous tab, public health emergency preparedness and response. And, we are going to expand that list and go down into representing laboratory operations, population laboratory surveillance, give that a click, and then, once again, the terminology code for representing laboratory observations is LOINC. And, that concludes the walkthrough of the lab-related ISA pages. Are we doing questions at the very end?

Arien Malec

Yeah, we will do questions at the end. I am just going to do a little editorial here because we had some questions about the standards process, and just to memorialize what is in the chat, in HL7, standards go through a pre-standard process, to a draft standard for trial use process, to a standard for trial use process, through a final published standard, normative standard. And, ideally, the way that works is in line with production use. We saw this very successful with FHIR, where FHIR went through DSTU 2, and then STU 3, and then final standard, and while it was in both the DSTU and STU phases, it got heavily used in practice, and a lot of the issues were worked out prior to the final standard, and it is really the final standard where you want to make sure that you have forward-looking compatibility so you do not break compatibility for a future publication.

And then, maybe the other explanatory thing is I know laboratory data routinely gets exchanged in the real world, and so, how are the LRI guide and the LOI guide in draft standard or balloted draft? And, just a little bit of walking down memory lane for the workgroup, we created the LRI and LOI spec as an ONC public-private collaborative with a wide stakeholder group back in, I believe, 2011. It went through its process to become a balloted standard. The expectation was it was going to be named into certification. The LRI spec was named into certification, but the way that the certification rules worked, we did not want to rip and replace existing working lab standards.

And then, subsequently, we topped out the electronic lab incorporation CMS measure, and we believed at the time that we should tie certification methods only to CMS measures, and so, because we topped out the lab meaningful use measure, we then removed the certification for LRI from the ONC certification program, and so, it is a weird, unintended consequence that because lab results were routinely performed and routinely electronically delivered, we have not gotten to the point where actually had standardization of lab results, we have not gotten to the next step of electronic orders, and because we have not done that work, when we were impacted by COVID, we did not have the infrastructure set up that both LRI and LOI would have provided us to flow directly into ELR, the electronic lab reporting, and then be the infrastructure back for SHIELD and LIVD.

And then, I would encourage everybody to go back and read the report we created under Steven's leadership in 2018 and 2019 because I think when you look at the lab and orders section, you will see just a lot of good requirements and recommendations already there. But, with that, let's turn it over to Hans to talk about LIVD.

Hans Buitendijk
Okay, and I believe that I need to share my screen, correct? Or, do you have the slides there?

Arien Malec
You are good.

Hans Buitendijk
I am good. Okay, great. So, I pulled a couple of the things and condensed them together on all these acronyms that are out there that we have in EHR and LIS. The ELR runs from the LIS to public health. Clearly, from the EHR, it may as well, so it needs to be able to do that, but it is just not always required based on the state or other jurisdiction. And then, LAW, the one that Riki references, is mainly focusing to the IVD devices to interact there.

So, IVD LIS test result mapping is all about trying to make sure that from right to left, as quickly as possible, the encoding and the availability of coding is based on LOINC and SNOMED rather than either IVD test codes or LIS test codes, that it is all standardized in that fashion. That is the objective there. So, if you go to the next slide, you have on the IVD device side, up at the top, the IVD test and the IVD result value, and we are only looking at those that are encoded in some fashion, so, where there is a standard vocabulary to be used. An IVD test can have multiple outcomes, and they are there, but when you start to go from that IVD test/IVD result value into the LIS result and the LIS result value, you will see that depending on context,

the same test can map to different LIS test results and associated result values, probably less so on the latter, but certainly on the first one based on context.

So, what we use today is that individual labs configure that, they go through that, and as they are now trying to say, the LIS test result needs to be mapped to LOINC and SNOMED to then be able to pass on to the EHR, public health, and everybody else. We need to map that. So, we need to get the LIS test result into LOINC, which is the arrow from left to right from LIS test result, and we need to get the result value to either LOINC or SNOMED, whichever is appropriate. So, those are the mappings that need to occur, and today, LOINC/SNOMED guidance generally is being used, which informs a human being to do the mapping based on their expertise that they need to understand how this IVD is used in the lab, and therefore, in what context is the right LIS test result and the right LOINC code or SNOMED code?

If you go to the next slide, where LIVD comes into play, which stands for LOINC IVD test mapping, that is trying to say if we let everything happen the way it currently is happening today, everybody in their individual implementations or chunks of that is going to try to interpret that the best they can and come up with mapping. If we can get already from the device manufacturer into the LIS a good understanding of what the likely encoding is, not the one-on-one, so you see a 0..* indicating that it is possible that the same test is used for different purposes, therefore different LOINC codes.

So, the LIVD is trying to create a mapping catalogue that identifies the most likely and most likely appropriate mapping that is in play. It is not doing a one-on-one mapping because clearly, an IVD test can be used in different contexts, and therefore, it is the same test fundamentally, but it is going to yield a different LOINC code in order to ensure that it is properly interpreted in the context that is being used. So, part of the mapping definition, then, is not just having an IVD test code, and having a LOINC code, and these are the likely ones. There is information around the results context, the specimen context, and perhaps some other context that is described to help get to a better mapping.

If you go to the next slide, where we are looking at it and saying that is what we are trying to do, the IICC initially developed a first way of documenting those mappings using a spreadsheet format. So, when you go to the **[inaudible] [00:45:33]** that Arthur shared earlier as well and you go to the IICC spreadsheet-based IG, it will go to the latest version, the second edition, that is available. You also see a couple other references, like the HL7 draft for LIVD.

On the published side, either through the ISA, which makes a reference to the IICC, or the HL7 FHIR drafts, they are mapping test codes. So, for a moment, if you go back to the prior slide, it is dealing with the LIS test results or, effectively, fundamentally, the IVD test to the LOINC mapping. That is what is currently defined in the spreadsheets, and Riki could talk further about that, wherefore as far as COVID, that specific set of relevant tests has been documented in that way as well.

Go back to the next slide. Then, in progress, what we have is that we also need to map the result codes. So, work is in progress to finish that work and to incorporate that in the FHIR-based, and then, it also still would have to be incorporated in the spreadsheet format that is out there, so that is a work in progress. That is not done yet. We are actually at the tail end of it, making sure that both the result code mapping as well as the needs that have come up from the COVID environment test kids, which, in part, is already included in the spreadsheet format, is also included as well, and then we can go out. So, what we have is that LIVD STU 1 was balloted twice, but not yet published because we were catching up with that work to get that done. That is in flight. We hope to have that done very soon. No specific date yet. So then, a FHIR-based expression is available. The intent right now is it is mostly provided in electronic format as part of documentation and otherwise, and at some point in time, there is the opportunity to make that data available through FHIR-based APIs as well by different parties that have an interest in that.

So, that is where we currently sit with the LIVD specific status, and again, once we have that, then as documents are already being used in different places using the spreadsheet, it is guidance. It is not authoritative, as in that is the only mapping you can do, because everything still has a dependency on the

local lab situation as to how they are using the test and for what purpose from the device that then associates with the appropriate LIS LOINC and SNOMED encoding. So, that is the current state, and I am happy to take any questions between Riki and myself.

Arien Malec
Both to Riki and Hans and Greg, Andrew, and team, just because we have gone so deep into the work to create the future state, it might be worthwhile to spend a little bit of time to describe the current state, so I am going to give you a current state from my perspective and invite you to correct me in areas that I got it wrong.

So, at the end of this, we want an interoperable lab in the EHR and in the patient's hands, and "interoperable" means that the information is available in a structure with terminology that is clinically interpretable and where we can provide decision support tools for the patient to enable appropriate clinical and patient self-management. To get that, we need the elements of the lab, which we just went over in our USCDI deliberation, and we need them to be coded with the LOINC code as the test, and then, the numeric result with a UCUM units of measure or SNOMED CT for a non-numeric, qualitative result. Cool. So, flowing from the lab into the EHR, we want a stream of lab results that are so coded, and in particular, have a LOINC code for the lab. Great.

All this information comes off what is called an LIS, a laboratory information system. That is really the EHR analog for the clinical laboratory. It is a workflow tool that helps the clinical lab manage specimens in, the workflow of specimens, how they hit each of the IVDs, collection, collation, and then reporting back out, and then it all triggers off of an order that provides the template and specification for that master workflow. Cool. All this information originates in an IVD, where we take a specimen, we plop it into a machine, it does its thing, goes ka-chunk, ka-chunk, ka-chunk, and spits out some electronic data.

Right now, in the current world, the terminology that the IVDs use is different from the internal terminology that the LIS uses, which is different from the LOINC terminology that we want the patient and the clinician to get into their hands. And so, the lab maintains, basically, a set of interface configurations and specifications that map the data that come off of the IVD into the LIS's internal terminology, and then, on top of that, if the lab is doing a good job, they are mapping their LIS terminology to LOINC so it can get resulted back.

Now, a bunch of hospitals that are small that need to maintain stat labs do not have the expertise to maintain those mappings, and so they essentially gave a set of proprietary terminology back. The amount of proprietary terminology is decreasing over time, but there is still a bunch of proprietary terminology. And then, as everybody knows, in the COVID world, we have new device approvals for IVDs, we have new diagnostics, we have new analyte machines that are more efficient, that are better, that go through a 510K approval cycle, yada yada, so if you are a lab, you are maintaining connections/interfaces to a bunch of new analyte machines, to a bunch of new IVDs, so you have to make the maintenance of the mappings from the IVD to the LIS and from the LIS to the result in LOINC currently manually.

What this new state of the world is describing is a world where we fix this at source, where the information that flows off of the IVD is already pre-normalized to the appropriate LOINC code, that it flows into the LIS pre-normalized, and those mappings back out to the result are pre-normalized, and then, if we really want to dream big, the order itself comes in a standard LOI and it gets resulted out in a standard LRI, and so, we actually have full end-to-end mapping in between the order and the orderable, which, again, should be a set of LOINC codes, potentially CPT codes, into the LIS workflow, flowing data off of the IVDs, back into the LIS, and then resulting back via LRI to the clinician, and then, if it is a reportable lab, to public health. So, I am going to pause there. That is the current state, is this crazy mapping with lack of standardization, interfaces going wild, and a lot of manual work to the future state that we are trying to get to. So, Riki, Hans, Greg, is there anything I have missed in that high-level overview of current state and future state? Riki is endorsing. All right.

Andrew Northrup
If I can, Arien?

Arien Malec
Go for it.

Andrew Northrup
One thing that we have identified is that even with absolutely 100% precision of LOINC mapping, the information there is still not adequate for all the variations of future uses that we want to do. So, in order to use real-world evidence, that is, using patient data generated in the routine clinical care to provide data for regulatory decision-making, you have to know the platform from which it was generated. You obviously cannot look at the performance of a platform if that information is not even known. And so, the fact that LOINC is a many-to-one mapping kind of precludes that use, and so, that is why we are taking an ecosystem approach, because of the fact that we recognize that no single ontology is sufficient to support all the robust interoperability uses that are out there. And so, the plan is to have a series of standardized codes that would serve as a fingerprint for the laboratory result so that as it flows through the healthcare ecosystem, none of that information is lost, and it can be used and adapted for whatever use cases currently exist or will exist in the future, including AI, machine learning, and decision support or what have you.

Arien Malec
Perfect. Thank you for that.

Steven Lane
We are going to go to hands. Clem very appropriately raised his hand first, and has been waiting patiently, so, Clem, do you want to go ahead? You are on mute, Clem.

Clem McDonald
There are a whole lot of things. Firstly, some statements were made that the lab tests go to the medical record system. Most lab tests go to the laboratory system first, and that is actually very important. So, the LIVD thing, which is a great thing and would solve a lot of problems, though not all, because it is just for instruments, not other kinds of tests, but if they could really push that to get that done, that would help a whole lot.

But, the problem is that some medical records systems say you should map to the medical record lab tests without the laboratory people being involved, which is a big mistake that has created some problems. Secondly, some tests are already very standardized. There are international standards for creatinine and some other tests. So, if we have to add a lot of other stuff to it, it has been hard enough to get people to map to just one code. We may never get this done. So, just be cautious about making the excellent the enemy of the good.

Arien Malec
Thank you.

Steven Lane
Thank you, Clem. Hans?

Hans Buitendijk
Yeah, just a clarification on the comments that were made, and I thought I heard Arien indicate that the ideal would be to get it all the way in the device. That actually has been a challenge to do that because to start the proper LOINC mapping, they do not have the data to do it, and the question is if we can get that there. You could theoretically argue you can get the information from the LIS order as they provide instructions to the device that they could do it, but realistically, the only place where the mapping can start is the LIS, and then the question becomes if it is realistic to drive that to an automated mapping or if the context is still variable enough, which it is considered today, that somebody needs to do the configuration

as opposed to the mapping guidance being specific enough based on context to always know which LOINC code to use.

So, I think we still have a problem there, but at least, in the LIS, no later than that, we should have a mapping that occurs so from that point forward, it can roll all the way through, and along with the data to the EHRs, public health, research, whomever. So, if the intent is to ask if we can already try to get the mapping down into the device to the proper LOINC and SNOMED, it is not likely. Should we be able to get it done in the LIS, and what can be done to make that easier? Yes, that is where the focus should be, and the question is how much automation you can get out of it versus a human needing to interpret it based on the lab's use of those tests.

Arien Malec
Thank you for that, Hans. I think my statement was that we probably should get the orderables to the LIS in a standard way so that the LIS can drive the underlying lab workflow in a more automated way, understanding that there is going to be some mapping between the orderable and the actual specification. All right, let's go to Ike.

Steven Eichner
Thank you. The other element we need to remember is that from a public health perspective, there is currently other data that is being provided through the LIMS, depending upon the particular nature of the test or sample, whether looking at pregnancy status or travel history, information that is currently coming across through the LIMS system, and I cannot help but wonder if there are other ways of routing data to help avoid having to have LIMS systems be continuously modified to support these extra fields that are not really of interest necessarily from a laboratory perspective, other than passing it off to public health.

Arien Malec
Yeah, thank you for that, and generally, the way that information is collected is using ask-it order entry fields, and there is some work in standardizing ask-it order entry as well as reflex ordering, and a lot of that work has been encoded in the LOI spec and some of the companion information associated with that, but the fact that we get some clinical information into labs is often done through ask-it order entry questions that are workflow questions that pop up automatically in the order. All right. This has been an awesome master class for all of us in terms of state of the art. I would encourage everybody to go back and reread the 2018-2019 recommendations that we made in this area. I think we are going to have to go back and potentially revisit some of them in the context of SHIELD and LIVD, but I think our response right here is, knowing the state of the art and knowing where we are, to put together some recommendations for ONC out of our work related to our ISA task. Clem, you have your hand up.

Clem McDonald
Yeah, I just want to add some other things. I think that one needs to understand the partitioning of the world of lab tests. So, PCORnet has 9 billion instances of mapping some lab to test from 60 different organizations, and of those, 94% are quantitative, so just be aware that the coding is a different level and much smaller numbers, but importantly have coded answers. And, the other thing is an awful lot of those have the specimen built into the test. Some are on the order of 80%, like glucose, serum glucose, and sodium urine, etc. So, we should partition the world before we target what we have to do to it a little bit to minimize the work and maximize the achievements.

Arien Malec
Thank you.

Steven Lane
Hans, we will get to you in just a second, but I do think we have to think quickly about how we are going to turn all of this into specific recommendations, and I think the one thing that you proposed, Arien, is going back to our earlier recommendations from a couple of years ago and basically refreshing those with this new knowledge and insight, and perhaps that is something that you and I and Hung, perhaps, could work

through, trying to put this together, or I do not know if we could lean on Riki to chime in with us as well, but putting together a draft revision with the latest updates seems to me a good first step, and then there may be some additional recommendations that need to be tacked onto that. Does that sound right?

Arien Malec
I would heavily endorse that. Our observation at the time was that through FDA, CLIA, CMS, CDC, and ONC, that HHS broadly had all the regulatory levers that it needed to be able to drive broad-scale lab interoperability, and that a lot of this was just lining up those levers in a consistent and sane direction, and then, since that time, the SHIELD and LIVD work have done tremendous progress in many of the areas that we called for in that report.

Steven Lane
Arien, I think you put in a link to the report up earlier in the chat, and I am looking for it. Maybe we can repost it at the bottom.

Arien Malec
I will do that.

Steven Lane
I think I found it. There it is, sorry. Oh, but I cannot copy inside of Zoom. Clem, your hand is up.

Clem McDonald
The levers have not been applied. So, CLIA has taken at least a published position about standardizing codes. I apologize to my good friends at ONC, but I think ONC made a mistake when they declared that the lab was already topped out. It was not, and there were letters from national laboratory systems saying that the coding was not very well done, almost not done at all in hospitals. So, taking off that pressure really hurt. I think we really need to push on getting some levers pushed.

Arien Malec
Yes.

Steven Lane
And, I think there is a key point there. What is ONC's position on that? And, I do not know whether anyone on the call is prepared to comment on that.

Arien Malec
Sometimes you do not want to ask ONC to take a position on a call in areas where you are about to make recommendations to ONC. Maybe we could ask Dr. Pappas to talk about the policy view towards the goods that we want to get to rather than ask a question about particular regulatory levers and position. But, Hung has his hand up. Greg, maybe if you can just give us the shared policy goals of HHS at a broad policy view, at least in the work that you have been doing between FDA and ONC, if you are available and off mute. Otherwise, we will go to Hung. Cool, we will go to Hung.

Hung S. Luu
So, my concern with using the regulatory levers right now is that we have already demonstrated that the laboratories are struggling to do accurate coding. A research article we put out a few years ago demonstrated that we asked the different laboratories what LOINC code they had in their system for comment tests, such as PT, PTT, INR, and troponin, and what we found is that across the board, there was only about 80% accuracy rate in terms of the correct LOINC coding for the common tests, and what we also found was that for standardized tests such as troponin, standard and high-sensitivity troponin, none of the laboratories got that correct.

And so, it is not that the laboratories are not trying, but I think to put additional pressure on them to force them to code things when they have already demonstrated that they are struggling would be a mistake

because obviously, the approach that SHIELD is trying to take is that we need to move that effort upstream to the IVD manufacturers, who would be the most knowledgeable about their test kit. That way, the information can be provided to the laboratories pre-curated as much as possible so that they are not put in the position of being set up to fail because of the fact that they just do not have the necessary knowledge or resources to do it accurately.

Arien Malec
As a counterpoint to that, the LIS is coding to something, and they are either coding to a proprietary code, which the EHR then has to cross-map to whatever it understands, so you have a failable mapping step by the downstream recipient, who is the least in touch with what the lab intended by its proprietary code, so I completely agree that our goal is to get this captured correctly, but you never avoid the mapping problem, and the later you do the mapping problem, not doing it in the lab means you are doing it in the EHR, and when you are doing it in the EHR, you are way downstream from the lab workflow, and the likelihood of getting it wrong is even more increased, but let us go to Mark.

Mark Savage
Thanks. Sorry, I have been responding to an urgent request and multitasking, so I apologize if this has already come up, but I want to lift up my question about patients, roles, and access to all of this, and making sure they have a connection. I am not sure if that is an ISA issue per se, doing my other comment about the difference between the catalogue, but I just want to flag that to the extent we are suggesting use cases, we want to make sure that patients have equal access to the lab results, and we want to be identifying standards for them to do that to the FHIR APIs, and I welcome anybody's thoughts on the overall question. How do we make sure that patient access is included? Thank you.

Arien Malec
Thank you for that. I think if you go back and relook at our 2018-2019 recommendations, you will see that basic point, that the end good of all of this is to get the result in the patients, the clinicians, and public health, though I think we left out clinical trials, but it is an important consumer research need, in an interoperable and interpretable way, and we do contemplate in the 2018-2019 report that the end goal should be to make this information available to patients via FHIR-based APIs such that it can flow electronically and get into the hands of the patient, so I would just encourage you to go back and look at that, and then, from the perspective of maybe doing a **[inaudible] [01:10:26]** of those recommendations, look to see whether we can sharpen any of those recommendations that we made.

Mark Savage
Thank you, will do.

Arien Malec
And, Steven helpfully points out the actual page where we made those recommendations. 2018-2019 seems like such a long time ago.

Steven Lane
Indeed. Other comments? A number of folks have been active in the chat. Grace, did you want to speak up?

Grace Cordovano
I am just going through all the recommendations as much as I can. I think that the document is robust, and I do think everyone reviewing it would bring everybody on the same page. I do think there is a lot about patient access. I appreciate Mark bringing that up, and as I dig into it more and more, I think there is a lot that is outlined to facilitate that, as well as access to other stakeholders, and I think there is a great opportunity to have continuity from that document with the rich discussion that was here. So, Arien, I do support that recommendation as to what we can do as a workgroup.

Arien Malec

Fantastic. Hans has his hand up. Go ahead, Hans.

Hans Buitendijk
Just a quick clarifying question. I went to the page of making data available to the patient, and I think perhaps as part of this round, a number of things have started to be addressed or are in flight with the current API rollout. It probably would be helpful to understand that it is maybe more USCDI where we have the discussion. What data is actually of most interest, and can we then make sure that they are included in current transactions? Arien, as we talked about before in LOI and LRI, you can already get a good idea what kind of data is being exchanged, what is made available from a CLIA perspective or otherwise. Is that rippling through enough for the intent that is outlined here? So, I think that goes back to our conversation in USCDI space on what data it is that then can ripple to the rest.

Arien Malec
Yeah, and fortunately, we did make recommendations in this round for USCDI to at least include some of those missing data elements with some obvious omissions, like reference ranges and interpretation codes. Cool. What I would propose at this point is that first of all, just a fantastic panel. Many thanks to Riki, to Hans for doing dual duty, to Andrew and Greg from ONC, to the broad leadership that we have been doing in the combined SHIELD and LIVD space. I think the experience on the ground relative to the pandemic and supporting lab interoperability relative to reportable labs for COVID has shown the value of this work, and it is a good time to revisit what I think are our pretty well done recommendations from last time, but actually putting on a public health and research hat as well as the clinical and patient hat that we were putting on last time.

But, as I said, I think we have made a huge amount of progress, and I think we also have a great proof point for why getting lab right matters, both for clinical care/research/patient engagement, but also for public health. Steven, what I would suggest before we go to public comment is to review the spreadsheet because we have already had folks making additions to the spreadsheet, and I just want to give a PSA for maybe a framework for thinking about how we put together recommendations based on some of the email dialogue that we have been having. So, the spreadsheet was posted to the full workgroup. Mark, Grace, David, and Christine have already put really helpful comments into the spreadsheet. In this round of recommendations, we are likely to make two kinds of recommendations.

One is the deep thought recommendations. Thank you for this. So, one is the deep thought recommendations that require deep deliberation in areas like lab interoperability, hearings, as we just expressed, and those are going to be the ones that we have up-prioritized in our prioritization framework. We are likely to be able to make a number of other recommendations that are of the form "We recommend that the ISA track Use Case X and track Standards Y and Z, aligning with FHIR Accelerator Project Z or whatever." David has done a really amazing amount of work. Grace and Mark have done work here on the HIPAA right to correction, and just pointing those use cases at the appropriate FHIR accelerator, and so, we are likely to be able to make recommendations that the ISA track use case for HIPAA right to correction, and then point that use case to the FHIR accelerator work, as well as to the draft standards.

Just because a use case or an area has been down-prioritized by the workgroup, please do not take that as a belief that we are not going to make recommendations in that area, and I would encourage you to go into the spreadsheet, find areas where the ISA is not tracking a use case or not tracking a known standard, and put that information in there. And then, Christine has made some really good recommendations for the ISA process itself, and better ties between the ISA and USCDI, so again, if you have thoughts about the overall ISA process, please use the spreadsheet. Just as we did last time, this is going to be the way that we turn workgroup comments into finalized recommendations. Hans, you have your hand up again.

Hans Buitendijk
Yeah, a clarification on the recommendations. Is the intent to focus on what updates are to be made to the ISA, which is more of a catalogue environment, to make sure it is the most current and up to date. The comments that relate to how and what kind of levers to use, be it certification programs or otherwise, to

further enhance uniform adoption of the common tools… Are you looking for that in these columns as well, even though **[inaudible – crosstalk] [01:17:50]** ISA?

Arien Malec
Yes. So, the distinction I was making was that we can make recommendations that are in line with the charge that we have, we can make recommendations that the ISA track FU and BAR, and we should. There are going to be areas where we go deep on a topic, like we are just going deep on the loop from order, to IVD, to LIS, to result, to EHR, to public health, to patient. There, we may color outside the lines and start making recommendations not just on what gets tracked in the ISA, but how to accelerate use of the standards that are named in the ISA, so that is the distinction I am making between going deep in an area, doing deep thought, versus making recommendations that we track things. We can only do that work for a limited number of things, which is why the prioritization framework is useful. Mark?

Mark Savage
I will just add that my sense is that by framing use cases, how you can connect some of the dots in ways that might not yet be in ISA, can be a helpful way forward too. We will see some of that on the SDOH stuff from Gravity Project.

Arien Malec
Right. It is even permissible to say, "We think the ISA should have a use case for blah, even when no standard exists," just to make sure we are tracking that as a priority use case. Cool. All right. And then, with that, Steven, I think we probably should go to see if we can do some early public comment.

Steven Lane
Thank you, Arien. We invited a number of people to join us today, some of whom have tremendous, deep expertise in this area in really trying to do this work within their systems or their applications, so I think giving people a chance to raise their hand now, if they like, and encouraging it as well. We do encourage members of the public to raise their hands, and we can see whether your hand is raised, so we will call on you in order if you had something to share.

Public Comment (01:20:00)

Michael Berry
All right. 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, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. We will pause to see if someone raises their hand. And, Adam Davis, you have three minutes. You might be on mute.

Adam Davis
Thank you. This is Adam Davis with Sutter Health. I am also the cochair of the CareEverywhere Governing Council for Epic and the cochair of the Data Usability Workgroup for the Sequoia Project. I wanted to ask our panelists and comment to our panelists. I think the lab interoperability is incredibly important to clinicians, as we all know. I think that the final solution of getting all the way back to the instrument level and having perfection of the mapping is a great goal, and I think there is a real vision for that, and seeing some of that vision laid out today was really inspiring. I do wonder if there is an opportunity for a parallel path for some lower-hanging fruits.

As Dr. Lane talked about at the beginning of the meeting, there are efforts at some health systems to map certain labs, but the process is quite laborious and has led health systems to abandon the mapping of that for trending and for clinical decision support and qualitative measures. I wonder if there is a pathway to doing some parallel work to allow already standardized or harmonized labs, such as sodium or creatinine, to be more easily mapped between health institutions while we wait for that instrument-level thing because at the end of the day, I think there is a big split between what clinicians care about in terms of those labs

and maybe what lab directors do. At the clinician level, I actually don't even really care what the reference range for that sodium is because I have a general idea that a 140 is a 140 is a 140. I know that is not true for all labs, but I wonder if for some of the labs, we could work towards that while waiting for this more permanent solution. Thank you.

Riki Merrick
This is Riki. One of the things SHIELD is working on is prioritizing which labs to identify, and we do know that there is a list of tests harmonized to an international standard, and those are definitely on the docket to be included, and part of SHIELD, as a parking lot/next step, is to look at the harmonization aspect of other lab tests that are not yet harmonized to an international standard, and so, that is something that comes up on our calls regularly, and is definitely on top of mind as well. That requires different expertise than the data side of things.

Steven Lane
Riki, I think the key that Dr. Davis is raising is can we make a plan that produces an early result for those harmonized labs that could be put into practice next year as opposed to this longer process, which clearly is needed and is on the right track, but will take time.

Arien Malec
Sounds like a "We recommend that ONC work with other federal stakeholders to accelerate interoperability for the class of lab results that account for…" There are usually 90/10 power law dynamics for the number of lab tests that account for the vast majority of lab results. Let's go to public comment first. Hung has his hand up.

Steven Lane
Actually, I think Tom Cantilina had his hand up first.

Arien Malec
Just in terms of process, I want to make sure we hear from the public first rather than members of the workgroup. Is there any more public comment?

Steven Lane
I do not see any other hands up.

Michael Berry
I am not seeing any other comments.

Clem McDonald
Whatever order you want. I am patient.

Steven Lane
I think we have Tom or Col. Ford, whoever it is who is behind that hand that was up, Hung's hand was up, and then Clem.

Jeffrey Ford
Hey, everyone. This is Col. Ford, stepping in for Col. Cantilina. Can you hear me okay?

Steven Lane
Yes.

Jeffrey Ford
Okay, great. So, I was trying to figure out a great way to ask this question because it is not directly accorded to what was presented to today. It is more of a selfish question. I am a dentist by trade, and I was wondering what everyone on the call thought about the dental community, and I know that opens up a whole can of

worms, and I do not mean to do that, but I just want to know what the thought process is between the dental community at large and interoperability, even with labs like what was discussed today. I know we could easily go to an EHR-type model with our technologies and local clinics, and even large corporate clinics, if you will, not to mention the DOD and the VA complex. What are the thoughts out on the call for dental interoperability standards and merging that into a healthcare delivery model that we are reaching for?

Steven Lane
Yeah. Jeff, this is Steven Lane, and I will just say that this has come up a couple times within the ONC context. It is the Office of the National Coordinator for Health Information Technology, and we all have mouths, and most of us have teeth, and I think dental health is clearly a part of health, and there has been a broad gap between the dental information and the other medical information that is out there, but I do not think it is at all unreasonable to consider dental-related use cases as we move forward. You tell us how much that relates specifically to this question about lab results, but I am sure dentists order some labs. I have never had a blood draw at the request of a dentist, but I am sure some people do. So, you tell us where that would fit in.

Jeffrey Ford
Great. I really do appreciate that, and I champion this cause. Like you said, it is healthcare delivery, and my boss, Col. Tom Cantilina, obviously says the exact same thing. There are not many mouths running around without the body attached to them, and we all can agree to that. It is that healthcare delivery model. Having said that, on calls like this, it is safe to say that most of us here probably get the lighter side of dental care, for the most part. We have healthy, routine examinations, X-rays, that kind of scenario. We definitely delve into the realms of dental specialties beyond that: Periodontal disease, craniofacial anomalies.

A lot of general dentists do IV sedations in-house. We have heard the use cases of that before too, checking on pregnancy statuses that way versus a urinalysis stick test, those kinds of things. And again, with the COVID presence on us like never before…I did not want to load the question too much here. I just wanted to get that thought out there and entertained of that dental healthcare delivery model. We have been separate for so long, and equal. I am just trying to close that gap as much as is humanly possible, especially in the standards conversations like this with the ONC. Thank you for the time.

Steven Lane
Thank you, sir. Hung, you had your hand up briefly. Did you have something more you wanted to add?

Hung S. Luu
Yes. In terms of harmonization, I do think there are effective measures we can take. One of the proposals for SHIELD is to have a harmonization indicator as a discrete data element that would automatically let the downstream players know that the test in question has already been harmonized at the vendor level so that it can be safely viewed as interoperable or equivalent to any other same test, but I think that in the short term, a future solution might be… I do not think that the public or healthcare players in general know of the harmonization efforts and what laboratory results are already harmonized, and so, I think there could be an opportunity there to raise the profile of these harmonization efforts and let people know what has already been performed and what laboratory values can be safely trended already, and so, that could be a short-term solution while we work on everything else, including the harmonization indicator, is to highlight that work and let the people know what lists of tests are safety trended right now. Clem?

Clem McDonald
Yeah. So, I wanted to comment on a couple things. Firstly, all the standards that exist in FHIR are perfectly fit for delivery of dental information, and there are probably a thousand dental codes in LOINC, too, so it is just a matter of the dental side embracing it and asking for more stuff if they need it. So, I think they are welcome, it fits, and the stuff will work. But, I wanted to go back to LIVD because I think there is a huge opportunity there. The upstream business is high.

People may not realize that there is a whole spectrum of differences among instruments. Some are totally stupid. They get fed a piece of tissue, analyte, or fluid, and they spit out a number. Some of them actually are little lab systems. They take in an order, and they can very well map LOINC to a given test. I think the evolution is toward the more sophisticated ones. So, as Hans was saying, it is the reason why you have to have a lot more data to figure out what the specimen is going in, like if it is urine, pee, or water, before you can tie it to a clinically meaningful code, but a lot of the newer instruments do that. So, again, push on it. We can get a lot done, but we are going to have to push because people do not do extra work spontaneously.

Arien Malec
And, with that, I think we are at time.

Steven Lane
How about that? Thank you, everyone, for your time and attention today. We are actually slightly over time. We will be meeting again next week. Arien, do we know what we are focusing on next week yet?

Arien Malec
We are lining up for Gravity next week.

Steven Lane
Perfect, which I anticipate may again take the whole time, and then we may have a couple more hearings planned for the next couple of weeks, and then we will also come back together and start focusing in on what people have put into our spreadsheet and recommendations.

Arien Malec
Meanwhile, populate that spreadsheet.

Steven Lane
Thank you all. Have a wonderful day.

Michael Berry
Great, thank you. Bye.

Adjourn (01:31:57)