

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

June 16, 2022, 10:00 a.m. – 12:00 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Aaron Miri	Baptist Health	Co-Chair
Denise Webb	Individual	Co-Chair
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	ORACLE Cerner	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Brett Oliver	Baptist Health	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Anthem, Inc.	Member
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative





Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division





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

Michael Berry

And, good morning, everyone. I am Mike Berry with ONC, and I would like to welcome you to the June 2022 HITAC meeting. We always appreciate when you join us. As a reminder, your feedback is welcome, which can be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about 11:45 Eastern Time this morning. So, let's get started with our meeting. First, I would like to welcome ONC's executive leadership team to the meeting, and with us today is our National Coordinator, Micky Tripathi, Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I will now call the meeting to order and begin roll call of the HITAC members, along with the federal agency representatives of the HITAC. So, when I call your name, please indicate that you are present. And, I will start with our cochairs. Aaron Miri?

Aaron Miri

Good morning.

Michael Berry

Denise Webb?

Denise Webb

Good morning.

Michael Berry

Medell Briggs-Malonson?

Medell Briggs-Malonson

Good morning.

Michael Berry

Hans Buitendijk?

Hans Buitendijk

Good morning.

Michael Berry

Thomas Cantilina? Steven Eichner?

Steven Eichner

Good morning.

Michael Berry

Cynthia Fisher? Lisa Frey?

Lisa Frey





Good morning.

Michael Berry

Raj Godavarthi?

Rajesh Godavarthi

Good morning.

Michael Berry

Valerie Grey?

Valerie Grey

Good morning.

Michael Berry

Adi Gundlapalli? Steven Hester?

Steven Hester

Good morning.

Michael Berry

Ram Iyer? Jim Jirjis? Meredith Josephs? John Kansky?

John Kansky

Good morning.

Michael Berry

Ken Kawamoto?

Kensaku Kawamoto

Good morning.

Michael Berry

Steven Lane?

Steven Lane

Good morning.

Michael Berry

Leslie Lenert? Hung Luu?

Hung S. Luu

Good morning.

Michael Berry





Arien Malec?

Arien Malec

Good morning.

Michael Berry

Clem McDonald? Jonathan Nebeker? Aaron Neinstein?

Aaron Neinstein

Good morning.

Michael Berry

Eliel Oliveira?

Eliel Oliveira

Good morning.

Michael Berry

Brett Oliver?

Brett Oliver

Good morning.

Michael Berry

James Pantelas? Raj Ratwani? Michelle Schreiber?

Jim Jirjis

Hey, Jim Jirjis here.

Michael Berry

Abby Sears?

Abby Sears

Here, sorry.

Michael Berry

Alexis Snyder?

Alexis Snyder

Good morning.

Michael Berry

Fil Southerland?

Fillipe Southerland





Good morning.

Michael Berry

Ram Sriram?

Ram Sriram

Good morning.

Michael Berry

And, Sheryl Turney?

Sheryl Turney

Good morning.

Michael Berry

Good morning to everyone, and thank you so much, and now, please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:20)

Micky Tripathi

Thanks. Hello, everyone, and thanks so much for joining this month's HITAC meeting. I will be brief this morning, just give a few updates, and really tee up for Aaron and Denise the meeting that we have today. We have a lot of really good stuff and we want to get to that as quickly as possible. I wanted to first thank everyone for joining the latest social determinants of health information exchange learning forum webinar this past Tuesday. We had a great turnout, with a lot of stakeholders on hand to share lessons learned, promising new practices, and challenges associated with exchanging SDOH data, basically a really, really important area, a high priority for us at ONC and with our federal partners, so we really are just very pleased with the engagement we are getting there, and the participation, and what we are able to glean from that so that we can move forward in this important area.

The next webinar is scheduled for July 19th, where the session is going to cover privacy and security considerations as well as financing models to support organizations pursuing SDOH information exchange. You can register by searching for "SDOH learning forum" on the ONC website, healthIT.gov, so we welcome your participation there and thank you in advance for your help and engagement.

I also want to thank and acknowledge the cochairs, Steven Lane and Arien Malec, and all the members of the Interoperability Standards Workgroup for their efforts to develop the recommendations that we are going to be looking at today. This portion is the second phase of a two-part charge. In April, the workgroup, as you may recall, presented their recommendations on the draft USCDI Version 3, and we really appreciate the immense dedication of the workgroup members who have served over the past five months.

So, just one comment on that. This work with the USCDI Version 3, as well as the ISA, is really an increasingly important kind of activity that we conduct and that we get tremendous feedback, engagement, and advice from the HITAC, both with respect to the importance that these things are having in the market as we have seen with respect to adoption and our collective need to move forward as aggressively as





possible with standards-based exchange and the use of open industry standards where available, as well as, I will say, with our federal partners, both with the USCDI as well as the ISA as being somewhat of a place for people to look, sort of a north star with respect to things that have reached a maturity level that they are usable and with things that are somewhat aspirational in some ways, but that can help to point directions where things may not be fully instantiated and regulation may not be as fully mature as in some of the other use cases. So, both of these things are incredibly important, and I think it is hard to overemphasize the importance of the work that this working group is doing to help us all move forward.

Today, we are also going to talk about forming a new Task Force to review the existing ONC adopted standards and implementation specifications found on the ONC standards hub. So, we push forward with the new stuff, but we also need to look back and talk about pruning as well, and are there things that we wanted to be able to think about pruning? And, that is what that new Task Force is going to be looking at, and Seth Pazinski is going to provide an overview of this work and the HITAC's charge.

I want to point you to two new ONC blog posts. We have been doing our best to get as much communication as possible through all of our various channels, and our blog is something that we have been spending a lot of time trying to activate, and hopefully all of you have been seeing that and hopefully appreciating it, and if you are not, let us know, and if you are, let us know as well. But, the first blog post that I wanted to highlight is really sharing the work of all of you, which is focused on the electronic prior auth work. I want to thank all the members of the E-Prior Auth Task Force for the tremendous amount of work that went into that and developing those recommendations, and I think as all of you know, this is a very active area of interest for the entire industry, and so, that work was really beneficial and something of great interest all across the board, and that blog just tries to communicate that and showcase that work.

The second blog is to highlight a new legislative proposal associated with information blocking that was put forward by the department, specifically the request that Congress provide HHS with the authority to issue binding advisory opinions for the information blocking regulations as part of our implementation of the 21st Century CURES Act. As I think most of you probably know on the HITAC, information blocking is very much a case-by-case determination, and often, the questions that we get are somewhat general in nature, or they may be specific, but we are not really in a position to be able to provide sometimes the kind of feedback that a requester may have in mind or may desire to help them move forward because it is so case-specific. The details actually matter a lot, and right now, ONC does not have the authority to issue advisory opinions where we would be able to look at the individual circumstances of a case and then be able to offer a little bit more focused and targeted advice regarding the different compliance aspects of it.

So, we think that that is something that would be very beneficial to the industry based on the feedback that we have been getting and the types of questions that we have been getting, and that is why we are happy that the department included that in our budget request. So, I am happy to talk more about that if people are interested in that in a future meeting, but I just wanted to flag that for you so that if you are in discussions with our congressional partners or with others to be able to provide a little bit of background on why we think that would be important for the successful ongoing implementation of the 21st Century CURES Act information blocking provisions. Both those blog posts, I think, as you all know, are on HealthIT.gov.

For a member update, the GAO has begun their HITAC appointment cycle for this year, and they just released a federal register notice requesting nominations to serve on the HITAC. The GAO expects to





appoint at least four new HITAC members, whose term will begin this coming January, January 2023, and the deadline to submit letters of nomination and resumes is July 22nd, so, just a little more than a month from today. So, for all of your awareness, if you want to communicate that to your various communities, again, the deadline for those nominations and resumes is July 22nd, 2022 to the GAO.

So, let me just close here, get off the stage, and move on to more important things. I do want to thank everyone for joining us today, and as always, and very sincerely, I thank the HITAC members for all of your support and engagement. You have dedicated a ton of time participating in the HITAC, especially those who have dedicated several months lending your expertise on one or, in some cases, a few of the subcommittees, where a ton of work happens. The HITAC traditionally has a break in the summer, and with that in mind, the July 14th full HITAC meeting is going to be canceled, and we will resume in August, but just to make sure that no good deed goes unpunished, the new Adopted Standards Task Force will be meeting during that time and will provide an update on their progress during the August HITAC meeting. So, for any who are thinking about participating in that workgroup, you might just want to keep that in mind. Let me now turn it over to Aaron and Denise for their opening remarks.

Opening Remarks, Review of Agenda and Approval of May 18, 2022 Meeting Minutes (00:11:10)

Aaron Miri

Wonderful. Thank you, Micky. I appreciate it. Welcome, everybody, to this month's HITAC. Micky, to answer your question, regarding ONC's blog posts and everything else, they are fantastic, and I also want to thank you and your team for being so accessible to the community, especially for all the hospitals that have questions and whatever. You guys have never made any shortage of availability, so thank you for that. Your team is excellent in trying to explain things. Denise?

Denise Webb

Yes. Good morning, everyone, and welcome to our June meeting. I am excited to hear, Micky, that the advisory authority got put into the budget. I think that is going to be absolutely critical, based on some of the work both Aaron and I have done with a number of the other CIOs at the various health systems and clinics. And then, also, I am one of those individuals who is going to term out at the end of this year. I was appointed by the GAO comptroller's office, and so, what that means is I will not get to finish my term as cochair, so you all might be thinking about your interest in that. I know ONC has a process for identifying a new cochair, so you all have six months to think about that, or a little less.

Aaron Miri

We will miss you, Denise. We will miss you.

Denise Webb

No, it has been quite a journey, so I am going to relish the last five months that I have with the committee, but hopefully, we will still get to stay involved. So, let me go over our agenda this morning. We have two main topics, and Micky gave a little preview. We are going to hear from Seth at the ONC on the adopted standards review, and the new Task Force, and what that is going to be all about, and then, we are going to hear from our cochairs of the Interoperability Standards Workgroup, Steven Lane and Arien Malec, and they are going to present their workgroup's recommendations on the 2022 ISA, or the Interoperability





Standards Advisory, and so, we will be taking a vote today on those recommendations. So, before we begin and I hand it over to Seth, we do need to approve our minutes from May, so if I could get a motion for approval of our minutes for May?

Aaron Miri

I will motion.

Hans Buitendijk

Second.

Denise Webb

Thank you. And, who was the second?

Hans Buitendijk

This is Hans.

Denise Webb

Thank you, Hans. All right, all those in favor, say aye.

Several Speakers

Aye.

Denise Webb

Anybody who does not approve, no. Any abstentions? All right, so, our main minutes are approved, and with that, I would like to hand over the podium to Seth Pazinski so he can give us the preview of our new Task Force.

Adopted Standards Review (00:14:29)

Seth Pazinski

All right. Thank you, Denise. Hi, I am Seth Pazinski, the Director of Strategic Planning and Coordination at ONC. Thanks for giving me the chance to overview some new work for the HITAC. It is not every day that we get to start and be a part of something for the first time ever, but today is one of those days, so hopefully I got you a little bit intrigued about this new Task Force, and I will just give a little bit of overview and background. Go to the next slide.

So, we have had to wait for about five years to take action on this CURES Act provision. The wait is over, so it is now time for us to take action to respond to this congressional requirement, as Micky mentioned, to bring stakeholders together to review the existing set of ONC adopted standards and make recommendations on whether to maintain those standards or phase them out, and the National Coordinator is charging the HITAC to serve as that stakeholder-convening body. Go to the next slide.

So, just recognizing, at least in name, some of the focus being on standards here, I wanted to talk a little bit about the difference between the Interoperability Standards Workgroup and the recommendations you will hear about from that workgroup later today to distinguish that from the charge of this new Task Force. So, the Interoperability Standards Workgroup, our existing workgroup, is an annual requirement that





responds to a separate CURES Act provision, and that workgroup is focused on recommending priority uses of health IT and related standards. Their work really focuses on informing the ONC Interoperability Standards Advisory, which is how we coordinate on interoperability standards that can be used to address a variety of interoperability needs that cover the broad spectrum of clinical and public health research, etc.

So, this new Task Force is more of a look at the existing portfolio as opposed to informing what is to come in the future, so this is just a little more targeted on only the standards and implementation specifications that have been adopted through ONC by regulation. So, this is kind of a process where the industry gets to provide a check and give its recommendations to inform how ONC uses one of its strongest levers, its regulatory authority behind adopting standards. Per the CURES requirement, this is something that we will be repeating with the HITAC every three years. And so, the HITAC recommendations that we will get from the Task Force will be an input to inform future ONC rulemaking. We can go to the next slide.

So, I will just read through the specific charge to the HITAC. It is to create a Task Force to review the existing set of ONC adopted standards and implementation specifications, and then, again, make recommendations to maintain or phase out those standards, and implementation specifications in the scope of those standards and where the set of adopted standards are maintained is on the ONC standards hub, and we will plug that link into the chat as well. And then, again, as Micky highlighted, this charge is not focused on seeking new standards for ONC to adopt, but just reviewing the existing set. We are asking the committee to complete their work by the September 14th HITAC meeting. We can go to the next slide.

This is the current roster. I want to thank the members, as well as the external subject matter experts who volunteered to participate so far, and a special thanks to Hans and Steven Eichner, who volunteered to cochair this new Task Force. If you have not volunteered yet, but just cannot resist being a part of this first-ever group to do this work, please reach out to Mike Berry to be added to the Task Force. We can go to the last slide.

From a timeline perspective, just a quick overview here. We are still working on scheduling the first meeting of the Task Force. We anticipate that to be in the next two weeks or so, and we should be able to determine that by the end of this week, so we encourage folks to check back on the HITAC calendar early next week. At that point, we should have the meeting scheduled and have a cadence down for the frequency of the Task Force meetings going forward. And then, as a reminder, we canceled the July HITAC meeting, so the first update from this new Task Force will be at the August 17th HITAC meeting, and then, final recommendations and a vote for the HITAC at the September 14th meeting. So, again, I wanted to thank everybody who is already signed up to participate and volunteered to be on the Task Force, and if you are interested and have not reached out yet, please contact Mike Berry. I think I will now turn it back to Denise to moderate if we have any questions.

Denise Webb

All right, thank you, Seth, and we do have a question from Dr. Lane. Steven, if you would go ahead.

Steven Lane

Yes, thank you, Seth, for that. I just wanted to say how excited I am to see the folks who stepped forward to participate in this Task Force. I think you have some really strong folks on that team, and I specifically wanted to call out Hans and Steven Eichner, who have both been very involved in the work of our





Interoperability Standards Workgroup and I think are well aware of the issues we have unearthed there and will be discussing in our recommendations, so this is a great group, and I am looking forward to seeing what they come up with.

Denise Webb

That will provide some nice continuity. All right, does anybody else have a question or comment? Aaron, yes, go ahead.

Aaron Miri

Yeah, a question. I am just curious. I think this is phenomenal, I think this is great, and the roster is really strong. I really appreciate everybody volunteering. Is there a mechanism yet for industry groups to be able to weigh in on proposed standards or items they would like to see addressed by the workgroup? Does that mechanism exist? I know usually, ONC is very open and receptive to it. Should everybody email you? Should they contact someone specific? I know there are a lot of folks in the industry working through this. It would be great to get the summation of all their information as well.

Seth Pazinski

Great point. Thanks for the question. Just as a reminder, for each Task Force meeting, just like we have in all the HITAC meetings, there is the opportunity for public comment, and that opportunity is for both verbal and written comments, so we encourage anyone who is interested in giving feedback to do it through that public comment process during the Task Force meetings. We will have a better sense once we connect with the Task Force cochairs to hopefully have a structured agenda of how we will be taking a look at the different sets of standards, so that will give folks a little bit more of a cadence on how to plug in, depending on which particular standards folks are interested in.

Aaron Miri

Thank you.

Denise Webb

Anyone else? All right, thank you, Seth. I am going to turn it over to Aaron to present our next topic.

Aaron Miri

All right, that was a good one. I always appreciate the opportunity to stay precise on things. Okay, the next one up is we have the Interoperability Standards Workgroup recommendations on the ONC's 2022 Interoperability Standards Advisory. This will go to a vote at the end of it, but first, we will be led by our experienced cochairs and always amazing colleagues here, Dr. Lane and Arien Malec, to lead us through it. So, the floor is yours.

Interoperability Standards Workgroup Recommendations on ONC's 2022 Interoperability Standards Advisory – HITAC Vote (00:22:57)

Steven Lane

Well, thank you so much. We are very excited to be back again with the second round of our recommendations from this workgroup that has been just incredibly engaged in the work and bringing forward these recommendations to all of you for your consideration. Arien?





Arien Malec

As I think Micky noted up front, we looked at our charge, we gasped with horror because it seemed impossible, and thanks to a fantastic workgroup, we have not just recommendations, but I think fairly meaty and well thought through recommendations for the advisory committee's consideration.

Steven Lane

So, let's go ahead and jump in with the next slide. We are going to go through the usual review of who has been involved, and we are going to do a bit of a deeper dive on the background of the ISA to bring everybody up to speed. There are a number of people on the HITAC that have not been through this before. We will go through our methods and approach, and then present a whole host of recommendations. So, on the next slide and the one after, you will see the members of the group, many of whom you saw recently on another slide showing the next Task Force that is coming up, so there is a nice overlap there, but we really had a broad representation on this group, and people really dug in and worked hard to bring you these recommendations.

On the next slide, we will jump in a little bit on the background. So, remember, like so much of the work that we are doing, we are being directed by the specifics that came to us in the 21st Century CURES Act, and the focus here was for the workgroup to focus on the HITAC priority uses of health IT that were specified in the CURES Act, including support of public health, the importance of interoperability, supporting privacy and security of health information, and, of course, patient access, so this was really the starting point for our workgroup.

On the next slide and the one after that, you will be reminded of the specific charges that we received when our workgroup kicked off. We were to review and provide recommendations initially on the draft USCDI Version 3, and then, onto other interoperability standards, which is within the ISA, the Interoperability Standards Advisory, itself. So, today, we are here talking about our Charge 2, to identify opportunities to update the ISA, to address the HITAC priority uses of health IT, including the related standards and implementation specifications. So, you will recall we had the HITAC priority uses that we reviewed, and that was where we started our focus.

So, I am going to step back now and provide a bit of an overview of the ISA and the role that it plays in the health IT ecosystem, so let's go on from here. So, as was referenced earlier, the ISA is meant to be a single public listing of the standards and implementation specifications that vendors and others can use to address specific interoperability needs, and this really is meant to be a dynamic resource with ongoing dialogue, debate, and consensus amongst the various industry stakeholders to advance this listing, to keep track of what is coming down the line in terms of the standards that are evolving to track those over time, but also being clear about the limitations and dependencies that exist that need to be addressed as we implement and utilize these standards to support interoperability.

So, the ISA does not require anything of anyone. It is really a catalogue, but it has a lot of rich information in it, and I invite everybody to go check out the ISA on the web. In order to fully interact with the ISA and provide input and comments, you need to create an individual login, and when you do, then you can post to that resource. So, let's go on to the next slide and talk a bit more about how the ISA is used.





There are many stakeholders who are busy administering both governmental and nongovernmental procurements, doing testing and certification, etc., all of whom need to look to the ISA to see what is out there and how they can use it. Health IT developers certainly look to the ISA to understand what standards they should be adopting and building towards. Implementers of those health IT tools also look to ensure that the products that they purchased are compliant with the standards that are out there and that are being supported, and then, there is a lot of informative content, as I mentioned, regarding the various conditions and dependencies involved in the use of these standards, and there are many of those.

On the next page, we talk a little bit about the process for updating the ISA. The ISA itself is updated throughout the year as new input comes in from stakeholders and awareness is raised within the ONC, and then there is an annual call for review and comment that happens in the summer. There are a number of folks on the ONC team who are responsible for the care and feeding of the ISA, and keeping that up, and responding to the various comments that are received, and then, once a year, there is a static annual version that is published/posted, and each of the annual versions is available on the web that you can see, and that provides a static reference that can be put into regulation or other documentation. There is also an RSS feed, which is nice, that you can sign up for. As changes are made in the ISA, you can be informed of those if you want to be, and there is also a page that lists the recent changes, so that is all very convenient and very user friendly.

On the next slide, we will talk about the structure of the ISA. It has evolved over time, and one of the things that our workgroup did this year was make some comments about how the structure might be improved to make this even more user friendly, but there is a section on vocabulary, code sets, and terminology, the standards that we look towards to support interoperability, content and structure, services and exchange standards, and then, a number of administrative standards inside each section. There are subsections that address various topics related. Then, there are these informational appendices that are included as well that really dig deep and provide linkages to resources that support the use of these standards.

There is a section that you can call Specialty Care and Settings, which was initially put up to support pediatric use cases and subsequently had the addition of opioid-related issues, social determinants of health, and COVID-19, and as you will be hearing, we have some specific recommendations on how that can be made more robust and helpful.

On the next slide, there are characteristics and other helpful information for each of the standards and implementation specs that are listed, and I am not going to read through this list, but you can see we really look at each of those standards from various dimensions to really understand them insofar as possible, and of course, not every standard has all of these characteristics listed, but as available, these are included.

On the next page, I will point out that the USCDI is actually a subcomponent of the ISA, so the USCDI, which we have talked about in our prior recommendations, really is a piece of the ISA, and that includes, of course, the published USCDI standards, the expansion process that you are all now quite familiar with, as well as the ONDEC submission system that is there. The standards version advancement process, which I trust we will be hearing more about at a future meeting, is also a component of the ISA, and then, as I suggested, there are a number of ways for public comment to be introduced. There are public comments related to the ISA itself, to the USCDI, and to the SVAP, so there are a lot of opportunities for the public to interact with, to review, and to provide input, and I will just remind everyone that the ONC team





is incredibly responsive to public input on these resources. They read all the comments, they take them seriously, and we do see that they lead to changes, so it is a very dynamic area within the ONC's profile and portfolio.

On the next page, we talk a little bit about some of the challenges that we recognize in looking at the ISA, trying to really optimize how the ISA is user friendly and easily understandable. As the platform grows organically, now and then, there is a need to shake out the dust and reformat things so that it becomes as user friendly as possible. There are clearly varying stakeholder perspectives and needs. As patient advocates and individuals get more involved in this work, we need to be sure that the resources that we make available are really appropriate and accessible for all stakeholders, and we really just want to make sure that the ISA remains a valuable resource across the board.

On the next page, you get a little sample of what the ISA looks like. This is specifically looking at the standards related to allowing a prescriber to send a prescription to a pharmacy, and you can see that there are various standards listed that are final and mature, either in a pilot mode or fully in production. There is a column listing whether the standards are required by a federal regulation, a little bit about cost and the availability of test tools, and then, of course, there is the emerging standard, which is the HL7 FHIR medication request in this case, which is in development, and you can see, again, what the various standards and their states of maturity are. And then, at the bottom, there is this detailed description of limitations, dependencies, preconditions, and, in this case, various security patterns that need to be considered as we are sending medications back and forth. So, there is a lot of rich information here.

On the next slide, there are some additional resources in the ISA just explaining it and how it works so that when stakeholders come to it, they can get a little orientation talking about the process and the timeline, as I just reviewed, and then there is a set of FAQs as well. So, that was meant to be an overview of the ISA for those of you who have not been participating in this over time. I think, Aaron and Denise, we are going to go ahead and go all the way through and hold questions to the end.

Aaron Miri

That is correct. Go for it.

Steven Lane

Perfect, all right. So, in that case, we are going to transition to Arien to talk about the approach that we took to this work and give you a little bit of an executive summary.

Arien Malec

All right, fantastic. We had a pretty heavy charge, and then we actually took on some additional work outside the charge, so I will give you an orientation to the types of recommendations that we are doing, as Steven tags me into the octagon, and then I will tag him back in for the next section, and then I will clean up at the end.

We put together recommendations broadly in three major categories. One is on the meta-recommendations on the process and structure of the ISA itself, ways of making the ISA itself more usable and user friendly for consumers, and then, our charge proper was to make recommendations relating to the updates to the ISA, and so, we made use case recommendations/additional standard recommendations for these six very





broad categories, and you will see that we have a whole set of detailed recommendations in each of those areas.

And then, we took the opportunity to revise a similar incarnation of this workgroup that met in 2018 and made specific recommendations for orders and results, and really, the tie to the ISA charge was that we noted at that time that there were applicable standards in these areas, but poorer adoption of the standards than we thought was warranted, and so, in 2018, we took pains to outline potential policy levers and tools and outline an approach to expanding adoption of standards-based exchange. Here, we revise those recommendations, really focusing on ONC's coordinating role, but really, a way to think about this is to say hey, we have things that are listed in the ISA that are fit-for-purpose, but we have more bespoke interoperability on the ground, and that actually impedes things like public health as well as patient health and safety, and more on that later. Broadly, I am going to take on the first section, Steven will take on the second section, and I will play cleanup at the end. Go on to the next slide.

Structure and process: Let us keep going. There is a whole bunch. As Steven already mentioned, there is a section of the ISA called Specialty Care and Settings. As we were looking through material in the ISA, there has been a broad view that you can divide standards into vocabulary, content, and transport or exchange standards. It is very useful categorization. At the same time, if you want to solve a particular interoperability problem on behalf of patients, on behalf of public health, etc., you have to mix and match across each of those areas, and we thought the Specialty Care and Settings cross-cutting view is very useful, and we recommend that it be made a little more broad, and that we have more of those cross-cutting views.

We recommend that it might be possible for ONC to create a prioritization or tagging scheme, as you can highlight standards associated with use cases and expand those use cases. And then, we also struggled in a couple of places where the look and feel of the ISA itself changed depending on what path you took into the ISA. So, for example, it was hard sometimes to find the Specialty Care and Settings view depending on how you vectored in through the website, and so, we recommend that ONC take a usability pass. Go on to the next slide.

Some of the priority use cases that we believe should be tracked in the ISA, or the same priority use cases already identified and voted on by the HITAC, though I will not list them all, and then, if we go on to the next slide, we also recommend that we further expand those use cases in the following areas: Public health, equity by design, requests for correction, which we will see a little bit later, price transparency, and the FHIR accelerator use cases, and you will see recommendations there as well in a bit. Go on to the next section.

All right, there is a lot here. We make a set of recommendations to marry the USCDI and the ISA better. So, as a little bit of preamble for this, in the past, there was one USCDI, and by definition, things in the ISA referenced the things in the USCDI. As we expand, USCDI will be versioned to Version 2, Version 3, etc., and then, USCDI Plus, so we have a need to better track which standards in the ISA track to which versions of USCDI. So, we want the USCDI update process and the ISA update process to be more closely harmonized. As we add things to the USCDI, we would like to add them to the ISA as well. For the limitations, dependencies, preconditions, and challenges, we want to drive better alignment between the USCDI and the ISA.





As mentioned, as the USCDI changes versions, we believe that the ISA needs to have tags or markers that associate different versions of standards with the appropriate version of the USCDI. We would like to see closer harmonization of data classes and elements in the USCDI to the ISA and a workflow to cross-coordinate USCDI submissions back into the ISA. So, again, just to orient people to this, as we making recommendations to the USCDI to track, for example, social-determinants-of-health data, we are making recommendations that there be a common core data set. We also need to think about where that common core data set gets exchanged and used, and you will see some examples of that later on in our recommendations.

So, if we go on to the next set of recommendations, in the past, there was one major federal program, meaningful use for promoting operability associated with stuff in the ISA and stuff in USCDI. As we have matured, we have a wider variety of programatics, and there is a need to be a little more specific about “federally required,” so we might have, for example, multiple CMS programs that reference versions of standards in the ISA. CDC may pick up and reference elements in the ISA. VA and DOD, relative to procurement for referral services, may reference specific elements in the ISA.

There is a really nice set of dot plots or indications in the ISA about maturity and adoption. There is a good explainer. We would like to see a little more evidence behind the determination of maturity and adoption so that stakeholders can assess what the evidence is for maturity and adoption and how we can progress maturity and adoption. Go on to the next.

All right. We saw a number of places where the ISA had gotten out of drift with, for example, HL7 accelerators. One of the most exciting things that has happened in interoperability itself is incredibly exciting, so that is saying something, is the notion of the accelerator function that I think started with the Argonaut Project, led by a little-known Argonaut Project coordinator. I do not know what he is doing these days. This accelerator notion has really expanded to take on additional challenges, and as we do that, one of the great things that happens is we go through a lot of prototyping and piloting of standards. It would be useful as we establish those that we have a place in the ISA to catch all of that work. So, we saw a bunch of places where the ISA was not even tracking something that was being promoted through an HL7 accelerator.

So, 1). Let’s add an indicator whether something in the ISA is being tracked by an accelerator, 2). Establish a streamlined process with SDOs and similar bodies to track updates, coordinate with accelerators and similar projects to make sure that we get a streamlined process to get the updated, and a first backhaul/backtrack to make sure that the ISA tracks all the use cases it is related to, and you can see the rather impressive list of HL7 FHIR accelerators, such as the PACIO Project, so that we get the ISA up to date with the current state of the accelerators. Next. All right, and now, I will tag Steven Lane back into the octagon.

Steven Lane

Thank you, Arien, for going through that. I really want to just pause and give you all a chance to take a breath. There is a lot of material here that we are bringing to you today. A lot of thought went into the very detailed wording of these recommendations. I want to remind you that this slide deck is accompanied by a multipage report that has also been distributed to you that goes into greater detail on a number of these recommendations, so I really appreciate all of you hanging in here as we go through these.





So, the next round here is really going to be the specific recommendations regarding the content within the ISA. This is sort of the meat of our charge, and we will just go through these one by one, and again, please collect any questions that you have at the end. Also, note that in the public chat, I did put in the link to the ISA. If you wanted to pull that up on your other screen while we are talking today just to get a sense of where we are pointing you, that might be helpful.

So, the first of our recommendations regarding the ISA content has to do with, again, one of the use cases, and again, we really did put a lot of thought into thinking of this in terms of use cases and what standards support those use cases, the need to track various use cases, as Arien mentioned earlier. So, the first one here has to do with the use case of referrals between providers and community-based social care providers, so, clinical providers and social care providers, and recommending simply that the ONC update the use case label on this. It is already in there, but it is called “referral to extraclinical services,” and we wanted to make that a little bit clearer by saying “referrals between clinicians and community-based organizations and other extraclinical services,” because of course, as we are collecting and sharing SDOH-based data, one of the key things we want to do with that is actually act on that data and integrate social and clinical care, and we felt that this would be helpful. Next slide.

The next recommendation has to do, again, with a use case, which in this case is achieving health equity by design, and specifically the SDOH standards, so, recommending that the ONC include and track in the existing use case of achieving health equity by design the relevant standards related to documenting social determinants of health, so, sort of saying where the SDOH standards go within the ISA. On the next slide, we go into a little bit more depth here. You heard our first round of recommendations about the USCDI.

I think you are all aware of the Gravity Project, one of the current accelerators, that is working hard on developing and advancing the data and implementation standards for SDOH data, and we are specifically recommending that the ONC update the ISA to integrate these data elements, domains, assessment tools, value sets, and implementation guides that were included in USCDI Version 2 as well as the reference implementation, which is continuing to evolve, and track those also within the ISA. So, again, this notion that the ISA is this catalogue of existing and evolving standards, and we want to make sure that the work of Gravity and the focus on SDOH data is clearly homed and being tracked within the ISA itself. Next slide.

Now, we are going to shift a little bit. Again, related to the SDOH standards is the issue of the race and ethnicity vocabulary subsets. This, again, is in the ISA. You will recall from our earlier recommendations on USCDI the importance of looking at and tracking the source and method of collecting various data elements within demographics, specifically race and ethnicity, and we want to make sure that that data related to source and method of collecting, when it is available, is also part of the data that we are tracking related to SDOH, and here, again, just the notion that this should be highlighted in the ISA as well. Next slide.

All right. So, shifting here to a new use case, one that we have not really discussed much within the HITAC, but one which really had a lot of support and interest in our workgroup, so we are bringing it to you, is the HIPAA right for individuals to request corrections to their medical records. We are all well aware that this is an important right that we have under HIPAA and an important challenge that we have with health data, where errors or omissions may creep into the health data, and as that data is moved around the ecosystem, those errors can be promulgated to multiple stakeholders. For many, many years, HIPAA has provided





individuals the right to request corrections, and a lot of work has been done by various groups to move towards a standard technology for the submission of those requests. This slide provides a number of the background resources that relate to this right and to the evolving technology to support it, so this is provided by way of background.

On the next slide is the recommendation itself for the ISA, recommending that the ONC include and track within the ISA the patient request for corrections as a use case and, as with all the other use cases that we are discussing, so we can watch the standards develop, and the implementation guides as well. Related to these ISA-specific recommendations are recommendations related to how the ONC can support this use cases more generally.

The first one recommends that the ONC clarify in its communications that the HIPAA right to request corrections broadly applies to all PHI in the designated record set, and again, this is not ONC's main focus, but just making it clear, as we create communications around this, recommending that ONC also consider health IT certification criteria that would look at this process, this use case of patients requesting rights to corrections, and then recommending that ONC collaborate with the group that is really digging deep on this, the HL7 Patient Empowerment Workgroup, and then, there are other stakeholders, of course, to help to address the existing and identify gaps in the standards capabilities and implementation specification. So, as I said, this was an area of great interest, so there was this ISA-specific recommendation to track this as a use case, and then, supporting recommendations regarding how the ONC can support this more generally. Let's go on.

All right. Another one, again, that is consumer focused, enabling consumers to download image files from their health records. Of course, some of these images are in the EHR, some of them are in imaging-specific systems, but there are evolving standards in this area that we feel should be tracked within the ISA so as to clarify for various vendors, be they patient-facing apps or EHRs, etc., how individuals can download these images, whether they are reference quality, full diagnostic quality, etc., from the systems that contain those. Next slide.

Okay, our next recommendation, again, has to do with consumers and enabling them to download their data, but in this case, their personal genomic variant data. Of course, this is a data class that is out there that is increasing in volume and the numbers of people who have these tests done, and again, there are evolving and emerging standards to enable consumers to download this data and then to utilize it, sharing it with apps, sharing it with providers, etc., and we feel that this should be tracked as a use case within the ISA as well. Next slide.

All right, care plans and chronic disease management, another important use case. There is some reference to this within the ISA that we felt could be clarified, so we are recommending that we include and track within the ISA the use case and emerging standards to support dynamic, longitudinal shared care plans. This is certainly something that most of us do not have the benefit of today. This would also support care planning and coordination, and then referencing the relevant terminology exchange standards, etc. that support this. Here again, we have the ISA-specific recommendation as well, so, supporting recommendation to the ONC that they continue to work with stakeholders, some of whom are listed here, to identify and close the gaps in existing standards around care coordination and care plan management. Next slide.





Here, we also dug pretty deep in the area of electronic case reporting, or ECR, standards. We had a presentation from some teams that have been working to evolve these standards. This was an area where we found that the standards that were listed in the ISA were falling behind the standards that are in use within the industry and that are being advanced to support electronic case reporting, so there are some very detailed recommendations here regarding the release versions that either have been published and are in operations or will be published next month, and again, we just wanted to assure that the ISA was tracking the latest standards as they come online.

We also wanted to assure that the ISA tracked three very specific transactions that are utilized to support ECR, and they are listed here, and again, very detailed recommendations, in part related to the close engagement that we had with folks from public health in evolving these recommendations. Here again, we had the specific ISA recommendations, as well as the supporting recommendation that the ONC continue to coordinate with the various federal/state/local/territorial partners to push forward and accelerate the maturity and adoption of standards for electronic case reporting, as this has really accelerated in its use and its utility over the course of the pandemic. Next slide.

All right. Now, this shifts again to some new standards that are actually evolving outside of the healthcare industry related to data provenance, specifically the provenance of online content. We had input regarding this Coalition for Content Provenance and Authenticity, or C2PA, which is an evolving standard that has been stood up through a foundation project with the engagement of a number of the large tech companies, so this is a standard that we felt will apply and can apply within the health IT community, and as such, should be tracked within the ISA itself. Next slide.

Clinical decision support: The issue here has to do with the rationale, the algorithms, the tools that are used to develop clinical decision support. Again, this came from the patient perspective, patients who benefit from where clinical decision support is utilized in determining their care. Today, it is not easy, sometimes not possible, for patients to know what decision support may have been used, what algorithms may have been used to impact their care, so the recommendation here is that ONC again track within the ISA this use case of documenting and communicating the decision rationale utilized in generating decision support alerts and recommendations. This is early on, but it is an important use case, important to patients and patient advocates, and one that we felt should be tracked and supported ongoing. Next slide.

All right. So, that actually came to the end of the specific recommendations that were within our Charge 2, as we reviewed earlier. As Arien mentioned earlier, we also spent a good bit of time digging deep into recommendations related to laboratory orders and results. This is work that has been done by a whole series of Task Forces that preceded our workgroup that were chaired by Arien, myself, and others, and a lot has been happening in this area of laboratory data interoperability. It continues to be an area of major challenge, but a lot of people have been doing great work in this area, and we felt it was important to bring forward updated recommendations based on earlier work that has been presented here to the HITAC that incorporates this additional work that has been done in this space. So, Arien, do you want to take us through these?

Arien Malec





Absolutely. Again, for context, as Steven just mentioned, we were asked to take a deep dive into the SHIELD Project, which is a collaboration between FDA and other HHS stakeholders and industry stakeholders to better encode its source. If you go back to our 2018 recommendations for an early incarnation, we made specific recommendations for lab and order content, and among those recommendations were the recommendations that ONC work with FDA to make sure that approval of IVDs, meaning in vitro devices or lab analyte machines, are done in such a way as to harmonize terminology so that in the ideal world, the lab device, the IVD itself, flows data to the laboratory information system, or LIS, and then flows all the way back to the ordering provider.

And, for context, right now, when we look at the ISA, we believe that the ISA appropriately tracks all of the related standards associated with lab interoperability, and we recognize that in the current day, standards-based exchange for orders and labs bidirectionally and multidirectionally, including to public health, is more bespoke than it is standards-based. If you think about the ordering and lab world, think about hamster wheels of informaticists who are hand-managing codes and code sets at multiple stages along the lifecycle, from IVD to LIS, from LIS to EHR, in the EHR itself being cross-mapped, and the actual standards that are used, with the exception of public health, that has adopted the ELR standard that is back to what is called the LRI standard, with the exception of that standard, most of the exchange is using HL7 V.2, but not using the implementation guidance that has been carefully vetted and curated and is really, really good.

And, the net of all of that is a lot of inefficiency across the U.S. healthcare system, underutilization of electronic orders, with concomitant patient safety issues, and then, in particular, I think we saw in our experience with COVID that was a weak link in case tracking and case reporting. We did not have a full end-to-end lifecycle view, and so, based on the analysis that we did, this was an area where we believe that the ISA is tracking standards appropriately, and we also believe that we are falling short as a nation of adoption utilization of those standards, and this is an area where we went a little extracurricular, but ISA-adjacent, to start thinking about a policy framework for ONC, to think about working with other federal stakeholders and industry participants to create more of an ecosystem view for orders and results.

All right, so, with that as preamble, we have separated our recommendations into information model, focusing on results and focusing on orders, so the first recommendation is recommending that ONC coordinate with HHS partners and industry stakeholders to create an interoperable information model. So, I think if you remember, when we looked at the USCDI recommendations, we noted that USCDI had some bits that were mapped to, for example, the CLIA standard for results transmission, but there is actually a lot more that is spelled out in ELR and the HL7 LOI and LRI guides, as well as HL7 FHIR, and so, here, we believe that aligning on a common information model would be useful. Go on to the next section.

So, here, we have a very carefully crafted statement that says that ONC work with other federal partners, SDOs, state and local public health, etc., to create and support a policy framework that encourages and incentivizes, requires, or otherwise enables closed-loop order-to-result communication and multilateral distribution of results, especially including to public health, using standards and comprehensive implementation guidance.

So, the net of this is it would be pretty good if we were using the standards and implementation guidance that has been carefully crafted. We are falling short of that, not because the standards and implementation guidance are bad, but because we are not taking an ecosystem view, and we believe that ONC is the





responsible party to put together a policy framework, and we also believe that there are multiple policy levers that are available across the federal government and with industry stakeholders to provide both carrots and sticks.

So then, we get down into some nitty-gritty bits. Electronic orders are hampered because we do not yet have a common orderables catalogue. We are getting a lot better. There are a lot of subset orderables, such as the unit that I order, and we believe that ONC can convene and create a consensus development process to prioritize and encourage or incent adoption of standardized coding for the most common and important orderables and panels of each order type, in particular, looking at the most common ones that are used for clinical care, population health and public health. Go on to the next one.

In the lab world, there is a bunch of stuff that is regulated by FDA related to IVD, the analyte machines themselves, and then there is a framework for labs to create their own self-developed test specifications. We believe it would be useful for ONC to create a policy framework for those self-developed test specifications to be harmonized to LOINC so that we can actually order them because if we have a set of common orderables but labs are creating new orderables and there is no way of getting those codes back to the EHRs, we are back to this sticky situation.

And again, a little gloss here, we have clinical orderables that are mapped to LOINC, and then there are procedural codes that are used for administrative purposes where labs get paid. It would be pretty darn cool if the clinical order could automatically generate the administrative transactions so that you do not have to have duplicative processes and duplicative mapping between the clinical orderables and the administrative payments, and so, it would be useful to create a policy framework to make sure that the coding standardization includes cross-maps to the administrative codes that enable labs to get paid. Oddly enough, in healthcare, people like to get paid. Next slide.

Right, let's talk about resulting. We recommend that ONC work with... And then, we have this common phrase that really looks at the broad ecosystem for resulting organizations to support the results information model that we previously referred to and associated communication content standards when exchanging via electronic messages, yada yada yada, or the future transport mechanisms. So, what this means is standards alone are not sufficient for interoperability. You have to have a framework for adoption of standards implementation guidance, and there needs to be some reason why resulting organizations are using, for example, the LRI spec as opposed to custom implementation guidance.

A set of recommendations relating to coding as early to source as possible, and again, the dream here is that the information flows off of the IVD in ways that either are precoded or automatically facilitate coding, and again, imagine, in the lab, informaticists on hamster wheels cross-coding everything which has patient safety issues as well as complexity and cost issues for the U.S. healthcare system. If we had a policy framework where LOINC and SNOMED codes were encoded as early as possible, we would mitigate and eliminate a bunch of manual work and improve cost as well as improve the safety of this critical part of our infrastructure.

We recommend that ONC, in coordination with yada yada yada, create sustainable mechanisms that lead to IVD test devices and LISes to automate mapping and translation. So, the SHIELD work is creating a framework where the IVDs, the lab analyte machines, include cross-maps to LOINC. That is being done in





conjunction, sort of in pilot, with the SHIELD Project. It would be useful if there were sustainable mechanisms to keep that work going so that, for example, as a consequence of registration, IVD manufacturers could update codes, and there was some shared infrastructure for keeping those code maps to date and available for stakeholders nationwide. Go on to the next slide.

I know this is incredibly exciting, getting into the nitty-gritty detail of labs, and for those of you who are not as close to lab interoperability, there might be too much excitement for you to bear, but just keep in mind that we had some amazing experts on this workgroup who knew this area and could contain their excitement enough to craft these very carefully crafted recommendations.

Aaron Miri

We are all bursting with excitement, Arien. This is phenomenal, riveting stuff.

Arien Malec

Exactly. We are going to keep going. So, again, same kind of process. Let's make sure that as there are new tests, needed variations, or self-developed tests, there is a process for keeping those codes up to date. We recommend that ONC, in coordination with the FDA, SDOs, manufacturers, and industry stakeholders, including SHIELD, enhance the ability for test results to include identification of the device using a UDI. It is pretty crazy that we could track, in a result, the actual analyte, the reagent test kit that was used to build that result in ways that would enhance patient safety throughout the lifecycle of labs. Crazy talk.

We recommend that ONC, in conjunction with yada yada yada, create policy levers inclusive of a bunch of stuff to create incentives to map internally generated results and result codes to standard vocabularies. Again, same kind of thing. You have self-developed tests, self-developed procedures. We talked first on the ordering side; here, we are talking about the resulting side to make sure that when there are self-developed tests, they are resulted with standard terminology that is cross-mapped and publicly available as opposed to proprietary terminology that is only held by that one lab. All right, next slide.

ONC, in conjunction with etc., etc., support and encourage proper and consistent LOINC/SNOMED encoding across result sources. So, let's make sure that we keep those codes consistent across labs, imaging centers, and other resulting organizations, and let's make sure that the reagents, test kits, IVDs, and device UDIs are registered in the GUDID, the Global Unique Device Identification Database, again, for safety purposes, for tracking purposes, so that we can properly interpret results end to end. All right, let's go on to the next slide.

So, as we all know, labs are complicated. As anybody who has tried to interpret the difference between a spike protein antibody antigen test versus an NTD antigen test knows, what does this mean, what do I get, what are the units, etc.? Sometimes it can be confusing, even to clinicians. There is some existing work in LOINC to create consumer names, patient-friendly order and result display names for patients. We believe future and continued investment in that area is warranted and recommend that ONC work with other federal partners and SDOs to encourage that development. Next slide.

All right. So, one of our observations is that the way that the lack of tying the existing standards that are in place to real-world practice for ordering and results manifests is that as an example, we have LOINC, which





is a fantastic terminology code set system, and we have some labs, particularly large national labs, that are using LOINC by default. We have often hospital labs or smaller labs that are using legacy proprietary codes.

We have, as we mentioned, self-developed tests that may be using proprietary codes, but we do not have a dashboarding telemetry system to figure out how codes are being used in practice to support care health and public health, and so, we believe it would be useful for ONC, in conjunction with other federal stakeholders, to create a methodology to track how this is working in practice, not just the theory and mechanisms and standards underlying this, but also, how is it going? Are we transmitting orders using standardized terminology? Are we receiving results in standardized terminology? Are there patterns? As I mentioned, I think there is a belief informed by evidence that we have failure modes for smaller labs, that we have failure modes for self-developed tests. Where are there patterns in terms of use of standards and standard terminology and failures to do so? We need data from the fields. Go on to the next slide.

All right, I think this is it. I know it is almost too much excitement for everyone to bear, so I think we are sort of there. Right now, the ELR spec, which, as everyone knows, is mapped to the HL7 LRI spec. ELR is electronic lab reportable...something. Anyway, it is the spec that is used for reporting reportable labs to public health. LRI is the lab results interface, the base spec that is used for results broadly. Because, in this country, and as I think we all know from the pandemic, we use labs as the early signal and the mechanism for triggering case reporting, we overload the ELR spec for case reports and case investigation.

We believe that as we get broader adoption of ECR, which is the electronic case reporting standard, much of the case reporting infrastructure will be done out of EHRs with direct transmission to public health, and we can keep ELR tightly focused on getting the information on the lab itself back to public health. There is a very carefully crafted set of recommendations. In the future, as we have adoption of ECR, we believe that we can trim down ELR to be tightly focused on the lab result itself and rely on ECR more for the case investigation. All right, I believe that is it.

Steven Lane

You did it, Arien.

Aaron Miri

Well done, both of you. Excellent, excellent, excellent. So, as everybody is marinating and can barely contain themselves in their seats, I am sure there are questions, I am sure there are comments. I will start by really thanking both of you and the entire workgroup. I will say that the precision that it takes to get to this level of granularity matters. It helps in discussions on a number of forums, HITAC and beyond, across the industry. I hear from fellow CIOs talking about USCDI Version 2 and all sorts of things now at a very semantic level, so it is great that people are being able to digest it, so, kudos. That is all I have to say, is kudos. Very well done. So, I am looking for hands raised, curious questions people have, any of those. Let's see who we got. Do not be bashful, HITAC. You have questions. If you are on the phone, not the Zoom call, and cannot raise your hand, please speak up as well.

Clem McDonald

This is Clem. Can I make a comment?

Aaron Miri





Go for it, Clem.

Clem McDonald

I put it in the chat. Firstly, about the term “local development test,” I think they used to call them laboratory development tests. It comes out the same, LDT. But, it is not true that the big labs are not getting standard codes for them. They are. So, Mayo, ARUP, and Quest do request LOINC codes for at least a lot of the laboratory-developed tests. I cannot speak to smaller labs, but they probably do not do as much development of that kind of test. So, for the record, it is not quite as bad as you were painting, Arien. That is all.

Steven Lane

Thank you, Clem, and I just want to give Clem tremendous thanks for his contribution to the workgroup generally and to the Task Forces that came before and that will continue to come after, but Clem always points out to us this broader view. I think we did see, especially in the early days of the pandemic, when a lot of people were struggling to come up with reasonable tests, the need to do this mapping so that we could start to share that data. It was a great example of where this need does continue to exist, but yes indeed, the big labs are doing a good job doing this mapping, and what our workgroup wants is to recommend that this be done more comprehensively across the board and be baked in, insofar as possible, to standards and certification requirements such that it can be more consistent and reliable.

Clem McDonald

Yeah, hear, hear, but I would like to add one more thing to think about. So, some places are not sending LOINC codes at all because they have not defined them, but importantly, the mappings are not always careful. So, in fact, we have done a study looking at 180 million mapping instances, and about nine percent are off, not always horribly, but still off, and there was a paper that just came out recently from the SHIELD group that suggests the percentage is much higher. They just are not paying attention, and I do not know what might be done, but it seems to me they do not have problems with billing codes at all, so whether it needs a little more enforcement or a little pressure, I do not know, but thanks for letting me comment on this.

Arien Malec

Thanks, Clem. It is shocking how good a job we do in getting paid relative to the job that we do in ensuring clinical interpretation and broad use of data for health in healthcare.

Aaron Miri

Well said, Arien. That is great. Sheryl Turney, you are up next. You may be on mute.

Sheryl Turney

Yup, thank you so much. First of all, I just wanted to state what a great job you guys did on your work here. I found it extremely helpful and beneficial. I do have one question or comment, I guess, regarding the standards applying to social determinants of health and also the right to request corrections. These are extremely important standards for all of us, especially with the emphasis to collect and report more information to demonstrate health equity, and I believe also, as more and more industry partners are utilizing machine learning, it is going to be really important.





But, one thing, which I do not think is something you could have responded to in this framework, but maybe in the future, is that some of the aspects of the data collection for social determinants of health are not... Well, there is specifically a point in time where often, data that is collected might be more static. This data might be changing over time depending on how an individual might want to identify themselves, etc., so as we move forward with standards relative to those things, is this something that the standards community can really take into consideration how that data will need to evolve over time? Because I think sometimes, people go into this thinking, "Well, okay, you identify yourself in a certain way, and that is static," but we are finding that is not necessarily the case. So, how standards might have to address some of those types of issues that will change over time might need to be different than the way that they were originally anticipated. So, I just wanted to get your interest or your input on that.

Arien Malec

I appreciate that, and I think we have made recommendations in the past about provenance, source of information, time of information, particularly for patient-generated health data. I agree with you that anything that relates to identity needs to include the provenance history so that you can interpret that information in context, and when we did the USCDI deep dive on, for example, gender identity, we recognized that it is an incredibly complex topic and that you need to identify the context and time series associated with each use of information to make sure that you are not making a point-in-time determination for an individual that you then improperly apply or a contextual interpretation for an individual that you then apply as a built-in demographic.

Steven Lane

Thank you for those comments, Sheryl. I will just add that this is something that our workgroup did discuss. Bringing the clinical perspective, I think these SDOH data elements are much more like vital signs than they are like surgical history, where they are constantly changing. As we all know in our own lives, one circumstance can shift moment to moment, and whether you are talking about housing, whether you are talking about identity issues, gender identity, it is not only changing, but also context-specific, where with a lot of this individually generated health data, different answers could come out in different situations, depending on the process by which that data is collected, hence our specific recommendations on capturing that metadata along with the SDOH data itself.

Sheryl Turney

Thank you, that is very helpful.

Aaron Miri

Wonderful. All right, up next is Dr. Luu from the great state of Texas.

Hung S. Luu

Thank you so much, cochairs, for these recommendations, and also for the excellent job that you have done with leading the group the past few months. I did want to address the comment about the accuracy of coding of laboratory testing versus the billing, and I think we have to be mindful that in hospitals, there are entire teams of people who have spent their entire lives and careers specializing in CPT coding and making sure that hospitals stay afloat by making sure that the coding/billing is correct, but also, the CPT codes are tightly controlled, they are curated, and they are simplified, because the need for a coding system for billing is different than the need for a coding system used for interoperability.





So, I think we do need to recognize that, and also, I think that at some point... There is a saying that if you have a problem with one person, that could be an acute case, but if you have a problem with multiple people, or if multiple people start to struggle with the same thing, it might be time to examine the source and see if there are issues with curation and control, or if the system is so complicated that it is hard to use.

And so, I think that one of the beauties of the SHIELD initiative is we try to shift the coding away from the laboratories and towards the manufacturers, who would understand their test menu the best, to be able to put the onus on those who might be able to accomplish that most accurately. At the end of the day, I think we all want what is best for patients, and I do think that coding is a weakness in our healthcare system, and I think what might be helpful is to address how best to go forward and ensure that accuracy is what it should be to support interoperability and what needs to be done to make that happen, rather than just saying that people are not paying attention. Thank you.

Arien Malec

Very well said, and again, my humor aside, that is absolutely the recommendation that we are making, and Dr. Luu has been amazing at contributing his expertise, and Hans as well. All of the workgroup members really did a deep dive here and made sure that we crafted very well thought through recommendations that take, as Dr. Luu suggests, a systems-based approach to this very complicated problem.

Aaron Miri

Great feedback. Excellent job. Okeydoke, any other questions, discussions, or curiosity?

Steven Lane

Well, I just want to remind the group that there is a 26-page document that goes through these recommendations in detail, many of them with the sub-bullets, if you will, that Arien and I tried to touch on in our presentation, but this is what we will be voting on, is the formal recommendations document. Just to remind you how this works, we as the HITAC will consider whether we want to approve the recommendations as they are or with modifications. They are then forwarded to the National Coordinator for their review and any changes that may be necessary, and once they are approved there, they really become part of the ONC legacy, if you will. So, that is what we did with our first task, recommendations around the USCDI Version 3, and now we have this before us today.

Aaron Miri

That is right. Thank you, Dr. Lane. I appreciate you reading my monologue. That is excellent. I appreciate you taking care of that. You are exactly right. As the HITAC team, though, before we get to a call for vote, I just want to get to any questions or comments. It is a lengthy document. There are some phenomenal recommendations in there that are desperately needed across the industry. Obviously, there is more to do. This is not going to end after this. It keeps going, which is great, but I just want to make sure we hear from all of you or anybody that has questions at the top of their mind. I am going to give it one more moment here for hands raised, comments, questions, anything. We do have a hand raised. Dr. Lane has raised his hand!

Steven Lane





Sorry, just more context again. Just to remind everyone that this is an annual process that we are involved in, that the work will go on on an annual basis, so, whether we are talking about our Task 1 with USCDI comments or our Task 2 with ISA comments and recommendations, this is iterative, and you will all have a chance to provide more input next year.

Aaron Miri

That is exactly right, and there is always a public comment here at the end of the HITAC, so for any of the attendees that have curious questions, that is your time to ask questions, during that period, but right now, for the HITAC members, one more call for any other questions before we go to a vote. I just want to make sure. Okay, I do not see any comments or hands raised. I think I will ask for a motion to proceed to a vote. May I have a motion, please?

Hans Buitendijk

So moved. This is Hans.

Aaron Miri

May I have a second, please?

Denise Webb

Second.

Aaron Miri

Okay. All those in favor of approving the ISA recommendations for this giant, wonderful, well laid out document and discussion, please signify by saying aye.

Several Speakers

Aye.

Aaron Miri

Any opposed, signify by saying nay. Any abstentions? Okeydoke, congratulations. Well done to this task force and these recommendations. They now will be transmitted on to Dr. Tripathi. All right, well done. Yay, congrats. Well done, team.

Steven Lane

Thank you.

Aaron Miri

All right. So, Denise, if you are in agreement with me, maybe it is now time to ask if we can go to public comment.

Denise Webb

I think that is where we are at, if Mike is ready.

Aaron Miri

Mike, go for it.





Public Comment (01:32:23)

Michael Berry

All right. I am ready. So, we are now going to open up our HITAC meeting for public comments. 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 dialed in on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute their line. We do have someone with their hand raised. Charles Gabriel, you can go ahead for three minutes.

Charles Gabriel

I have a general question, if that is okay. My general question is how do we bring the new standards to be discussed, namely maternity, for example? I am working with a couple of experts on maternity. Is that the right forum to bring such topic or domain?

Aaron Miri

I will let our cochairs respond to that.

Steven Lane

So, I think what you are asking about is some new changes to the data classes and elements that are included the USCDI. Is that true? Is that data specific to maternity?

Charles Gabriel

Correct. I would say no changes, but add to it, or amend, or expand.

Steven Lane

Right. So, I will pull up the link here. You can go to the USCDI page on the website, and from there, you can register and provide public comment directly on the data elements and classes that are included or not included in USCDI.

Charles Gabriel

That is it, thank you so much.

Steven Lane

And, there is the link in the chat.

Aaron Miri

Perfect. Thank you, Dr. Lane. You are always quick with the links. Excellent.

Michael Berry

Thank you, Charles. I just want to remind everybody while we see if there are any other public comments that our next HITAC meeting will be held on August 17th, and if you are looking for any other HITAC materials, either past or present, they can be found on the HITAC calendar on HealthIT.gov. I am not seeing any hands raised, Aaron and Denise, so I will turn it back to you.





Aaron Miri

Sure. Denise, do you want to go first?

Final Remarks and Adjourn (01:34:51)

Denise Webb

All right, sure. So, thank you, Seth, Steven, and Arien, for your presentations today, and to the workgroup for the great work. You all did a yeoman's job getting all of those recommendations pulled together. I want to wish everybody a nice time off with us being off this next month. However, I do know our new Task Force is going to be busy, so I thank everyone who has volunteered for that Task Force for the work you will be doing, and we will be looking forward to what you have to recommend to the committee. So, with that, I wish you a good next month, or few months, actually.

Aaron Miri

And, I will also say the Annual Report Workgroup is also starting to meet at get that going too, so there is a lot of activity going on, even though we as a HITAC are not meeting next month, so, definitely enjoy that time off. I also want to just do a plug and remind everybody the October deadline for the full electronic health information definition is coming relatively very fast. Make sure you are doing due diligence in ensuring that every data element is accessible as per that EHI definition, and as a reminder, not everything is in your electronic medical record. So, that is just a friendly plug, and Denise and I are doing listening sessions and roadshows all the next couple of weeks. If you are curious, just google us, and you will hear how we are handling it at our institutions and what we are doing. Anyways, with that, have a great, great time off. We will talk soon, and take care of yourself.

Denise Webb

All right.

