Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

March 7, 2024, 10:00 AM – 12:15 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health, Co-Chair
Sarah DeSilvey, Gravity Project, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Michael F. Chiang, National Institutes of Health
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Steven Hester, Norton Healthcare
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Ciitizen
Katrina Miller Parrish, Humana Health Insurance
Aaron Neinstein, Notable
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Mark Sendak, Duke Institute for Health Innovation
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

FEDERAL REPRESENTATIVES

Keith E. Campbell, Food and Drug Administration
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Director, Strategic Planning and Coordination Division
Wendy Noboa, Designated Federal Officer

PRESENTERS

Elisabeth Myers, ONC
Matthew Rahn, ONC
Brett Andriesen, ONC

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

Wendy Noboa
Good morning, everyone, and welcome to the March 2024 HITAC meeting. We are so glad you could join us today. I am Wendy Noboa with ONC, the Designated Federal Officer of the HITAC. This meeting is open to the public, and your feedback is welcome. Comments can be made in the Zoom chat during the meeting or can be made verbally during the public comment period scheduled at approximately 12:00 p.m. Eastern Time. Let's go ahead with our meeting. First, I would like to welcome the Office of the National Coordinator's (ONC's) executive leadership team. With us today is our National Coordinator, Micky Tripathi, Steve Posnack, the Deputy National Coordinator, 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 begin with roll call of our HITAC members. When I call your name, please indicate that you are present. I am going to start with our co-chairs. Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Wendy Noboa
Sarah DeSilvey?

Sarah DeSilvey
Good morning, everybody.

Wendy Noboa
Shila Blend?

Shila Blend
Good morning.

Wendy Noboa
Hans Buitendijk?

Hans Buitendijk
Good morning.

Wendy Noboa
Michael Chiang?

Michael Chiang
Present. Good morning.

Wendy Noboa
Derek De Young?

Derek De Young

Good morning.

Wendy Noboa
Steve Eichner?

Steven Eichner
Good morning.

Wendy Noboa
Lee Fleisher?

Lee Fleisher
Good morning.

Wendy Noboa
Hannah Galvin?

Hannah Galvin
Good morning.

Wendy Noboa
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Wendy Noboa
Steven Hester?

Steven Hester
Good morning.

Wendy Noboa
Bryant Thomas Karras?

Bryant Thomas Karras
I am here.

Wendy Noboa
Hung Luu?

Hung S. Luu
Good morning.

Wendy Noboa

Trudi Matthews?

Trudi Matthews
Good morning.

Wendy Noboa
Anna McCollister will be joining us later today. Deven McGraw?

Deven McGraw
Good morning, everybody.

Wendy Noboa
Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Wendy Noboa
Aaron Neinstein?

Aaron Neinstein
I am here. Good morning.

Wendy Noboa
Eliel Oliveira?

Eliel Oliveira
Good morning. I am here.

Wendy Noboa
Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning, everyone.

Wendy Noboa
Randa Perkins?

Randa Perkins
Good morning.

Wendy Noboa
Rochelle Prosser?

Rochelle Prosser

Present, good morning, everyone.

Wendy Noboa
Dan Riskin?

Dan Riskin
Good morning.

Wendy Noboa
Mark Sendak?

Mark Sendak
Good morning.

Wendy Noboa
Fil Southerland?

Fillipe Southerland
Good morning.

Wendy Noboa
Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Wendy Noboa
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Wendy Noboa
And now for our federal representatives of the HITAC. Keith Campbell?

Keith Campbell
Good morning.

Wendy Noboa
Jim Jirjis?

Jim Jirjis
Good morning.

Wendy Noboa

Meg Marshall?

Meg Marshall
Good morning.

Wendy Noboa
Alex Mugge?

Alex Mugge
Good morning.

Wendy Noboa
Ram Sriram?

Ram Sriram
Good morning.

Wendy Noboa
Good morning. Thank you. Is there anyone that I missed, or who has just joined us? Okay, hearing none, please join me in welcoming Micky Tripathi for his opening remarks.

Welcome Remarks (00:03:24)

Micky Tripathi
Great, thanks, Wendy. Good morning, everyone. Thank you so much for attending today's HITAC meeting. There is a lot of exciting stuff to talk about today. Let me just kick off, and then I will quickly turn it over to the agenda. First, we certainly want to welcome our new Centers for Medicare and Medicaid Services (CMS) federal representative, Alex Mugge. Alex is the Chief Health Informatics Officer and Director of the Health Informatics Interoperability Group at CMS. She is a dedicated and fantastic partner to ONC, and we are really excited that Alex has joined. There are a number of Trusted Exchange Framework and Common Agreement (TEFCA) updates from last month that are also exciting because we are forging ahead in a number of different areas with TEFCA.

First, as I think all of you know, TEFCA went live in December with seven Qualified Health Information Networks (QHINs) now. Last month, ONC announced the designation of two new QHINs, the CommonWell Health Alliance and Kno2™, so we now have seven QHINs that are live on TEFCA, which is really exciting that we now have a full group of seven. We are obviously delighted to welcome these organizations in to see TEFCA continue to grow. We are making a lot of progress to keep pushing forward with TEFCA, both in terms of the promises we have made regarding Fast Healthcare Interoperability Resources (FHIR), as well as public health engagement and payer engagement, so, just to break those down for a second, we are hard at work on the next version of the common agreement, which we are calling Common Agreement Version 2, to fully support FHIR-based exchange in TEFCA. As we have said from the beginning, it is tremendously important that we bring together all of the work that ONC and CMS have been doing to bring FHIR-based exchange to the market, and TEFCA is part of the strategy to make that scalable and available in ways that best benefit patients and improve the healthcare delivery system overall.

So, the Common Agreement Version 2, on which we are working very hard with the Sequoia Project, our Recognized Coordinating Entity® (RCE) partner, as well as the QHINs, is to fully establish TEFCA-based exchange in the TEFCA framework. So, we anticipate finalizing that in the next couple of months, meaning the QHINs will have adopted it, and that will then set us on a path to having FHIR-based exchange operational in TEFCA in calendar year 2024. So, we are very excited about that. It is very complicated because there are a number of things that always come up as you start to really roll up your sleeves and think through the ins and outs of a different kind of pattern of exchange, but with the partnerships that we have gotten with the QHINs as well as the RCE, I think we are pushing through all of those to be able to fulfill that need for us to be able to have TEFCA support FHIR-based exchange as a pattern that many stakeholders want to be able to support.

The FHIR-based exchange is tremendously important to a couple of use cases. One is individual access. With the difficulties that we have had in scaling individual access at a network level, I think we will be partially satisfied by the availability of FHIR-based exchange and Open Authorization (OAuth) patterns of authorization that are supported in FHIR-based exchange. So, that is one of the keys to opening up individual access in a way that has been somewhat of a high friction point in networking interoperability up until now. So, that is one of the reasons that we are pushing very hard to make sure we get FHIR-based exchange up and running this calendar year so that we can fully support the individual's ability to be able to directly participate in TEFCA and be able to get the benefits of network interoperability and the benefits of being able to get all of their records through a single mechanism safely and securely.

The other very important use case that is critical for FHIR-based exchange is the payer use case, and here, I will give tremendous credit to and call out to Alex Mugge and the CMS team, who, in the final interoperability and prior auth rule, which was released in January, had a number of requirements related to FHIR Application Programming Interfaces (APIs) that are required to be put in place by regulated payers, and a particular provider access API, a prior auth API, and a payer-to-payer API are now conversations that we are having with a group of payers to say, "How do we make those real in a TEFCA-based framework so the providers have the ability to access the claims data that they are authorized to be able to get access to, and that allows payers to be able to get access to the clinical information from providers that they are authorized to be able to get to. So, there is a lot of hard work there, and there have been a lot of issues historically with being able to do that at scale, but I think we are making really good progress in being able to get providers and payers to start to think really hard about that, and as I said, we are working with a group of payers to move that ahead.

The last thing I want to point to, which is also a really exciting development, and I want to give tremendous credit here to Jim Jirjis as our Centers for Disease Control and Prevention (CDC) representative and the entire team at the CDC, led by Jen Layden, who we have been working very closely with to get public health agencies engaged with TEFCA. They have just done fantastic work doing reach-outs to public health agencies across the country, and these are Jim's numbers, so, hopefully I am not misquoting them and he can correct me if I am wrong, but I think we have 16 different public health agencies, from states as well as cities, who we are in conversations with regarding TEFCA engagement. Eight of them are in regular calls to talk about TEFCA implementation, and I think half of those, four, have actually committed to implementing TEFCA and going live this summer. Again, there are a number of others who are on biweekly calls, and a number of others with whom we are starting the discovery calls, and it is very exciting.

As we have said from the beginning, we want to make sure that TEFCA fully supports the public health community to make sure that public health is not an afterthought as we think about network interoperability, as it has been historically. We want to make sure we are fully supporting the public health community, both for the integration with the healthcare delivery system and the public health system, which have been very siloed and which we want to loop together, and, importantly, for the public health agencies to be able to securely communicate with each other, which is something they do not have the ability to do at scale, and, as we saw during the pandemic, is a tremendous need. So, this is very exciting. Again, we very much value the partnerships that we have with CMS, CDC, the public health community, and with the payer community in helping us move forward. So, there are a lot of exciting things in TEFCA, and there will be more to come soon.

I have a couple of updates on Artificial intelligence (AI) because it would not be a health IT meeting if we did not talk about AI these days. As many of you may know, in addition to my formal title as national coordinator, I have been tasked by Secretary Becerra to co-chair the Health and Human Services (HHS) AI Task Force, which is now well under way. Not all, but a bunch of the work that we are doing under the Task Force is specifically called out in the President's Executive Order on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, EO 14110, that was released in October. As all of us know, AI has certainly become a part of our everyday lives in recent years, in some ways that we do not know and in some ways that we know more and more. Certainly, the advances we have seen are going to be more and more incorporated in healthcare in all sorts of different manners, things that are patient-facing, things that are related to clinical decision-making, and things that are related to administrative decision-making as well.

So, we are taking a multifaceted approach in the department as we think about the safe and effective uses of AI in healthcare, human services, and public health. We have a number of deliverables that are on track for April 27th, and those are called out in the Executive Order. I will not take time here to lay those out. And then, there is another set of deliverables that are on track for October, which is 365 days from the issuance of the Executive Order. I certainly would be remiss if I did not remind everyone of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1 Final Rule), which was finalized and published in December, that has policies in it related to creation of transparency mechanisms in certified electronic health record systems so that provider organizations, who are the users of those systems, have available to them more information about the AI-enabled tools that are in the electronic health records so that they can make appropriate decisions by and with their patients about the use of these tools to improve care.

So, all of that is work that is very well under way, and we are going to dedicate a portion of the April 11th in-person HITAC meeting to focus on AI, and perhaps the co-chairs can talk a little bit more about that if they have that on their agenda, but there is more to come on that. I think that is going to be a very informative and timely hearing to be able to provide feedback and input on these very important issues. So, certainly recognizing that we have leading AI experts among our HITAC members here, if you are interested in helping inform the hearing, please reach out to Wendy Noboa, and she would be happy to discuss that further with you. So, I am looking forward to seeing you in person next month and benefiting from your thoughts in advancing safe, secure, trustworthy development in use of AI in healthcare, human services, and public health. Thank you, and now, let me turn it over to Elise Sweeney Anthony for her opening remarks.

Elise Sweeney Anthony

Good morning, everyone, and thank you to Micky. As you can see, we have a lot going on at ONC, and part of what we like to use these beginnings of the meeting for is to share a little bit about some of the activities and some upcoming dates, so I have a couple of additional updates to share, and then we will jump over into the full agenda.

So, first, I want to note that ONC has hit a new milestone in advancing interoperability across the care continuum. We are really excited about the new series of voluntary tests that are to support APIs, and they are available through our ONC Inferno testing tool. We encourage health IT developers, the standards community, and other folks to use these tests to enhance the interoperability of health IT and to facilitate further advancement of the relevant implementation guides.

So, the new set of tests focuses on accessing payer drug formulary information, accessing payer insurance plan network director information, and consumer access to their digital health information from a payer via a third-party application. These tests are written using the Inferno framework, and are available on ONC's hosted instance of Inferno at Inferno.HealthIT.gov, and you can visit HealthIT.gov to read our latest blog that talks about this and to learn about this more.

Also, ONC and Substance Abuse and Mental Health Services Administration (SAMHSA) launched the Behavioral Health Information Technology Initiative, and we are really excited about this new aspect of how we are thinking about health information technology, how we are thinking about behavioral health, and the ways health IT can really aid in behavioral health. So, we are partnering with SAMHSA to overcome health IT challenges that are facing behavioral health providers. We are investing more than $20 million in funding over the next three years. This project is support the HHS Roadmap for Behavioral Health Integration, and it is consistent with the President's call to action to prevent, treat, and provide long-term recovery supports for mental illness and substance use disorders. Together, we will identify and pilot a United States Core Data for Interoperability (USCDI) + domain for behavioral health and develop educational tools and resources for the behavioral health community.

We are going to hear more about other USCDI+ efforts today, so we really look forward to this presentation because not only are we going to talk about USCDI+ and how it works, but some of the initiatives we have under way and the ways you can engage with us. But, for more information on the Behavioral Health IT Initiative, check out our latest blog post on HealthIT.gov. We put a lot of stuff in that blog post, so this is a wonderful opportunity for me to say if you are not signed up to get our updates through our listserv, if you are not checking out our blogs, please, do check them out. It is called the Buzz Blog, and we put a lot of great information about initiatives and activities we have under way, as well as updates on work we are working on.

In terms of ONC events, join the ONC health IT certification for the upcoming quarterly ONC health IT certification program developer roundtable. These are public meetings, and they are open to all health IT developers regardless of their participation in the ONC health IT certification program. We encourage folks to engage and check out these meetings. The next meeting will be on March 27th at 12:00 p.m. Eastern Time. You can check out the events page on HealthIT.gov to register.

I also want to echo Micky's excitement for the upcoming April 11th in-person HITAC meeting. Not only are we focused on AI, but there are a number of great topics that we are going to cover. Because this meeting is in person, I want to note that if you are a member of the public and you are interested in joining us in Washington, District of Columbia (DC), please visit the HITAC calendar at HealthIT.gov. So, if you go to HealthIT.gov, go to HITAC, and go to the HITAC calendar, you can register for in-person attendance at the meeting in April, but please do register before April 4th. There are also going to be virtual attendance options as well, as we always have. With that and with those updates, I look forward to jumping into the agenda, and I am going to turn it over to Medell and Sarah to provide the opening remarks.

Opening Remarks and Review of the Agenda (00:18:04)

Medell Briggs-Malonson
Thank you so much, Micky and Elise. It is such a wonderful pleasure to be with all of you all today for our March HITAC meeting. As you can see, my voice is a little hoarse, so I am going to try not to speak as much today as normal, but I definitely have to give acknowledgement and kudos to the leadership of Micky, Elise, and all the rest of the ONC leadership. Underneath you, we have been able to make exceptional strides in so many different areas, and we just want to say thank you for all of your hard work and your dedication, and for making sure that we are considering so many entities that are necessary in order to move forward our standards, our policies, and the new infrastructure of how we need of health IT here within our country, so I just want to say thank you for your leadership and all of your consistent hard work.

In addition, I do want to mention exactly what Micky and Elise mentioned. Our next in-person April 11th meeting is going to be fantastic, and so, for all of our new HITAC members, the in-person meetings are definitely a highlight because not only do we get to be together and actually be in one space, but it also allows us to have even more engagement. And so, there will be an artificial intelligence hearing, and it is going to be divided into three primary areas. First is the implementation of Fair, Appropriate, Valid, Effective, and Safe (FAVES) and what really looks like, the second one will be focused on equity-centered AI design, implementation, and monitoring, and the third one will potentially be around safety. As Micky mentioned, we have so many different experts in AI here on HITAC, but we also know various different experts that are not on HITAC, so if you have any ideas or special people that you think need to be part of this hearing, please do email Wendy, and we have also provided some recommendations as well.

Last but not least, before our next HITAC meeting, for those of you all that will be flying into DC a little earlier, we will have our traditional welcome meeting, and so, there will be an email going out from my assistant in order to help to coordinate that dinner, so I hope that everyone will be able to join us from there. Again, we have an exciting meeting today, and Sarah, I am going to turn it on over to you.

Sarah DeSilvey
Thank you for talking, Medell, even though your voice is quite hoarse. I want to reiterate gratefulness to Micky and the whole team at ONC. Because Medell has covered everything so elegantly, I am just going to add one other little element that I know personally from my area of expertise, just appreciation to details and attention to elements of health equity. It is in everything that we see coming from the ONC at this time, driven by the vision there, and so, I am just grateful for your leadership across the board there. I also just want to say I am excited to see you all on April 11th, and because Medell has covered everything else so perfectly, I am going to move on to highlighting an opportunity for our new-but-not-new member of HITAC,

Alex Mugge, to briefly introduce herself, share her organization, title, and role. Just because we welcome you here to HITAC, if you could do that, Alex, that would be great.

Alex Mugge
Sure, thank you. I appreciate the opportunity to say hi to everybody. I am Alex Mugge, the Chief Health Informatics Officer at CMS, and I am also the Director of the Health Informatics and Interoperability Group, or HIIG, as we refer to ourselves because we love acronyms in government. Our team is located in the Office of Burden Reduction in Health Informatics, or OBRHI, and HIIG is responsible for CMS's interoperability and health IT strategy, as well as standards, oversight, and adoption. So, in practical terms, some of our work includes coordinating and publishing the CMS interoperability rules, we also coordinate the TEFCA engagement at CMS, and we are responsible for the national directory efforts. Some of our colleagues within the office are also responsible for the adoption of Health Insurance Portability and Accountability Act (HIPAA) administrative standards, so, in that way, our group within CMS is highly involved in healthcare standards from a variety of different perspectives. So, I am very happy to be here. Thank you.

Sarah DeSilvey
We are so happy to have you, Alex, and thank you so much. Now, I believe we are going to our next topic. Medell is going to be reviewing the agenda.

Medell Briggs-Malonson
Thank you so much, Sarah. Here on the screen is an overview of our agenda. Of course, we have already done the roll call, as well as the welcome remarks, and our first presentation will be focused on the USCDI+ overview on platform demo, followed by the updates from the incredibly exciting Interoperability Standards Workgroup (IS WG), and then we will open it up for public comment, and then have our final remarks. Next slide. At this time, I am going to turn it back on over to USCDI in order to do the presentation. We will move forward from there.

Sarah DeSilvey
We are very grateful to Elisabeth Myers, Matthew Rahn, and Brett Andriesen from ONC for leading us through the conversation on USCDI+. Thank you so much for coming.

USCDI+ Overview and Platform Demo (00:23:36)

Elisabeth Myers
Hi there. Thank you for having us. So, I will go ahead and get started. I am actually going to be providing a little bit of an overview of the engagement that we are planning with the HITAC over the next several months, and then I will be passing it off to my colleagues Matt Rahn and Brett Andriesen. Matt will be covering an overview of the program itself and the status of our different initiatives within the program, and then, the part I am most excited about for today, actually, is Brett's part, which will be walking you all through the USCDI+ platform that we launched earlier that is really a great, dynamic tool that we think will support not only the overall public engagement, but our engagement with the Federal Advisory Committee Act (FACA). As you get a chance to look at it while Brett demos it for you, just keep in mind how it can be used as a tool for the work that we plan to engage on together.

So, I am going to go through that part of the agenda a little bit quickly first, and then we will move into the slides and the meat of the presentation from my colleagues. So, at the January 18th HITAC meeting, we presented the HITAC work plan for 2024, and that HITAC work plan included a focus on USCDI+, so, today, we are sort of kicking off that part of the work plan for the 2024 HITAC, and what we want to do is provide an overview of the USCDI+ program. I know we have done that in the past, but as the program is now at this really great stage where the platform has launched, we have versions of some of the data sets for domains that have actually gotten public comment, the first round of which we are working through and really trying to further refine, and the total scope of the projects that we are working on under the USCDI+ umbrella to really harmonize different data sets for a broader set of needs is expanding pretty dramatically, which you will see from what Matt covers today.

So, now is a really good time for us to be having more in-depth engagement with these types of activities with the HITAC, so our intent today is to provide you with an understanding of the USCDI+ as a whole, where it currently stands, and where we think it is going, and then to also set a foundation of how to navigate the USCDI platform to inform that work, both as a committee and in your work in your daily roles. So, for this year, we plan to engage the HITAC in a series of full-committee presentations and discussions. Each of those discussions will build on what we talk about today, and we will focus on the various USCDI+ initiatives that Matt is going to cover, so we may do some in-depth deep dives on individual areas or individual domains over the course of the next few months. The USCDI process follows the same basic principles that we use for the USCDI.

So, all of the transparency, putting together versions, and modifying those versions based on public comment is very, very similar, but we have some additional pieces for USCDI+ because it is filling this niche of gap-filling and harmonization that is a little bit different, so we are going to cover those really briefly, and those include first doing a discovery process and charter. Matt will talk a little bit more about some of those individual details, but what we end up doing with the USCDI+ projects that fall under this umbrella is a discovery process to try and identify the need, how it is going to work, where the real gaps are, and how we can frame the concept or structure of it so that it is relevant to the user, so it is a really important point for thinking about what we do for a domain and how we engage from the very beginning in fleshing out what an individual domain might look like.

And then we go through a process of the identification of use cases, data specifications, and programmatic initiatives and requirements, because these are all really important tools to keep in mind. Some of the USCDI+ effort is basically just trying to figure out how to harmonize and bring together data concepts, but some of it is to fit a really, truly burgeoning need as our federal partners and our HHS program partners continue to engage in data modernization efforts, and those needs for reporting, or public health tracking, or understanding things that National Institutes of Health (NIH) needs for cancer research are all part of understanding the specific use case and the gaps that we are trying to fill.

And then we go through a process of evaluation of the data classes and elements according to specific objective criteria such as the industry priority and readiness, the level of standards maturity, and, as mentioned, the identified agency needs, because in a lot of cases, those agency needs are driving the standards and technology adoption across the country, so trying to meet both our federal partner needs and the evolution of the nationwide health IT infrastructure includes this need to really see what those needs are and how we can ensure that we are meeting them through this program so that we are bridging between

what the health IT care continuum looks like and what the agency needs are that are driving these changes. So, depending on the specific initiative, we will be looking for your expertise and insights to inform both the discovery process and the identification of specific use cases that we might want to consider or the refinement of use cases that we are looking at.

And then, in addition, as you all have been familiar with doing for a very long time, actual evaluation of data classes and elements and standards associated with them in a similar manner to what we do with USCDI, but also what we do with standards more broadly. So, the anticipated format for the HITAC engagement will include that you will receive materials about the USCDI+ initiative that we will be discussing for that given meeting in advance of the meeting, so you will have a chance to look at it, or in other words, you will get homework, and we will ask you to review the materials because we are going to want to use the sessions where we are meeting together to address your questions, think through ideas that you may have, get your insights during those meetings, and really make them productive working sessions.

ONC and other Subject Matter Experts (SMEs) involved in the USCDI+ initiative will actually present an overview at a detail level of that specific initiative or domain, including focused areas where we might be looking for your insight for that specific area. So, that is sort of what these will look like. Over time, obviously, the HITAC co-chairs will facilitate the discussion, and we will engage together on exploring the areas that are brought forward by each of the domain teams as we go through that process.

So, the USCDI+ program and its various initiatives are in the very early stages of development. Some of them are starting to get a little bit more form and shape to them. You all know we put out the Quality Initiative, for example, last year for public comment, and we are going through those public comments now. So, they are at sort of different stages, but we are going to tailor each presentation and work with you through the stages and the need for that individual initiative, which is why we are going to be looking at them as a sequence throughout the next several months.

So, we are looking to a series of discussions, along with our overall public feedback efforts, and you will see how some of the platform can support that, and we are hoping first off that this will help us validate initiatives that are moving in a good direction, including use cases or domain constructs that are moving in the right direction, so it is not just feedback on where to fix, but we would love to hear where you think we are getting it right, provide course correction where needed, or help us to identify any gaps or opportunities that you might see that we should explore further, especially to flow back into the discovery process, because like the USCDI, this is going to be continuously engaged in a cyclical process that is going to be continually updated, reengaging, readvancing the discovery process, and then going through those analytical points as we go. So, next year, we anticipate bringing the USCDI+ initiatives back to you for even deeper engagement, especially on the ones that we might bring to you now in discovery phase, to evolve and make sure that, again, we are validating them and doing it the right way, that we are continuing to identify gaps, and if we need to adjust or course-correct along the way.

So, in just a minute, I am going to hand it off to Matt Rahn and Brett Andriesen to go through, at a more detailed level, the specific initiatives, an overview of the program itself, and then, obviously, the platform, which we are very excited about, but before I do, I want to provide a few contextual points for you to keep in mind as you learn more today, and as we continue our collaborative work on the USCDI+ in the coming months. First, I say this all the time, but as a reminder about USCDI, the same applies to USCDI+. It is

intended to serve as both a policy construct and as a technical construct, so that means that we do intend to potentially consider future adoption of USCDI+ domains or implementation specifications based on those domains in future rulemaking, so the USCDI is both a data set and a standard for baseline requirements, but it also includes the United States (US) Core Implementation Guide (IG) that goes along with it, so it is a similar construct. We do intend to have the USCDI+ follow in the same way, and will consider how that should work over time, and how it could support our federal partners.

We also do expect that, over time, our federal partners may reference USCDI+ domains and versions of the data sets in their program requirements in a similar manner to how they do the USCDI today. For some, the USCDI is viewed as a list of the types of things that need to be moved as sort of a policy construct. In other cases, our federal partners may point to the USCDI as a technical standard for implementation. So, we expect that a similar set of rules will apply for the USCDI+, and for this reason, I want to hit on my second point, which is Matt is going to talk a little bit more about the core principles of the USCDI+ and the relationship to USCDI, and I am just going to mention them really briefly before we go into that presentation so that it is in your heads now as you are thinking through all of this.

Those three core principles are collaboration, harmonization, and specification, and I want to emphasize a couple of key points. When we talk about collaboration, whether with the HITAC, our federal partners, the community, the health IT community, the healthcare community, the care continuum, public health, all of these areas, I want to reiterate that it is essential to have deep engagement with a wide range of partners, from federal partners, to public health, to healthcare developers and researchers, not only at this development stage and not only through the comment process on the individual domains, but on an ongoing basis. The USCDI+ can only have a meaningful impact through a long-term commitment from all of us as a community to engage in the analysis, the harmonization work, which is work, and we are going to talk about that more, but also in testing, in piloting, in adoption of these data elements and of the domains within systems as you are planning new development, new programs, and new initiatives, but also in stewardship.

So, it is a continually iterative process, which means that we need continually iterative engagement in each step of that process, including stewardship of the data sets across the continuum in the future. When we talk about harmonization, I do want to, again, reiterate back to that commitment to engage together. In order for harmonization to work, we have to agree that we are going to come together with the intent of trying to build consensus, identify commonalities, and try and work towards collective and collaborative harmonization that pulls data elements of different constructs together and identifies where they really should be harmonizing around one concept or where there actually are differences that are necessary and important to capture.

So, again, it is about a commitment together to work toward this effort in order for harmonization to actually work, and the same actually applies to the last point, which is specification, in that in order to get to standard specification, which I will not go into because Matt and Brett will talk quite a bit about it in just a minute, it is absolutely essential that we commit to engagement together on specification at the front end of this process. We need to have clearly defined clinical goals, clinical priorities, public health goals, public health priorities, research goals, and health equity goals and concepts. With those concepts, we need to commit to making that specification of what they really mean, what is really needed, up front so that we can build those computable tools and resources to actually be able to have technology support those in a meaningful way,

in an accurate way, in a safe way, and in a way that is really meeting these needs. That will absolutely continue to evolve over time.

There is a lot of working going into how to think about computable clinical guidelines and concepts from a starting point, from the actual development point, but we do believe this will continue to evolve over time, we believe we will all get better at this, and we also believe that there will be tools like AI in the future that could help us do this, but I do want to emphasize the need for a commitment to that process in order for these things to work. So, that is really the theme of my core goals, is the commitment to engage together, the commitment to continue to collaborate, not only now, in the development phase, but over time. So, we believe the HITAC can have an important role in supporting each of these core goals, and we very much look forward to working together to advancing these goals through the USCDI+ program over the series of this year and into future years. With that, I will pass it to Matt for the actual exciting detail of the presentation on the various initiatives, and then Brett for the platform.

Matthew Rahn
Thanks, Beth. Can everyone hear me all right? Hi, everybody. My name is Matt Rahn. I am the Director of our Standards Division in the Office of Technology, and one of the leads with Beth and a few others in the Office of Technology (OTECH) and the Office of Policy (OPAL) in the USCDI+ program. Can we go to the next slide? I will be brief on the overview part because Beth went into a decent amount of it, and I want to be able to get to Brett, and I do not want to spend so much time on that. So, as Beth said, USCDI+ extends beyond USCDI. It is for unique program and use case specific data needs that are sometimes not fully met by USCDI. It is to help us partner with the government and industry folks that build on our USCDI construct to help meet their specific needs. We do apply some of our USCDI processes to help with the harmonization that Beth spoke to across the different initiatives, and we want to make sure that we are leveraging different programs and authorities across HHS and elsewhere to help drive adoption. On the slide, you can see a few different domains that we have kicked off, and I will talk a little bit more in depth about what specifically we are working on there. Can you go to the next slide? Thank you.

So, USCDI+ is meant to be an iterative process where we make exchanges and updates on a rolling basis. As mentioned before, it is similar to USCDI, so we will have new use cases build on existing work, but focus on meeting the needs in real time and coordinating with ONC requirements and other agency requirements as well. On regular intervals, we will update our findings, and we will update them on the USCDI+ platform, as Brett will speak to. Earlier, we will engage with pilots to help inform any bright spots and barriers to success. The data requirements are paired with test kits for conformance, and potentially, in the future, tied to certification requirements. And so, partners across the ecosystem can adopt consistent models for data capture and exchange. That will help ensure better treatment, prevention, and research for all patients, so our hope is the work will allow for partners inside and outside the government working in the same program areas to be able to reference these different data standards, and this is an ongoing process. Next slide.

So, this is just to illustrate that with USCDI, in a sense, you could have a superset or subset of data elements in USCDI+. On the right side, there might not be a data element in USCDI, but it is in a USCDI+ data set, and there could be four USCDI data elements that are in a USCDI+ data set, so our goal is to make sure there is alignment across those different data elements specifically. We do not want there to be the same data element name with different definitions across programs, so that is something we are really working

on, and that is the alignment piece across the different domains that we are doing, making sure there are no differences in definitions based on a data element name. Next slide, please.

Beth spoke about this, so it is hopefully ingrained into your brain, but the three principles are collaboration, harmonization, and specification. Collaboration is to collaborate across the entire ecosystem to inform and support health IT advancement for priority use cases, including data element lists, standards, implementation specifications, and, again, potentially into certification criteria in the future. For harmonization, we want to make sure we are harmonized across all initiatives as it pertains to our relevant partners that include federal agencies, clinical stakeholders, the health IT community, and users of health IT in general as folks are adopting data element lists and standards, and potentially certification criteria in the future.

Specification is specified foundational principles and process for the development of these lists to make sure we are in this transparent initiative, similar to USCDI, so people are aware of what is going on. Lee, I see that you have your hand up. I think we have set aside 30 minutes or so at the end to do questions, so if you can save your questions until the end, that would be great. So, again, collaboration, harmonization and specification. Next slide, please.

I am going to move into the specific updates based on the particular active USCDI+ program initiatives we have going on. So, there is USCDI+ Cancer, Behavioral Health, Maternal Health, Public Health, Quality, and Uniform Data System (UDS) Plus is our Health Resources and Services Administration (HRSA) work that also falls under our USCDI+ Quality domain. There are others. At the end, I will show some active engagements we have that are potentially kicking off in the near future, and if you do not see an engagement that you would like on here, please reach out to us and we can explore how best to address any use cases that we are not already covering, or, if we are, making sure we are bringing some of our federal partners that have specific interests and our partners outside the government, making sure there is awareness of the work that is going on in a specific domain. Next slide, please.

So, I am going to try to go through these pretty quickly. I think there are seven or so. So, with USCDI+ Cancer, we are partnering with the National Cancer Institute (NCI), the Center for Medicare and Medicaid Innovation (CMMI), CDC, and the Food and Drug Administration (FDA) to support the White House Cancer Moon Shot Initiative by establishing USCDI+ Cancer, and the goals in this initiative are to capture the data needs for cancer reporting that fall outside the scope of USCDI to harmonize these cancer data elements in a common data element list that addresses the multiple partner needs and use cases, support the integration of federal data systems, and then identify opportunities for policy alignment around cancer reporting programs under existing authorities across HHS.

So, as you can see, on the right side, we are actually planning the inaugural USCDI+ Cancer Data Exchange Summit. That will be on May 8th and 9th, and this will help identify the strengths, weaknesses, and gaps in the existing data standards that are needed to implement the USCDI+ Cancer Moon Shot use cases. We will also be developing FHIR testing plans for the Moon Shot use cases, starting with the Enhancing Oncology Model (EOM) data set. We are planning to have a connectathon track in May, so if you are interested in that, please join us. And then, we are also starting use case development for cancer registry track extraction and immune-related adverse events, and then continue refining use cases for clinical trial matching. Next slide, please.

So, with USCDI Public Health, Micky talked a lot about this in his opening remarks, but there is a lot going on with public health. The goal is to capture the data needs of public health that fall outside the scope of USCDI to improve data quality and availability. We have been working very closely with our CDC partners on their public health modernization work, so the current use cases are case reporting, laboratory data exchange, immunization data exchange, resource reporting and situational awareness, and risk behaviors and health equity. We currently have a comment period for case reporting and lab data exchange open until the end of this month, and Brett will show that on the platform and how you will be able to provide feedback on that. There are data sets that are under development for other use cases. We have previously had other open comments on the other use cases as well. These data sets are going to help inform updates to core public health profile implementation guidance in Health Level 7 (HL7). Next slide, please.

So, in USCDI+ Quality, there is a lot going on in this work with CMS, HRSA, and others, so the whole goal is to capture the data needs for quality reporting, again, that fall outside of USCDI that would help streamline development and reporting of quality measures, harmonize the quality data elements into a common data element list, and support CMS's digital quality measures strategy and development of harmonized data element list for FHIR-based quality reporting, and then identify those opportunities of policy alignment across HHS agencies. We have already been doing that with our HRSA folks and CMS, making sure we are harmonized so there are not different things going on between those, that they are all in alignment and working towards the same thing. We are currently under public comment processing, as Beth said, for the new version of USCDI+ Quality, and Brett will show that on the platform as well. Next slide, please.

So, I mentioned HRSA a few different times. We are working with HRSA on their UDS modernization goals, and this is to capture the data needs of the health centers, health center control networks, and primary care associations for UDS Plus reporting, so we are working with them to design, test pilot, and deploy HRSA's FHIR infrastructure for UDS Plus reporting and establish a USCDI+ Quality data set to support the UDS reporting. So, again, there is alignment across the different quality-related reporting. We have developed and published a UDS Plus reporting implementation guide. As you can see on the slide, 1.0.1 was published in December on the FHIR Foundation. It has not gone through a ballot process yet. There are potential plans to do one in the future.

We do have testing on the Inferno tooling, and then, we do plan to have a FHIR educational session at the upcoming May working group meeting on this particular implementation guide. We have been piloting with a few different health IT vendors. Three have successfully connected to HRSA's environment and submitted 20 of the UDS Plus FHIR resources. The go-live for the UDS Plus reporting cohort is under way, and scheduled to end at the end of this month. There are going to be three different cohorts based on the vendors' availability to join the cohort, but essentially, the hope is that over time, utilizing FHIR, the health centers would be able to report all of their patient-level data that they will be required to based on the UDS modernization goals. Next slide, please.

So, USCDI+ Behavioral Health is a collaboration between ONC and SAMHSA, launched in September of 2023. We have drafted a USCDI+ data element list. We are currently doing some Phase 1 stakeholder engagement interviews with SAMHSA grantees. We are very close to releasing the data element list, and it will go live on the platform that Brett will go through in a minute or two, and then we will start the Phase 2 stakeholder interviews and complete them with providers and advocates. Essentially, this is to support

SAMHSA's data strategy to modernize behavioral health reporting and improve interoperability across the care continuum, and there are similar goals as the other ones to capture those data needs that are currently not in USCDI for behavioral health reporting and make sure there is alignment across all the different initiatives. Next slide, please.

So, for USCDI+ Maternal Health, we partnered with NIH. The goal is to establish a core set of data necessary for high-quality care equitable outcomes in maternal health research and to facilitate standards implementation and support of core data for maternal health with one or more implementation guides and the healthcare technology systems. We have already completed Phase 1. Phase 2 is under way. We are engaging pilot partners, as well as ones that are going to continue. We are updating the data element list on the platform, and we are going to reopen the public comment on this list, targeting for late spring. Next slide, please.

So, those are the ones that are active, and we have a lot going on. As Beth said, we will do a deeper dive into specific ones and spend a lot longer time on each initiative in a future HITAC call or calls, but these are two that you see on the screen. One is around sickle cell disease, so we are coordinating with the American Society of Hematology (ASH) and other partners to develop a minimum coordinated set of data elements for sickle cell disease to allow the clinicians, researchers, patients, and payers better access to their data. We are working with Patient-Centered Outcomes Research (PCOR) and acute respiratory failure as well, and that has a similar type of goal, but we are working with FDA on that. I am very excited to kick off these two potential projects soon, but these are just two examples.

We have other conversations happening, but these ones are further along, and we are actively engaging with our federal partners and figuring out how we can work on creating data sets to help improve access for data and improve care for these specific related initiatives. So, there is more to come on those two, but in the interests of time, I am going to turn it over to Brett, but again, we are going to do a deep dive into the domains as a whole, and we will spend a significant amount of time in future calls to go into each one. So, I am going to turn it over to Brett Andriesen to go through the platform. We are looking forward to seeing that.

Brett Andriesen

Thanks, Matt. Thanks, Beth. Hi, everybody. I am Brett Andriesen, the Deputy Director of the Networks and Scalability Division in our Office of Technology. I have a few slides on here. Go to the next one. We have really just put these in as placeholders, and you can see the uniform resource locator (URL) for the site here, USCDI-Plus.HealthIT.gov, and I am going to share my screen and bring you through a live demonstration of the site so you can see some of the key features. Just one second here. All right, hopefully everyone can see my screen and it is big enough for folks. So, again, I want to thank everyone for your input and patience as we work to develop the USCDI+ platform, and just make a note that we will be continuing to improve the site roll out new functionality, and can be responsive to some requests for new features where that is possible.

There has been a lot of work by a strong team of folks here at ONC, as well as some of our contractors, to build out the site, prepare data sets, and whatnot, and really, we created something that we think is a big improvement from what we had initially put up for our USCDI+ processes, certainly a lot better than working through Excel spreadsheets, and our goal is really to make everyone's lives easier in reviewing the data

sets, being able to see commonalities across and differences between the data sets, as well as USCDI and managing the content and process for working through these data set updates. So, this is the homepage. It has largely a similar look and feel as the previous USCDI+ system that was on our Interoperability Standards Advisory (ISA) platform. Much like USCDI, there is no login requirement to view the data sets and poke around, and also like USCDI, there is a registration required for submission and making comments, and then, there is also a button right here on the front page for submitting new data elements for consideration.

Unlike USCDI, we do have a news feed here on the right-hand side of the page. Right here, we have a place where there are some user guides, so if you are not following along as I go or you want to reference stuff later, there is a place to come in here and click. You can see information about creating accounts, how to navigate through the different data sets, as well as how to make submissions for comments. But looking back at the homepage here, we also have a comment feed here where you can see some of the different comments throughout the different USCDI+ areas as they come in.

Looking here at the submission system for data elements, we took a look at this and really looked at our USCDI submission and significantly simplified the information required to what we felt were key components necessary for USCDI+ after examining things a bit closer to reduce some of the burden of entry while also adding a number of features. There is some logic built directly into the form. So, if you come in and select domain, let's look at public health here, you can select your use case, let's do case reporting, you can select an existing data class or add a new one, and then, one of the nice things we have here is some logic, so, for example, if there is a data element that already exists around medications, within the next area, it will tell you that there is one that already exists with that same exact name, or if it is similar, it will show you the list of everything that is there, so if you decide there is already one that exists for this, you can click into that, see that it already exists, if you want to make a comment, you can jump to this comment tab and add that comment directly on that one, or if it is truly something new, you can make that new addition.

There also is the ability to have a little more structured data within the form, so we can see things and do some filtering and searching on those. For example, if you want to see something that is in USCDI at a particular level, you can add those. If you want to see something that is tied to a specific vocabulary standard… I am not sure why that is not working during our demo. Of course that would happen right now. But it allows us to essentially better relate the information to each other, and I will show you some of the features based on that a little bit later. The nice thing here is you have the ability to save these as drafts as well, so you can start a submission and come back to those later, and I will show you where those happen as well. There is a link up here in the hamburger so you can see our existing submissions, comments, or drafts that you have in the works.

Going back to the homepage, we will start to dig into the data sets a little bit. So, here, you can see the cards for the different domains that are available. We will start and dig into public health. The nice thing here is that you can dig into the level that you are looking for. So, here, you can kind of see the two different use cases we have live right now for public health and go to descriptions about them, or if you want to see all the data elements that are within public health, you can click over here into details and see everything at this level here. So, if you want to sort by different data classes and see how those look, you can see them here, and now we start to see everything in work information here. You can see the data class and use cases here. So, each of these fields at the top are sortable. You can also use search to take a look

within something here. So, I will pick demographics, and it will bring up everything that is within demographics across public health.

So, going back to the use cases, you can dig into one here. Let's click into case reporting. Again, this is that similar list, except at this point, it is just constrained at the case reporting level. You can also see comments case-reporting-wide, so you can see there are a couple comments in here that folks have left at the case reporting level, and this similar structure appears throughout the site for consistency. So, looking here within the use case level, again, you can do that sorting by data class to see what operation is there, and you can sort by data element name. Also, throughout the site, where you see this little hamburger menu, you have the ability to export content. So, Excel and comma-separated values (CSV) are likely to be the most common, but basically, at this point, it will export whatever is on the screen. So, right here, it will export everything from case reporting, or if you constrain this one by demographics, again, it would export exactly everything that is in demographics for you at this case reporting level.

Looking into current address as an example to dig into the data element, the nice thing about that export feature, too, is it not only shows you what was on that previous screen, but it also will pull up all the information that is listed in each data element record, so it kind of just shows you that summary information at that title of the screen, but whether you go into an export or the actual data element information, it shows you everything, and you can see where the information is currently in the USCDI system and the current level with a link to it there. You can also see some of those vocabulary standards. In this case, US@ for patient addresses is in here. You can also see that this current address is associated with the US public health patient profile, as well as the US Core patient profile.

And, a feature that I think we are really most excited about is the ability to see these relationships across different parts of USCDI+. So, if we dig in here, you can see it, and it shows that this data element is not only within that case reporting public health use case, but also in maternal health and cancer as well. It shows it three times that it really is that same data element and system, so you can see where those are located, and as additional domains and use cases come online, we can associate that same data element record with those. Again, you can click each of these if you want to then look at the maternal health data set that we have to see all the information that is within that one and jump back and forth through that as well.

Another really nice feature that we have, too, especially if you are looking to kind of compare different things is we have a global USCDI+ All view, so if you click up here to the USCDI+ link at the top, again, it is a very similar structure to the way it is laid out in each of the different use cases and domains. You can do some of the same sorting here as well to see where that alignment exists, you can sort by use case, data class, domain, and data element name, you can do that same export as well, but then, here on this page, you also have the ability to filter items, too, so you can get a little more hands-on and dirty with the data to see the information you want. So, if we click this here, it allows you to sort by anything that is in the system. So, let's do the public health domain, and then, let's add criteria for data element, associated US Core profile, and then, let's do "is not empty" and run that query. Now we can see a list of everything in public health that has a US Core profile associated with it. Or, if you wanted to do the opposite and see which ones do not, you would select "is empty" for that field.

And then, you can export this list here, as you filter it down, as Excel, and that will give you all the data elements sorted by this view, as well as all the information about them, so you can kind of look at things that way. Or, if you want to export the whole thing, you can use Excel, Google Sheets, or whatever software program you would like to run some of your own filters and queries that way. I think those are some of the high-level basics. If this was a little too quick to remember, remember that the user guides are right on the homepage. You can look at those without needing to create an account.

Also, this latest news is where we will include updates about new data sets and new features that are coming online. You can see here that we have the feedback requested about each of the different public health data sets with some key questions we are looking for answers on, and we have those deadlines there, and as I mentioned, we also continue to work on improvements to the site that will roll out as they are available. I know right now, one of the big things we are working on is improvements to commenting that will be coming online in the next several weeks, which will include the ability to format text, have things like bold, bullets, URLs, and whatnot, as well as including attachments, but we are working on a few security pieces before we get there. So, with that, I will stop sharing and turn it back to the team for any questions.

Sarah DeSilvey
Thank you so much, ONC friends, for this amazing presentation on USCDI+ and the advancement you have made. We are going to move into the HITAC questions and have our HITAC members elevate some of the questions they have in the chat for our ONC friends. Ike?

Steven Eichner
Thank you so much for sharing. This is really exciting. I am really happy to see the progress that is being made on USCDI+. I would ask one favor. It is great to see the comment period extended. I think it is still showing that the comment period closed on March 4th on a couple of the public webpages, so if that could get updated, that would be fantastic because I am sure there are folks with comments that they would love to make, and that extension will really make it possible. From a connectivity standpoint, what is the next step for expanding public health going beyond traditional public health reporting from infectious disease to look at other types of case reporting, and where do we see this expanding with things like birth defects or other types of data exchange supporting other types of public health surveillance?

Elisabeth Myers
Either Matt or I can take this, but we are in constant contact with CDC about how they want to help us think about that as well, and we do have engagement with the state, tribal, and local jurisdictions about some of their priority areas. One of the challenges we have had in some of the expansion is identifying use cases where they have even gotten to the point of specification that I was talking about earlier, where there is enough focus in order to do so, but I will say that the specific one that you are mentioning, thinking about different types of newborn screenings and developmental things, are pieces that are actually being raised in both public health and quality right now, so it is something that we are proactively looking into in this moment. In terms of expanding the scope of public health use cases, it is on our radar, and it is an ongoing conversation. Jim, I see that you tagged that you would like to also talk about it, because you are obviously involved in those conversations.

Sarah DeSilvey
Jim, do you want to speak now, or do you want me to move to the next one?

Jim Jirjis
I was on mute. Sorry about that. Thank you, and thanks for the question. It is our team that is working closely with the ONC team to develop the strategy. Obviously, if USCDI+ ends up with 943 items in it, then it becomes less useful in some ways because we are trying to get the vendors' attention. So, we have some thinking about how to prioritize and make it meaningful and not too expansive to begin with, but at the same time, if any of you would like to hear what we are thinking on that or participate in that, please reach out to me. Obviously, these are things that are going to be supporting regulatory needs, things that are high-value use cases to public health that are in production now that would benefit from it. Those are a couple examples of how we are thinking about prioritizing, so I would love to hear people's thoughts if they have any suggestions or just want to hear what we are thinking.

Sarah DeSilvey
Thank you so much, Jim. I am going to move to some of the other comments, but my guess is some of our HITAC members have thoughts related to your statement there. Let's get to Lee.

Lee Fleisher
I am only laughing because I think Jim answered my question in many ways. When I left the agency eight months ago, one of the questions was how we prioritize. A lot of things really do fall in the public health bucket, but how many of them are actionable through other regulatory levers as opposed to just important academic questions that may have prognostic, but not immediate actions?

Jim Jirjis
That is one of them. Thank you for pointing that out. When we talk to the programs, they have hundreds of data elements they want, but one of the things we realized is to ask what their plans were for it, and if they do not actually have plans to do anything with it right away, then we feel like that may dilute things. Excellent point. That is why we are really focusing on what is being used, what has actual plans to be used, and what is tied to regulation and real problems.

Lee Fleisher
Can I also ask something in the hospital space? Given all the levers we pulled during the pandemic of data elements that we wanted, have we thought about getting the input of the industry who you are hoping will actually input this data so it is more FHIR-based so we do not repeat what we just did, where we had them taking spreadsheets out and trying to provide that data to HHS in a central way?

Jim Jirjis
Absolutely. Go ahead, sorry.

Elisabeth Myers
I was going to say I think this is actually similar to Hans's question in the chat, and I think Avinash did a response there, but I will let you go, Jim, on the specific thoughts for CDC and for public health. But in general, as Avinash noted, in USCDI+, we have this balance that we are doing, as Jim mentioned, with the prioritization process of the policy construct of the scope of the information we are talking about, and then the very real need for implementation specifications as this evolves to being in place, and FHIR is one of the questions that we have there, but in some cases, some of our use cases are really varied in the

readiness of use of tech at all. So, what we are trying to figure out is how to use USCDI+ to get at some of those really important questions. How do we pilot test and implement this in FHIR in the very near term, and how do we also bring along…? Both from a health equity point of view for patients, but for providers as well, access to technology has not been equitable, so how do we bring along people who have been left out by using USCDI+ as a tool to get them started on the modernization path?

We are trying to accomplish both things and really balance that in how we are approaching USCDI+, so I think you will see that part continue to evolve as well, Lee. We do not want people just using an Excel spreadsheet, but we do want them to start using an Excel spreadsheet at least if they are currently on paper and get in the right direction so that data can at least be reusable by others who might have more advanced technology. How do we bridge to get them there?

So, it is an important piece that we are thinking through, and Avinash, I do not know if you want to reiterate any of your points in the chat as well, but I also know that Jim had a follow-up comment, so I will defer to the chairs on how they want to handle this part of the discussion, but it is a really good and important question, and Avinash did put in the chat that we want to hear both parts. We want to hear readiness for FHIR use, but we also want to hear about data concepts that we desperately need that is being used in unique settings that are providing maternal healthcare in urban areas that are literally still using paper because they do not have mobile tech. How do we bridge the gap for them to get there? So, I will stop there.

Sarah DeSilvey
For the sake of time because we do not have very much time, I am going to try to get to the HITAC members who have had their hands up. Medell?

Medell Briggs-Malonson
Thank you so much, Sarah. Elisabeth, you mentioned something that I was going to bring up. I will be very fast, but I am the executive sponsor for a huge interoperable collective of both federally qualified health centers as well as medical centers and others, and as we have been trying to enhance interoperability, one of the key factors that we noticed is that several of our FQHCs have not been able to engage with so many of the different levels of USCDI and all the various different data sets due to that lack of technology and ability, whether it is due to capacity within their centers or versions of their Electronic Health Records (EHRs), whichever it is.

So, similar to what you just mentioned, I want to make sure we are not leaving people behind because what we are doing here is wonderful, and especially when it comes to serving our most vulnerable populations, but there is a significant accessibility gap that we continue to see, so I just wanted to find out how we are addressing that and keeping that center in mind so that we are truly achieving health equity and justice for those communities and those patients that will benefit most from USCDI+ and all of our other efforts. Thank you for that.

Sarah DeSilvey
Beth, do you want to answer? My guess is that Shila from North Dakota, my rural friend, might have very similar questions, but Beth, do you have a quick answer to Medell, and then we can try to wrap up?

Elisabeth Myers
Absolutely. I know we have to keep on the agenda. What we have been trying to do is very deliberately have these types of conversations in the discovery phase so that we are trying to get those broader perspectives from more people, including parties that may not have always been part of the conversation. So, for example, in Quality, we have literally been going out to specialty societies that are specialties that may not have been covered before, we have been trying to talk to behavioral healthcare providers who, again, may not have been covered before and may be facing different challenges, we have been leveraging some of our federal partners' levers for their networks and their threads, including talking with the state groups and local groups, we have been having one-on-one conversations with health centers, including federally qualified health centers and some critical access health centers, we have been doing all these types of things to try and ensure that we are getting a diversity of voices and a diversity of perspectives, but not just from the clinical community.

We have been talking to researchers and public health-facing groups that may not be as focused, as mentioned earlier, on disease tracking, but are focused on public health activity. So, we are trying to do all of that. We do have to rely in large part on some of the networks that our partners have to make that happen because they are closer to providers and the folks on the ground who actually make sure that those conversations are happening, so we welcome any opportunity to continue to advance that, as well as recommendations the FACA might have on entities to engage to talk to further, and I am getting the hook, so I will stop talking.

Matthew Rahn
Can I add 30 seconds? Is that okay?

Sarah DeSilvey
You can add 30 seconds, and then, Shila, if you would not mind, put your question in the chat so that we can make sure your thoughts are registered. Yes, Matt?

Matthew Rahn
Sorry. Medell, that is great, and we have been working directly with HRSA and their partners, and they have the uniform test collaborative, and we have been working with them to get feedback on the implementation guide and get feedback on barriers to be able to move along to these updated standards and implementation guides. And so, we definitely do not want to leave anyone behind, but specifically Federally Qualified Health Centers (FQHCs), and so, we are working with them directly. We have been going to the National Association of Community Health Planner conferences, presenting the work, and getting feedback, and we would love to touch base with you on the side if you have any ways to provide feedback to us on how we can get this up there more, but we are trying to be as public as we can with how we are moving, and as HRSA decides to put these requirements on, I know they have slowly been doing these cohorts, and that hopefully will make sure people can come along at a reasonable pace to make it so we are not leaving anyone behind. Thanks for the question.

Medell Briggs-Malonson
Thank you all so much. This was absolutely amazing. Obviously, there are a lot of engagement and questions about this. This is not the last discussion we are going to have here at HITAC about USCDI+, so we look forward to having you all back. So, we are going to continue to transition into our next portion of

the meeting, which is an update from our Interoperability Standards Workgroup, so I will turn it over to Sarah and Ike to lead us through that update.

Interoperability Standards Workgroup Update (01:21:12)

Sarah DeSilvey
Thank you so much, Medell, and luckily, it is not the Annual Report Workgroup this time, it is the Interoperability Standards Workgroup, so we can let your voice rest. I am happy to present the updates from the IS WG, which I have the honor of co-chairing with my colleague Ike, and we are happy to present an update to the HITAC at this time. Ike, are you with me?

Steven Eichner
Absolutely.

Sarah DeSilvey
Awesome. Okay, next slide. We are just going to briefly go through the roster, charge, and progress. Again, as a very high-level update, the IS WG is a very intensive and dedicated workgroup that meets weekly for a very intense period of time in order to get our transmittal letter back to HITAC in time for the April meeting, and so, there is a lot going on in that space, and we are very grateful to everyone who is participating in the work and to our ONC friends. Next slide.

It is a wonderfully robust IS WG this year. We have experts across HIT expertise, patient-led expertise, patient advocates, and clinicians. We really are grateful that many of the new HITAC members are with us in the work of IS WG. These folks predictably come every week for a couple hours to sort through the charge, and we are very, very grateful to all of them. I am not going to read them out all in turn, but again, just a note of thanks to the vast membership of the IS WG and the collective work that we do in that space. Ike, any other comments before we move on?

Steven Eichner
No.

Sarah DeSilvey
Okay, next slide. Just as a reminder to HITAC, the charge that we have at IS WG is to review and provide recommendations on Draft USCDI v.5. Specifically, though, it breaks down into two different elements of that charge. This includes the necessary review of any elements and classes from Draft USCDI v.5 that have been presented to us. In addition, we regularly review Level 2 data classes and elements not included in Draft USCDI v.5 that should be considered for final USCDI v.5 release. For those of you who participate and watch the IS WG, there is often this lifecycle where concepts get presented as Level 2 elements, get refined across multiple years, and then slowly make their way, as we refine them and socialize them, into USCDI v.5 drafts, so we are very grateful for the longevity of members of the workgroup to help us through that process. Next slide.

Now we are going to present on our progress. Again, this is our first formal update to HITAC, and we are very grateful to everybody who has helped us get here. Next slide. So, this is an overview of the workgroup meetings and the areas of focus we have addressed over the course of our initial months. We started with a really wonderful review of Draft USCDI v.5, and then we moved into past HITAC recommendations. We

are incredibly grateful to our friends at ONC who gave a wonderful overview of how USCDI v.5 is operationalized, the process of public comment, and the iterations of data elements across previous IS WGs. They did a really great job of laying the groundwork that we have to do in IS WG this year and helped orient our new members. Since then, we have been going through the v.5 and Level 2 elements in turn. We have had a series of subject matter expert presentations in February and early March, and we will talk more about those in future slides. Next slide.

So, these are the data classes and elements from Draft USCDI v.5 that we have reviewed so far. Of note, in line with our charge, we have reviewed and discussed all of the Draft USCDI v.5 elements at this time, touching base with author and author role in the last meeting, and that completed the initial review. Ike, anything to add here?

Steven Eichner
No. Again, you are doing a great job.

Sarah DeSilvey
Thanks, friend! So, again, those elements include elements within the clinical notes data class, emergency department note and operative note, and elements within the immunizations class, including lot number. Again, part of what we do because of our various expertise, including deep pharmacy expertise, is analyze and discuss not only the element as presented, but alternate use cases, alternate elements, or additional data classes that we might need to include in order to complete the objective of that element. We also have addressed test kit unique device identifier, medications route, observations advance directive, and observation and sex parameter for clinical use. Of note, the sex parameter for clinical use, pronoun, and name to use are part of the Gender Harmony subject matter expert presentation that we will talk about shortly. We have also addressed orders, interpreter needed, author, and author role. Again, these are all the elements as recommended in Draft USCDI v.5 by ONC. Next slide.

This is the list of Level 2 elements that were not included in Draft USCDI v.5 that we have begun to discuss or have discussed. Again, this is the second part of our charge, so this includes a discussion on care plan, and we will talk more about our subject matter expert leadership there. Health literacy status, specimen collection date and time, substance food, and family health history are on the list as of 3/5/24. Next slide.

And then, we also have a robust set of information, health insurance information, coverage/payer policy number, Medicare patient identifier, PR name, plan name, plan identifier, and group name. Some suggestions were maternal Social determinants of health (SDOH) note within clinical notes, medication administration within medications, and refinement and addition of portable medical orders that came out of our conversation advance directives that would be within the orders data class. I am trying to make up for lost time, so I am tripping over my words. Again, these are the Level 2 elements that are an additional part of our charge. What I had mentioned, again, is that both driven by the members of IS WG and driven by our subject matter experts, oftentimes, what we do is start with a given data class and data element, and then offer additional elements that might need to be offered and elevated in order to complete the objective of the use case as presented. Next slide.

So, these are our subject matter expert presentations that we have had the honor of bringing into the IS WG process. On February 20th, we had the well-known leadership and experts from the Gender Harmony

Project, Carol Macumber and Rob McClure, who came back to give their expert opinion on the three elements that I mentioned that were aligned with Gender Harmony work in the past. We are very grateful for their leadership. This is a Gender Harmony and HL7 initiative focusing on aligning use cases, so we were very honored to have them come and speak to us. On February 27th, we had the brilliant Maria Moen from MyDirectives come and speak to us on the advance directives observation element and observation orders, and this is partly what split out the conversation on portable medical orders that we are currently having in IS WG at this time.

And then, we just had experts in the care plan initiative, experts both from CMS and the Multiple Chronic Condition e-Care Plan Initiative within HL7, speaking on the care plan element, and again, these are the three groups of subject matter experts we have had so far. We are always grateful for their expertise blending into the various voices we have within IS WG. Ike, anything to note?

Steven Eichner
No.

Sarah DeSilvey
I am trying to keep us on time. I still have my co-chair hat on. Next slide. So, what we will be focusing on in the next meetings is fairly straightforward. We have a job to do. We are not meeting next week because so many of us will be away at Healthcare Information and Management Systems Society (HIMSS), so on March 19th and 26th, we are going to be getting to those Level 2 data elements that we have not yet addressed. I want to note that our members are very dedicated and working on final recommendations that the IS WG can review for everything that we have discussed so far. Our aim is to get a final recommendations letter to HITAC drafted by April 2nd, and then, we will only host the April 9th meeting if needed so that we can meet our objective to review the final findings of IS WG at our in-person HITAC meeting in April, when we will see you all together. Next slide. I think we are set. So, now we are open for comments, and thank you so much for allowing us to present on IS WG.

Medell Briggs-Malonson
Thank you so much, Sarah and Ike, for your leadership on IS WG and to all of the members. So, we will open it up now for any questions about the update from the IS WG. Any questions from HITAC members? Any additional comments? All right, well, I am not seeing or hearing any, so therefore, this is, of course, not the last update from IS WG, so we look forward to all of you all coming back and providing an update on the work that continues to happen, so, thank you so much, Sarah and Ike, and Sarah, I will turn it back on over to you.

Sarah DeSilvey
Yes. I believe it is my honor now to bring Wendy back because this was the last formal agenda topic in our meeting, and I believe we might be transitioning early into public comment. Wendy?

Public Comment (01:31:30)

Wendy Noboa
Hi, thank you very much. Yes, we can go ahead and open the meeting now for public comment. So, if you would like to make a comment and you are on Zoom, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you are on the phone, please press *9 to raise your hand, and

once called upon, press *6 to mute and unmute your line. Let's hold on for a second here and see if we have any comments. In the meantime, I would like to remind everyone that the next HITAC meeting will be held in-person and virtually on April 11th. If you are a member of the public and would like to attend the meeting, please visit HealthIT.gov to register, and while you are on HealthIT.gov, you can actually look at all the HITAC materials and find notes on the HITAC calendar. At this time, it looks like we do not have any public comments, so I will go ahead and yield the time back to the committee. Medell and Sarah, please proceed.

Final Remarks and Adjourn (01:32:28)

Sarah DeSilvey
It is my honor to then close us out for the day. Thank you so much for all of the expertise. I want to offer deep expertise to the team at ONC who led us through the presentation on USCDI+. I want to thank ONC leadership for your leadership across all the initiatives we had updates on today. I want to thank our members of IS WG who are also on HITAC because it is a lot of work in this period of time, and we really look forward to seeing you in person in April. Medell?

Medell Briggs-Malonson
Thank you, Sarah. I just ditto everything that Sarah mentioned. Again, we are really looking forward to seeing all of you in person in April and engaging in a wonderful meeting, as always, during that time. So, that is all for me today as well, and Wendy, I will turn it on over you to officially close us out.

Wendy Noboa
Okay. Well, thank you, everyone, for joining, and we look forward to seeing you very soon in April, maybe even in person. Take care.

Public Comment (00:52:24)

Wendy Noboa
Thank you very much, Sarah. Okay, everyone. We would like to open the meeting now for public comment. If you would like to make a comment, please use the hand raise function on the Zoom toolbar at the bottom of your screen. If you are on the phone only, you can press *9 to raise your hand, and once called upon, press *6 to mute or unmute your line. Let's pause for a moment and see if anyone from the public raises their hand. While we wait, just as a reminder, the next HITAC meeting is on March 7th, and we will be having our first in-person 2024 HITAC meeting on April 11th. You can get more information about both those meetings on HealthIT.gov. I am just checking that there are no hands. At this time, it does not appear that we have any public comments, so I will yield the time back to the co-chairs. Medell and Sarah, please proceed.

Final Remarks and Adjourn (00:53:26)

Medell Briggs-Malonson
Thank you so much, Wendy, and again, thank you, everyone, for all of your comments, and even for us making sure that even to the last moment, we have the best report that we can. Once again, thank you, everyone, for joining us in our HITAC meeting for February, and we absolutely look forward to being with all of you all again in March. Sarah, any last comments?

Sarah DeSilvey
I was going to echo the same. Thank you so much, and again, a specific thank you to all those who put effort into the annual report this year. It is an excellent document, and the labor is very, very clear. We look forward to seeing you next month, and very much look forward to seeing you in person in DC. Have a lovely day, all.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Deven McGraw: Mud and black fly season, right?

Sarah DeSilvey: Welcome, Micky!

Rochelle Prosser: Welcome Alex!

Sarah DeSilvey: And welcome, Alex! We are so lucky to have you.

Medell K. Briggs-Malonson: Welcome Alex!

Alex Mugge: Thank you! Happy to be here.

Jim Jirjis: thanks for all of your special efforts over the past 3-4 years, Micky, to jump-start TEFCA and get us to where we are. Your focus and approach has been very effective

Fil Southerland: 👏

Wendy Noboa: Register for the 4/11 HITAC meeting here: https://www.healthit.gov/hitac/events/health-it-advisory-committee-67

Hans Buitendijk: Is USCDI+ primarily meant to be supported by Restful APIs and documents (FHIR US Core/CDA/C-CDA)? Or would HL7 v2 messages used for reporting and queries be considered as well, e.g., USCDI+ PH where much is being reported using HL7 v2? I.e., is the focus of USCDI+ on query/access only, or operational reporting as well for each of the areas?

Avinash Shanbhag: USCDI+ is agnostic of actual implementation specifications; similar to USCDI. So, it could be realized using various imp. specification, not limited to FHIR and C-CDA.

Hans Buitendijk: @Avinash: To clarify, with USCDI inclusion is in part, but not only, based on maturity of supporting standards where we currently consider for USCDI query/access standards/implementation guides in particular. Should we therefore consider primarily consider query/access focused standards maturity to provide feedback for USCDI+ as well, or reporting/workflow standards maturity as well?

Avinash Shanbhag: @Hans - Certainly, comments on standards maturity is useful. We will note that USCDI+ elements will be based on agency priorities and will not be all necessarily at "Level 2" maturity. Nevertheless, as was mentioned, the goal of each USCDI+ initiative is to develop relevant implementation specifications and piloting them.

Medell K. Briggs-Malonson: Excellent approach to have specific population and health condition centered data sets. This will help greatly with addressing health inequities and improving outcomes.

Hans Buitendijk: @Avinash - Thank you! EHRA is about to submit USCDI+ PH feedback and it actually includes data that is widely used in reporting, very mature, but not yet part of USCDI+ PH. We'll keep them in our feedback to be considered for addition.

Hans Buitendijk: The new layout has been very helpful and much appreciated! I did "miss" the summary layout that USCDI has to understand at a glance the data classes and data elements for a domain. Having both, these tables and filtering capabilities, plus a summary view would make it ideal. When can we have the USCDI+ approach applied to USCDI? :)

Avinash Shanbhag: @Hans - we are exploring it , as we speak to see if we have the resources and functionality. So, testing the tool would be helpful

Rochelle Prosser: This overview was amazing

Shila Blend: Great overview

Katrina Miller Parrish: Agree the search, filter, list, query tools are so helpful!!

Jim Jirjis: can comment also

Jim Jirjis: I was going to comment on public health related items and how it impacts the hospitals

Sarah DeSilvey: We have 3 more minutes for this agenda item and I will do my best to get to the remaining HITAC member questions.

Jim Jirjis: Happy to field questions on the PH side of USCDI+. One comment was that part of what we are prioritizing si the intersection between healthcare and PH HIT-1 for example and FHIR. of course FHIR readiness depends on the use case, the maturity of FHIR currently for capabilities needed for that use case, and the adoption of mature components of FHIR and related technologies by vendors and healthcare and public health entitites

Hans Buitendijk: Considering the variety of readiness, applicability of certain data for specific use cases, and not HIT covering all data either, we have the same challenge we need to address as with USCDI on how USCDI+ can serve as a superset of data of interest, and then use the supporting standards' implementation guides, whether FHIR, CDA, v2, other, to identify the relevant subset of data that then needs to be supported.

Jim Jirjis: Hans agree. We are trying to keep USCDI+ tight and focused on actual real world use cases etc so that USCDI+ is viewed as actually useful by the tech vendors (like you)

Sarah DeSilvey: we do have to move along

Jim Jirjis: thanks for all of your work on all of this. USCDI+ has many hungry kittens that want to be fed by it

Elisabeth Myers: We have also been talking specifically with IHS and HRSA and AHRQ and SAMHSA to engage across their programs and their networks

Sarah DeSilvey: as a rural FQHC provider this is noted and appreciated.

Elisabeth Myers: also VA

Hans Buitendijk: Jim: Perhaps we need to consider though that USCDI(+) covers "all" across use cases in scope, and let the supporting implementation guides focus "tightly" on the specific data set needed for that individual use case/interaction set.

Elisabeth Myers: Thank you, Hans, for the suggestion. That is the type of approach we are exploring.

Jim Jirjis: yes agree that is the plan

Shila Blend: My HIE has worked closely with public health for many years. During HITECH we were able to assist in costs for providers to contribute additional data types. The discussion that has been occurring now especially in a rural state is how we as HIEs along with public health incentivize providers or assist with cost burden for data interfaces etc. The data is important but as mentioned those that have limited resources or even are on paper, we need to find a way to assist.

Elisabeth Myers: Great point, Shila. We agree that the HIEs/HINs could have a significant role in advancement of USCDI+ adoption and use too - including for use cases expanding beyond care coordination. We envision the data set and related specifications being user agnostic - and that balance of policy construct (baseline of information to share, capture, etc.) technical construct (technical implementation specifications) will hopefully help HIEs/HINs and similar organizations to be part of the bridge for parts of the continuum that have not been able to connect previously

Katrina Miller Parrish: Great discussions! Thanks to our leads!

Shannon Vogel: Is there a link for the USCDI+ Cancer Summit mentioned earlier?

Rochelle Prosser: +1 Shannon

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HITAC Webpage
HITAC - March 7, 2024, Meeting Webpage

Transcript was approved by Wendy Noboa, HITAC DFO, Medell Briggs-Malonson, HITAC Co-Chair, and Sarah DeSilvey, HITAC Co-Chair, on 3/20/2024.