Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

June 13, 2024, 10:00 AM – 12:40 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
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Ciitizen
Katrina Miller Parrish, Patient.com
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
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Hung S. Luu, Children's Health
Aaron Neinstein, Notable
Mark Sendak, Duke Institute for Health Innovation

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, Designated Federal Officer

PRESENTERS

Katie Tully, ONC
Rob Anthony, ONC
Jeffery Smith, ONC

Ashley Hain, ONC
Mark Knee, ONC
Zoe Barber, The Sequoia Project
Desiree Mustaquim, CDC *(Discussant)*

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

Seth Pazinski
Good morning, everyone, and welcome to our June 2024 HITAC meeting. This meeting is open to the public, as a reminder, and public feedback is welcomed throughout. Comments can be made in the Zoom chat feature throughout the meeting and can also be made verbally during the public comment period that is scheduled towards the end of our meeting at about 12:30. So, let's get started with our meeting, and I would first like to welcome our ONC executive leadership team who is with us today, so we have Steve Posnack, who is our Deputy National Coordinator, and Elise Sweeney Anthony, who is our Executive Director of the Office of Policy, and we also have Micky Tripathi, who is our National Coordinator for Health IT. And then, I will begin now with a roll call of the HITAC members, so when I call your name, please indicate that you are present, and I will start with our co-chairs. Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Good morning. Sarah DeSilvey?

Sarah DeSilvey
I am here.

Seth Pazinski
Shila Blend?

Shila Blend
Good morning, everyone.

Seth Pazinski
Good morning. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Michael Chiang?

Michael F. Chiang
Good morning, present.

Seth Pazinski
Good morning. Derek De Young? Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Good morning. Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Seth Pazinski
Good morning. Steven Hester?

Steven Hester
Good morning.

Seth Pazinski
Good morning. Bryant Thomas Karras?

Bryant Thomas Karras
Present and accounted for.

Seth Pazinski
Thank you. I did get a message that, unfortunately, Hung Luu will not be able to join us today. Trudi Matthews? Anna McCollister?

Anna McCollister
Good morning.

Seth Pazinski
Good morning. Deven McGraw?

Deven McGraw
Good morning, everyone.

Seth Pazinski
Good morning. Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Aaron Neinstein? Eliel Oliveira?

Eliel Oliveira
Present.

Seth Pazinski
Good morning. Kikelomo Oshunkentan? Randa Perkins?

Randa Perkins
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Good morning.

Seth Pazinski
Good morning. Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Mark Sendak? Fil Southerland?

Fillipe Southerland
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. And now, I will go through our federal representatives of the HITAC. Keith Campbell?

Keith Campbell
Good morning.

Seth Pazinski
Good morning. Jim Jirjis?

Jim Jirjis
Good morning, present.

Seth Pazinski
Good morning. Meg Marshall? Alex Mugge?

Alex Mugge
Good morning.

Seth Pazinski
Good morning. Ram Sriram? Okay, is there anyone that I missed or who joined a little late that wants to announce themselves? Okay, with that, then, please join me in welcoming Micky Tripathi and Elise Sweeney Anthony, who are going to give some opening remarks. Micky, over to you.

Welcome Remarks (00:04:08)

Micky Tripathi
Great, thanks, Seth, and good morning, everyone. Thank you for joining today's Health IT Advisory Committee. We have a bunch of really exciting stuff to talk about, as usual, in the meeting today. I am very excited about the discussion of the United States Core Data for Interoperability (USCDI) Plus (+) for Public Health. We talked last time about maternal health. Just as an aside, the USCDI+ for Maternal Health data elements are open for comment for 60 days, so if you have comments there, please weigh in. We appreciate any and all input from HITAC members and the public at large. USCDI+ for Public Health might be the first, if not one of the first two, of our USCDI+ initiatives that has been a tremendous collaboration among ONC, Centers for Disease Control and Prevention (CDC), jurisdictions, and other stakeholders to help us to, as the USCDI+ effort in general is doing, say how we build additional, more specific use cases on the core of the USCDI that allow greater integration.

In the case of public health, I think one of the goals that we and CDC have been working very closely and very hard on is to say how we get better integration between public health and the healthcare delivery system, first and foremost, that those are not living in separate silos, they are just different aspects of the healthcare ecosystem. That is one of the goals we want to be able to accomplish there. How do we get better, higher-quality, more reliable, and more accurate data for public health reporting?

I think the USCDI+ initiative is directly in support of both of those things to say how we leverage the standards and the types of data that are already required to be supported by the healthcare delivery system,

both providers as well as the electronic health record (EHR) developers that support them, and then, how we think about additional data elements that are more public-health-specific that can be tethered to that USCDI core, but can be used for public health reporting in a way that makes sure that the base is the base, and that applies across all use cases, whether it is public health, quality, or just healthcare delivery, but that we have these data elements that are tethered to that core, and being able to build a maturity pipeline the same way that we do with USCDI to say how we add those through a process of collaboration and standards maturity in a way that gives everyone a good expectation of how those can be built and how those can be matured, but it also helps serve the needs of greater alignment in the data requirements across our public health ecosystem.

Right now, I think as all of you appreciate, we have too much heterogeneity across the public health ecosystem, too many differences between jurisdictions about the data standards that they require, some of which, though not all, perhaps, because it is a jurisdictional authority, and hopefully most of which can be ironed out with a USCDI+ for Public Health initiative that takes into account the base that everyone across the country is required to support, builds on top of that, and then allows for jurisdictional alignment around that. The incentive for that, I think, would be that they would have a much greater chance and much greater ability to be able to get higher-quality data for more sources if they do it that way, rather than continuing to ask for unique data elements that are harder and harder for providers and EHR vendors to support. So, Katie Tully is here, who has been leading all of our efforts with CDC, which is just one dimension of the efforts we have with the CDC, so I think that is going to be a great discussion.

The other thing I will mention, because it is also very timely here, is Trusted Exchange Framework and Common Agreement (TEFCA). We are advancing very aggressively, as we have been from the beginning, with TEFCA, and one of the areas that I think has been incredibly gratifying to watch and is a testament to the CDC team, the ONC team, and our jurisdictional partners, and I think Jim Jirjis is on the call, and he can hopefully speak to this as well, and it is a testament to him and all the great work that they have been doing, but we have jurisdictions now who are going to be starting to go live on TEFCA-based exchange this summer, and there is a queue of organizations and jurisdictions who have interest in it and who are stepping up and partnering with CDC and ONC to be able to go live on TEFCA for TEFCA-based exchange.

I think that is an amazing testament to the dedication of everyone to be able to make nationwide interoperability more real, and to making our public health system and our public health ecosystem better and more able to be responsive to the needs of the country. So, we are really excited about that. Again, it has been a lot of hard work and continues to be hard work. The CDC has put money on the table as well to help support those jurisdictions who want to move forward to provide them with resources, both technical and financial, to help them with that implementation. So, we are really grateful to those organizations, and we will have more to come once we have those firm announcements in place, but that is just to give you a sense of how much really good, exciting work is going on there that may not be apparent to everyone.

The last thing I will mention, since it is certainly another exciting development for the ecosystem at large and certainly for ONC, is that, as many of you may have seen, I have been named the Health and Human Services (HHS) Acting Chief Artificial Intelligence (AI) Officer, part of which was to fill a requirement from the Office of Management and Budget (OMB) that every cabinet-level department have a senior-level chief AI officer, but it also starts to allow us as a department to really be able to exercise the policies and our

strategies regarding AI in a strategic manner across all of the agencies and across all of the activities that go on across the department.

So, we will have more to share as we start to align the resources to make sure that we can execute on all of those requirements that are both internal federal government requirements as well as working on the HHS AI strategy, which we are working on this year and anticipate being able to release in the very early part of 2025. So, there is more to come on that, but I just wanted to flag for all of you our Federal Advisory Committee Act (FACA), who are very close to us. A whole bunch of that has relied on and continues to rely on the expertise, experience, and real collaboration that we get from all of you, so I really want to thank all of you for everything you have done to date and for the ongoing engagement. Let me turn it over to Elise Anthony now. Thank you.

Elise Sweeney Anthony
Good morning, everyone. Thanks, Micky. I just have a few updates for folks to keep in mind, and also for me to express my thanks on as well. First, I wanted to give folks an update on the Leading Edge Acceleration Projects (LEAP) Initiative. This is a program that we have in place where we seek applications to fund certain types of projects that are really leaping forward, the leading edge. In this case, we have been seeking applications on developing ways to evaluate and improve the quality of artificial intelligence tools and healthcare, but also accelerating adoption of health IT and behavioral health settings. Thank you to everyone who has taken a look at that. The application period closed yesterday **[Amendment: The application period closes on July 12, 2024, at 12:00 PM ET. All questions about this opportunity should be submitted to ONC-LEAP@hhs.gov.]**, so there is more to come, and we look forward to the next steps for LEAP. If you are interested in finding out more about the program, you can check out HealthIT.gov, and we can drop a link in the chat as well.

I also wanted to give thanks for all of the feedback that folks have provided on a range of different initiatives lately, including the draft 2024–2030 Federal Health IT Strategic Plan, the 2024 Standards Version Advancement Process, or SVAP, as well as ONC's Advancing Health Equity By Design whitepaper. All of your feedback is greatly appreciated. It is so important for us to be able to hear what is happening on the ground and the impact that the work we are considering could have in your daily engagement with patients and providers across the care continuum, so, many thanks to the HITAC members, as well as the public, for providing that feedback to us.

I also want to highlight what I think is a great way that ONC shares activities and initiatives that are happening in our space, and that is the Health IT Buzz Blog. There are a number of blogs we have done recently that I want to point your attention to, but definitely check out the website, where you can see a range of different issues and projects that we are engaged in and what we are thinking about on certain activities. One that I did want to highlight is Interoperability Standards Advisory (ISA). So, we are at a decade of ISA, the Interoperability Standards Advisory, and we are excited to receive your feedback on that. The comment period is going to be open from yesterday, June 12th, to August 12th, so please do take a look at that. We are really excited about the new platform as well, the Interoperability Standards Platform, or ISP, so take a look at that as well. It is really important. ISA is a big part of our work and an important part of our standards initiatives, and when you think about USCDI, SVAP, and USCDI+, ISA is another piece of our standards work that is a really important part of engagement, so we look forward to feedback coming in there as well, and there is a Buzz Blog on that to check out.

I also want to note that Melinda Kidder, who is our Chief Nursing Officer, released a blog recently on a nurse's perspectives on our recent Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) rule, so check that out. Micky also released a blog on reminders regarding how the information-blocking regulations recognized privacy rules, and that would include the recently released the Health Insurance Portability and Accountability Act (HIPAA) privacy rule to support reproductive healthcare privacy. So, that's another great one to check out, but as I mentioned, there are a number of blogs on our website that are great resources to really see what is happening at ONC as well. If you have any questions or want to take a look at those any more, check out HealthIT.gov, and we will drop the link in the chat as well. With that, I am going to turn it over to Medell and Sarah for opening remarks.

Opening Remarks and Review of the Agenda (00:15:09)

Medell Briggs-Malonson
Thank you so much, both Micky and Elise, for some of those amazing updates, and good morning to everyone. It is such a pleasure, as always, in order to convene HITAC. As Micky mentioned, we have several different exciting topics we are going to speak about today, and congratulations, Micky, on your new appointment as well. So, before we actually dive into the meeting, I do want to give a quick update about the Annual Report Workgroup (AR WG). We have officially launched the Annual Report Workgroup, and we have actually extended the workgroup this year. We have now gone up to 11 members. One of the things I do want to highlight is that we have a brand-new co-chair, so I want to extend a sincere congratulations to Eliel Oliveira, who is now the new co-chair for the Annual Report Workgroup, and we look forward to working together over this entire year.

Now, one other update to give to you all is that we are on a little bit more of a condensed timeline in order to get the report finalized, sent to Micky for approval, and then to Congress by the end of the year. This annual report is still going to focus on the five primary target areas that are defined in the 21st Century Cures Act, which of course include health equity, public health, interoperability, privacy and security, and patient access, but we are also going to incorporate a fair amount of artificial intelligence into this year's annual report, so please, if you have any topics that you would like to be considered in the annual report, please send those to Seth, as well as to the rest of the Annual Report Workgroup, as soon as possible so that we can get those incorporated into all of our additional discussions. There are going to be more updates, and we are going to provide an official update starting next month during our July HITAC meeting, but I wanted to give you a little bit of a preview of what the Annual Report Workgroup has been doing. So, with that, after this update, I will then pass it on off to Sarah to give her opening remarks, and also to review today's agenda. Sarah?

Sarah DeSilvey
Thank you so much, Medell. It is my honor to be here with you all today. I am super excited for the agenda. One thing I noticed as we were prepping for this call was all the different turnovers, changes, graduations, and events that are happening across the ecosystem, including new positions, so there are exciting times all around. Next slide. We will run through the agenda, and then we will transition to the next topics of the day. It is really exciting to lean into our agenda because it has a topic near and dear to me and many on the committee, and that is USCDI+ and Public Health, our first content topic of the day, starting at 10:20, right after the agenda reading.

We will then go into a brief on the ONC health IT certification program resources update, and we are looking forward to that, and then, as Micky mentioned, we are going to have an update on TEFCA, which should be very exciting. This is a really great meeting today. We will have our public comment start at 12:30, and then we will close at 12:40. Again, our primary topics are USCDI+ and Public Health, the ONC health IT certification program research update, and TEFCA. We are all so glad you are here. We are looking forward to really robust conversation. We had a great meeting last time with lots of time for you all to add your insight, import, and presence into the topics of the day, and we are looking forward to having that again. We have been very careful to give enough time to these topics. Over to Medell to introduce our first speaker.

Medell Briggs-Malonson
Thank you so much, Sarah. Without further ado, we are going to dive directly into the USCDI+ Public Health topic update by Katie Tully. Katie?

USCDI+ Public Health (00:18:43)

Katie Tully
Awesome, thank you, and thank you all for having me today. I am going to go off video after the intro just because I am still in Pittsburgh after the Council of State and Territorial Epidemiologists (CSTE) conference this week, where I got a chance to connect with a lot of our public health HITAC colleagues, Dr. Jirjis, and Dr. Karras, and really heard a lot around the topic, so the timing of this is really exciting. Next slide, please.

I will say that Micky did a really great job at introducing the topic in his opening remarks. He stole my thunder a little bit with the remarks I had planned, but just in terms of an overview of how we got here today, as Micky mentioned, USCDI+ for Public Health was one of the first domains that we explored the whole USCDI+ process with, along with our quality colleagues, and really, with USCDI+, we have come a really long way, I would say, in terms of collaborating with CDC in particular to really define what it will mean to align the work that is happening around expanding USCDI to the work that CDC is doing on data modernization.

As Micky mentioned and as a very quick reminder, USCDI+ is really intended to extend beyond what is represented in USCDI. When we were going through the initial rounds of USCDI, we were getting consistent feedback from both CDC and our public health colleagues that there are needs and benefits that need to extend beyond. So, while harmonization around USCDI is really important, public health really needs a lot of information in order to adequately respond to an emerging public health threat, and the concepts of standardization and harmonization across different programs and disease silos really are needed to help set us up for our next response.

So, with that, USCDI+ Public Health was established. When we first launched this program, as you will see when I get into what we are working on in the next slide, we had a very different conceptualization of the use cases under the domains, and now, after a few years of collaboration with groups included on this call, we have really come up with a more streamlined set to inform future directions. Next slide, please.

And so, with that, right now, we have been working really closely, again, with CDC to really focus in, if you look on the bottom right of this slide, on data sets that are informing CDC's minimum data necessary efforts. The data sets that you see there came out of recommendations from their own FACA, the advisory

committee through the director, which I think was the Data Standards Workgroup, though my CDC colleagues can correct me if I am wrong on that. That came out of a series of recommendations there where they charged CDC with really looking at the core data sources needed to respond to an emergency, and really, that is focused particularly on the early stages of a public health response, so we were focused on getting timely, available data for decision making, so, really thinking about the bare minimum that we need in order to respond to a threat across all these different data sources.

And so, CDC has been doing a lot of work to really look across programs and coordinate with state, local, tribal, and territorial public health colleagues to try to identify **[inaudible] [00:22:39]** that we need to really hit the ground running so that if there is another threat, such as COVID-19 or something that we have not thought of yet, they can really avoid having to do a lot of that harmonization/standardization work then and be able to hit the ground running and have the data already in their hands and at their fingertips in order to respond. And so, at the direction of and in collaboration with CDC, we have really shifted our strategy for USCDI+ Public Health to more directly align with the Minimum Data Necessary (MDN) work. I do want to call out my colleagues from CDC. Desiree, who is on the line, is also available to answer any questions about the MDN efforts and has been a great colleague in this effort.

So, really, with USCDI+ Public Health, our intention is to be able to pick up the work that CDC is initiating, and then make sure that every one of these concepts that are represented for minimum data necessary is also available for exchange or has available standards so that, again, the next time there is a threat, a lot of the work to come to consensus around doing the pre-work now for how we actually get this data electronically from healthcare or other partners so that, again, if we need to really move quickly, we have that data available electronically ahead of time.

And so, really, our goal for USCDI+ Public Health for each one of these use cases under the domain is to build out an additional core around the minimum. As I mentioned, as CDC is going through their efforts, we are really focused on the absolute minimum data elements, and we recognize that when that translates into a standard for reporting or when that translates into other efforts needed at the state or local level to inform a response, there are going to be additional data elements that are needed. And so, really, for USCDI+, for each one of these data sets, we are planning on picking up the work that CDC is doing, incorporating those data elements into our data sets, and then building out some data elements around it, and then, really going through the process up in the bottom left to go through, collect comments from additional partners from STLT partners as well, and really iterate on the process.

One thing to emphasize and one of the benefits of USCDI+ as a whole is that we can move a bit more iteratively and rapidly to develop these data sets and collect feedback along the way. Right now, we just finished a comment period in April for case and lab reporting. We are kind of at the stage of looking at comments and figuring out if we need to cut out another version of these data sets and collect additional feedback in order to iterate. At this point, it looks like we probably are going to want to do that for both case and lab data exchange. Again, we are really going through this cycle multiple times to really think about how we get these data sets right before moving this forward in the standards.

For public health, we are planning on going through a versioning process to release different versions. We are still working through the exact terminology of what that will be, but if we look up at the timeline at the top of the slide, this is going to be our immediate focus for the next little bit. As I mentioned, right now, we

are working on developing the data sets around case reporting and lab data exchange. We are working with our CDC colleagues around the case work to also think through a bunch of different efforts that are going on around case notification, including some really great work happening through the CSTE Data Standards Workgroup where they are going through, data element by data element, and digging through what they need represented there. Again, we are working with those colleagues to really make sure that what we are representing there is harmonized and is what we need it to be.

So, really, over this next year, we are going to be really focused on getting case and lab data sets finalized, probably through another comment cycle as well, and then, quickly on its heels, there have been a lot of conversation and work being done around the healthcare capacity and utilization data, and there are colleagues from the Administration for Strategic Preparedness and Response (ASPR) who have been thinking through a lot of these sections as well, so I know that, right now, we are kind of in the early exploratory phases and our CDC colleagues are going through the effort of really starting to think through that data set, so we are hoping that, early next year, we will have some data sets to click on. Next slide, please.

And so, just to speak a little bit more to priorities, as I mentioned, we have been working with CDC. Over the next year or two, we are going to be pretty laser focused on going through each one of the core data sources and building on the MDN to establish data sets that USCDI+ can support. After we establish these data sets, our goal is to then partner with our colleagues from the standards development space to make sure that each one of these concepts has representative dictation standard sets available for exchange.

One thing I will also mention as well is that we have heard a lot of feedback from our STLT partners that there may be data sets that expand beyond where the core data sources are, so, over the next little bit here, I do think we are also going to be thinking through. Once we get through this exercise of going through the core data sources, how do we establish a process to have some consensus from the public health community as a whole to drive future data sets? That is one thing I always like to mention, that we are trying to really represent the core and make sure we are getting that right, but in the future, we do want to make sure we have a process to respond to other needs from public health. Next slide, please.

And so, just to summarize where we are and where we are going in the next immediate bit, as I mentioned, we just closed our comment process. I always say “just,” but at this point, it is June already, which is shocking. The comment period closed on April 5th. We did receive a lot of comments that we are really excited about, so, thank you to anyone on the line that submitted a comment. Right now, we are going through the process of going through all these comments, and just in terms of scope, I think we did some analysis, and through USCDI, we usually receive around 400 or 500 comments, depending on the topic, and so, getting almost 400 comments from public health is really exciting and just shows how engaged everyone is in the space.

And so, we received these comments across 14 organizations, which was a lot of representation from different groups, which I was also really excited about. There were public health associations, and we also did get some feedback directly from public health agencies, which we are really excited to receive, and really also shows there is a lot of work that’s happening at the state, local, tribal, and territorial level right now, but there are also established data governance processes, and I know some are looking at USCDI and USCDI+ as the starting point for some of those data governance conversations, which is really exciting.

As I mentioned, right now, we are also in the process of really thinking through what is going to be our process. Once we have these data sets, how are we going to hand this off to our standards development colleagues in a meaningful way to get them tied to the standards? I know that we are in active discussions, we are trying to establish a process, and next time we come, we will have an update on that. Next slide, please. With that, I am done with my presentation. Thank you all for having me today. Obviously, I am very excited about the work and very excited about the engagement we have had from the HITAC to date, so, thank you.

Medell Briggs-Malonson
Well, thank you, Katie, for providing us with this very informative overview. What we tend to see in the near future is that public health is very near and dear to many of our hearts here on HITAC, and I know that there have been some great questions in the chat, so I encourage the HITAC members to come off mute and raise their hands. Let's go ahead and ask some questions to Katie. I first see Zeynep.

Zeynep Sumer-King
Hi. Thank you so much. This is so exciting, and I am so grateful that it is happening. Micky touched on this, but I guess it is more of a comment. I would love to think about how we as HITAC, but also as the CDC, engage states that are not currently part of the discussion or that are not looking for this kind of federal standardization. Just as an example, here in New York, as hospitals, we still continue to submit 80-plus data elements to New York State, and have since the early days of COVID, and I am not sure that it is useful data or that it is being used, and that is not intended to be a criticism.

I think there is an effort to really do something with that information, but I think a standard data set is exactly what we should be working towards. I am just not sure there is enough awareness of or engagement in the process as we would like. I am glad there were some comments from jurisdictions, but more is probably better to inform the USCDI development in general so that it does meet the needs of the jurisdictions and the states, not just the CDC. I think we need to meet all of them. But I stand ready and have been trying to figure out how we lead that engagement, so I would love your thoughts, too.

Katie Tully
I am really glad you raised that because it definitely something that is top of mind for us a lot of times. I think in reality, on a state and local level, with a lot of the folks that are engaged with data modernization, there has been a lot of progress to hire new staff, but there is still a reality where, most of the time, people are wearing dual hats, as an epidemiologist who is also taking on the informatics role. And so, I really think the challenge there is resources. The reality is if I have an hour to complete a disease investigation versus joining a federal advisory call, not that I am calling out this call, it is going to be a challenge to engage, especially for lower-resourced jurisdictions.

I do want to emphasize the role of the public health associations here. I have mentioned the Data Standards Workgroup that CSTE is leading, and I have been really impressed by that effort. They get a lot of representation and a lot of active discussion on the data element level in those calls. I have been working with CDC and CSTE to really figure out how to better harmonize with those groups and to leverage those existing groups to inform updates to these data sets, because I agree. We cannot just be getting feedback

from 10 states. We have to make sure they are really thinking across the whole gamut of public health because these requirements will ultimately impact them, so thank you for raising that.

Medell Briggs-Malonson
Thank you both for that question and answer. Bryant, you are up next.

Bryant Thomas Karras
Katie, thank you, first, for a fabulous update, and I really want to thank you, ONC, and our CDC colleagues for showing up and meeting the state, local, tribal, and territorial folks where they are. Coming to the CSTE meeting is a great show of respect and gathering of the process on the ground where we are doing our work. Today, as we speak, the state and territorial epidemiologists from every jurisdiction are voting on what conditions should be reportable to CDC. I think many people in our country do not realize that that is a state-based authority and process that determines what gets reported up the chain to CDC. In fact, the council had to have an emergency meeting in order to vote COVID-19, before it was even called COVID-19, as a reportable condition to share that data with the CDC.

So, coming to that meeting was really important to show that you are engaged in understanding what the data needs are on the ground for public health practice, not just national authority. I think it is super important, and I think it will be a process. I totally agree with and hear what you are saying, that it cannot just be the 10 most capable states that provide comment and feedback into that process. We need to figure out how to solicit input from others, and that may involve supporting those states, territories, and our partners on the tribal side in getting the resources they need to have people with the time to think about this re-envisioning of the data ecosystem, so I am looking forward to it.

Medell Briggs-Malonson
Thank you, Bryant, for those comments. Ike?

Steven Eichner
Thank you, and I just want to echo what Bryant said about the appreciation and commitment of ONC to attend things like CSTE. There were about 3,000 epidemiologists and related folks here in Pittsburgh over the last couple days, so the attendance was very much appreciated. Can you talk, just for a moment, about collaboration input between public health and healthcare providers about building the data set and building the resources? Really, thinking about the collaboration and looking at the data supply makes it a whole lot easier to update and get the data that we need, so what can we do to foster collaboration about getting good input from healthcare providers in getting to a better and more useful data set?

Katie Tully
That is a great question. I think there are a couple of different ways we were thinking through this. First, throughout the process, we have been really mindful in engaging our healthcare and developer community because I do think making sure that the work that is being done by public health to identify the minimum, getting feedback from healthcare and vendors along the way to make sure they can provide that information, and that is the way that public health is conceptualizing the information, aligning with that. It is really important.

This week, in one of the presentations I saw, I think I heard someone reference how sometimes, on some of these data elements, there are just different ways that healthcare and public health conceptualize the information. Again, having those conversations and getting that feedback captured from both sides is really important. Moving forward, we have thought about if there are areas where we need to be holding more focused calls or more focused engagement to have direct conversations between both sides, and as we have been reviewing the comments, I do think that need has become apparent on a few of these. Again, there are no plans right now to hold some of those more focused webinars, but it is something we have been thinking about pretty actively.

Steven Eichner
Thank you so much.

Medell Briggs-Malonson
Thank you, Katie. Thank you, Ike. Now, I noticed there were some additional questions in the chat, and especially Eliel, I noticed you mentioned something in the chat. Do you want to ask that question right now? I am putting you on the spot.

Eliel Oliveira
Sure, Medell. I think that is something that we all saw, and it may require some standards consideration around a home test. I know we have an open comment period there, but I think it is so large in terms of how to define and can touch so many areas and risks that individuals, like during the pandemic, whether they believed or not that there was a pandemic, may be infectious and spreading the contagion to others. It is a big aspect in my mind. If we are doing a home test, how can we validate how the data flows back somewhere to be able to see the spread, and what strategies will be put in place? I would love to hear if there is anything that is being looked at with that, not only from a USCDI standards perspective, but overall, a national strategy on how something like that is going to be addressed, because we could be faced with another pandemic, and home tests would become another important aspect of that management.

Katie Tully
Great. So, one question that we asked around this data set when we put it out for comment from the lab data exchange was asking for feedback on the use cases that would be important. The data set that we put out for comment was pretty narrow and really minimum, and so, we were recognizing that and realized we just needed to build it out. It is just that lab, in and of itself for public health, expands across a lot of issues, so we did want to make sure we were being cognizant. That is just to say that I do think thinking through a home test as a part of that landscape is really important. I know there has not been a lot of standards development in that space through some Implementation Guides (IGs) that were established, so we will definitely consider that as an input. I do want to put my CDC colleague Desiree, who is on the line, on the spot. Desiree, in terms of feedback that you have had on the CDC side, I would love for you to weigh in with perspectives on that question as well.

Desiree Mustaquim
I think Bryant has some stuff to contribute as well. I think that this is on our radar. We know it is a concern. We have some tools in place that have been trying to figure out how to get lab data from nontraditional sources, so that might be a good group to approach about getting better about this, but yes, I have done national lab surveillance for many years before coming to the PSD, so I know the importance of this, and I

hear you. There was so much change during COVID that I actually have to have a little catch-up about some of this stuff, but I think Bryant knows a lot about this and can add a little more.

Bryant Thomas Karras
I think that it is something that was not really the focus in this USCDI+ engagement. The prompts were not there. It was more traditional laboratory data streams that were focused on for the USCDI+ comments. Eliel, I think you make a very good point, and maybe in the next circular round that Katie was talking about of coming back for more feedback, there is an opportunity to expand the scope to those home test kits, which we were in the middle of exploring in our state with the NIH RADx program, which I think has been renamed as an organization, so I will have to fact-check that for the record, but the RADx program was working on data collection from individuals through nontraditional data collection means, such as the exposure notification apps that were on everybody's phones in many states across the country. It starts to become a really good source of plus outside of healthcare data that could inform decision making.

Medell Briggs-Malonson
Thank you. Eliel, thank you for that important question. As we know, as our entire ecosystem continues to evolve, home-based tests, as well as other types of nontraditional tests, are continuing to make their emergence, so, thinking about the importance of that, especially in the area of public health, and the interoperability between all of our public health agencies, as well as all of our health systems, is going to be incredibly important and key, so, thank you, and thank you for all the responses. Anna, I see your hand.

Anna McCollister
This is not my point, but I would argue that home-based tests are important to include regardless of whether it is within the context of public health. It is health. We have more and more tests being done at home, so we need to figure out a way to get that incorporated into USCDI, whether USCDI+ or regular. On a related note, my question is about lab values. Obviously, lab values related to testing positive for a particular virus, bacteria, or whatever are important, but does this also include important other lab values, such as potential inflammatory markers, lab values around comorbidities, and other things? That is one thing that USCDI is currently lacking, any presence of lab values.

Desiree Mustaquim
This is Desiree. I posted the description of the USCDI+ laboratory data exchange use case, and it was very broad, and it was not focused on any particular type of value, so if it applied to the public health domain, then it would be fair game to me. We did not specify particular Logical Observation Identifiers Names and Codes (LOINCs), Systematized Medical Nomenclature for Medicine–Clinical Terminology (SNOMEDs), or any particular topic, other than if it fell within that description. That is how we gave our feedback on this use case.

Anna McCollister
Awesome, thank you.

Medell Briggs-Malonson
Thank you, Anna. Ike?

Steven Eichner

I think it is also important to consider the self-contained laboratory kits that may also be used in physicians' offices, quick clinics, or things in that space that go beyond what has just been traditional lab work, with data ending up in a laboratory information management system, and a more traditional EHR. We have to think about how we want to accommodate data from those testing environments as well, so it is not just home kits.

Medell Briggs-Malonson
Absolutely. Great point. Thank you for that. Ike, is your hand up again?

Steven Eichner
Sorry.

Medell Briggs-Malonson
That is okay. Any other questions or comments? I am also going to ask our Accel team to see that all of our speakers are ready for the next portion, but are there any other questions or comments?

Bryant Thomas Karras
I will put it in the chat, but to the point-of-care test kits, I think CDC has some strategies for an easy report mechanism to gather test results in settings like schools, workplaces, and even clinics that do not normally do testing onsite, but are suddenly asked to do so. Having an easy mechanism for their results to get into the ecosystem is a great idea.

Medell Briggs-Malonson
I completely agree in every way. As we know, public health and overall healthcare is transforming so quickly, so as much as we can capture all of this data, and especially as we are going to meet people where they are, that is so much better in terms of making sure we are transferring the correct information to everyone who is providing care services. Michael, I see your hand.

Michael F. Chiang
Medell and Katie, thank you so much. I am not sure if my question is out of scope, but the premise of my question is in some ways, I think public trust in government and in science and health is about as low as I have seen it in my career, and I am just wondering if it is considered part of USCDI+ Public Health to deal with these issues. In other words, what should motivate people to want to submit, especially if these tests are coming from home? We had a lot of "If I submit, maybe I will be forced to do whatever." I would just love to hear your comment about that if you have one.

Jim Jirjis
Hey, it is Jim Jirjis. Can I comment on that?

Medell Briggs-Malonson
Go ahead.

Jim Jirjis
I think you are absolutely correct that what we are focusing on here is the language with which we capture and communicate information as we share it and use it. The incentives for people to actually participate is

what you are talking about, and that has been eroded somewhat by the national discussion about public trust, but it is really necessary, but not sufficient, that we do this USCDI/USCDI+ work so we know how to communicate and represent the information. It is a challenge we all have to address adoption, collaboration, and participation. Go ahead, Bryant.

Bryant Thomas Karras
Oh, finish your thought.

Medell Briggs-Malonson
Yes, Jim, finish up. Great points.

Jim Jirjis
I wanted someone with certainty to talk. Absolutely. There are a host of different reasons, not just COVID, that there is a national discussion about trust in how much people want state or federal government actually having access to information and for what use, so those are really important points where we have lots of work going on. I see Bryant is commenting as well.

Medell Briggs-Malonson
Thank you, Jim, for those comments, and especially Michael, because that is a very important observation that we have across the entire continuum, so, thank you, Jim, for responding to that as well. Bryant, I think you will be the last comment before we start to transition.

Bryant Thomas Karras
Sure, and Michael, I can follow up with you on this offline. I hope my career is long enough that we see the resurgence of trust in governmental public health. We actually contracted with the University of Washington to do focus groups, and did a survey of nearly 3,000 people to try to understand, of the people who did not want to report their home test results to us, why they did not and what we could do to improve the situation. We had built a cryptographically secure deidentification process so that people could report, and I would have no way of tracking who or where they were, and people still did not want to do it in some areas of our state, so I think there is some work to be done to figure out how to regain that relationship with the public. Thank you.

Medell Briggs-Malonson
Thank you, Bryant, and thank you for that insight. Okay, Rochelle, I am going to take you, and then we are going to transition to the next section as well. Rochelle?

Rochelle Prosser
Thank you, Bryant, for raising that specific key trust factor from patients. As a woman, certain states, unfortunately have different policies that require protection, and I thank Mr. Tripathi for definitely protecting those vulnerable populations in the use of those data. So, I wonder how we go forward to further codify looking at government response versus certain climates that we have nationwide to help protect the privacy and private use of patient data in ways that are punitive and building algorithms that would potentially expose people.

I think recently, the American College of Radiology (ACR) actually asked for non-cancer-patient women, only African-American, to look at a study of allostatic load and stressors, and that was very concerning to me because it is a cancer organization, but they want to ask for people's keys to the kingdom on their health record who do not have a cancer history, and there was no clear use to the strategy protection after it was done for what process was going to be identified. So, there could be inferences that are made in one classification of a population because they are so segmented that would include everyone else. Honestly, I think stress is an equal opportunity offender, not just for one population.

Medell Briggs-Malonson
Thank you so much, Rochelle, for that comment. Of course, this goes much further than what we were discussing with USCDI+ Public Health, and I think what you are referring to really goes into one of the primary target areas that we are also charged to look at in terms of privacy and security of our patients, but also health equity, and I think we are and should be providing our feedback on the topics that you brought up in all the areas that you just mentioned, but also reproductive health and so many others that we know, that there has been this emergence, and really thinking about how we safeguard our patients' data, as well as their overall care, in different ways.

So, I highly encourage you to elevate that topic to the Annual Report Workgroup so that we can further discuss that and peel back the layers, especially because it does fall very nicely within one of the target areas that we do focus on as HITAC, so, thank you for that comment. With that, I want to sincerely thank Katie, as well as Desiree, for this wonderful discussion about USCDI+ Public Health, and, of course, all of the amazing comments that came out during this discussion as well. We look forward to seeing the next evolution of this, and also providing any additional feedback that we can as HITAC. In this moment, we would like to proceed into another incredibly exciting point and area, and that is the ONC health IT certification program resources update, and I would like to introduce and bring to the virtual stage Rob Anthony, Jeffery Smith, and Ashley Hain. Rob, I guess we will start directly with you.

ONC Health IT Certification Program Resources Update (00:56:16)

Rob Anthony
I am actually going to pitch it to Jeff Smith, our deputy. Jeff and Ashley Hain are going to walk through a couple of different major areas of updates and releases for health IT certification program, including, I think, some areas of great interest for decision support intervention and some of the testing toolkits that we have released, so I will go immediately to Jeff.

Jeffery Smith
Thanks, Rob. In fact, I am going to pass the baton over to Ashley, as her slides are up first. Ashley is the branch chief of our tools and testing branch, and she has a few slides that are going to highlight some of the test tools that we have and an announcement about some new tools that we are bringing online. Ashley, do you want to go ahead and take the mic?

Ashley Hain
Sure. Thank you, Jeff and Rob, and good morning, everyone. If we can move to the next slide, I will just be providing a quick overview. We have the Inferno test tool for our ONC certification program. This tool supports Fast Healthcare Interoperability Resources (FHIR) standards and associated implementation guides, and we have it as open source, so the entire community can download and use this testing tool,

but we also host all of our certification program tests related to our certification program that are in the FHIR states. So, our G10 patient and population services test kit is directly in ONC certification, and that is what health IT developers certify to. Let's jump to the next slide, please.

So, for our specific certification program test kits, we have a general G10 test kit that includes all aspects of our certification criteria for G10, so it combines the SMART app launch, bulk data, and US CORE, and it behaves like an Application Program Interface (API) consumer and exchanges real-world client situations and testing, but we also have a standalone test kit for USCDI and multiple versions of USCDI, as well as the multiple versions that we have for the SMART app launch. If we could move to the next slide, in addition to our certification program test kits, we also have a few test kits that we have just to support the FHIR community. They are not required in certification, but they have been freely available on the Inferno framework test tool, so developers can use that and try to test and utilize those test kits to try to inform IG implementation as well as real-world testing. Those include UDS+, FAST security, the International Patient Access International Patient Summary, SMART health cards, and SMART health links. Next slide, please.

And then, we have recently released a series of test kits that are voluntary for the community to support payer data exchange and prior authorization, as well as bulk data access and search base URL test kit, so those were recently released, they are voluntary, and they are to support some of the IGs that are recommended in the Centers for Medicare & Medicaid Services (CMS) Final Rule that was published in January, so they are out there for the user community. As I mentioned before, they are not a part of ONC certification, but we felt the need to release that and to help the developer community and the IG authors to better help inform future updates to the versions of the IGs. Next slide, please.

And then, we have some upcoming plans for Inferno, and the first three on this list are three payer IGs. There is a payer data exchange, PDex, the document template rules, and the coverage requirements discovery. We just released them this week, so it was Tuesday that we officially launched those voluntary test kits, so they are now available for developers to certify and use. We brought some prototypes at the Health Level Seven (HL7) connectathon back in May and received feedback before we officially released them into production so we could gain further feedback to make sure that the workflows were accurate. We also have plans late this summer for Inferno, which would include an update test kit to support US CORE Version 7, and we also have additional exciting news with the FAST security IG update that would include the extension for unfair or deceptive acts or practices (UDAP), and that is very exciting. It is another extension that the community wants to start testing, and it is greatly supported for future development.

And then, the (g)(10) test kit will be released to support HTI-1, so that will be around late summer, July/August/September, when we are hoping to release those test kits. In the fall, we plan on releasing our annual SVAP update for the (g)(10) certification criteria. With those test kits that we plan on releasing and have recently launched, which are the ones on the previous slide, we plan on having further discussions at the CMS connectathon and HL7 connectathon, so we are hoping to gain more feedback and talk to the user community, and some of those test kits will hopefully be tested during some of the breakout tracks. We are happy to gain further feedback and iterate on our testing so we can further improve and ensure that our workflows are matching what the health IT development community's IG authors are developing, but also real-world health IT implementation. So, that is the overall summary, the main key highlights for our Inferno releases, and the upcoming plan timeline. Let's move to the next slide, please, which I will be handing off to Jeff Smith to talk about our Decision Support Interventions (DSI) resources.

Jeffery Smith

Thanks, Ashley. I do see we have some questions coming in, and we will be happy to take those questions momentarily, so get them ready related to the test kits and some of those other resources that we walked through. I did want to highlight that, a couple weeks ago, towards mid to late May, we actually released the long awaited and highly vaunted DSI resource guide. It ended up being somewhere north of 25 pages, but we did our best to distill down several hundred pages, I would say, maybe not with the tri-column formatting, but certainly, a lot of information that was contained in the proposed rule as well as the final rule for HTI-1 related to decision support interventions can be found among the pages that comprise the resource guide. We really tried to provide a crosswalk, primarily for developers who are going to be subject to these requirements if they choose to certify modules to (b)(11) within the program, and we really tried to plain-language what specific requirements meant within the context of the reg text and associated preamble.

Now, we also received and have been receiving several inquiries through our feedback portal, and have dialogued with individual developers as well as groups of developers, like the Electronic Health Record Association (EHRA), on a range of topics and questions. Many of these interactions have resulted in clarifications that we felt would benefit from wider visibility beyond individual and group questioners, so these clarifications really do not represent new or different policy, but they do try and provide some answers or clarify some ambiguities for those who are doing the hard work of trying to meet the end-of-year deadline.

I think a good example is around feedback loop functionality. Now, those who have been watching this program for many years may remember that ONC actually proposed feedback loop functionality many years ago, during the 2014 edition, and at the time, we were told by industry that EHRs routinely provided opportunities for users to give their feedback on Clinical Decision Support (CDS), so such a thing was not required for programmatic purposes, and after monitoring this over the course of several months and years, we realized that, in fact, users did not have routine access or capabilities to provide feedback on CDS, and so, this feedback loop functionality was one of the main differences between (a)(9) CDS and (b)(11) DSI.

In the guide, we note that the requirements under the program do not specify when or how feedback should be gathered. Real-time workflows where user feedback is provided immediately and post-talk workflows where user feedback is provided afterwards or through a separate application, for example, are all acceptable. Our requirements are intended to be flexible to enable users to provide feedback in a manner appropriate to their workflows. And then, we underscored that nothing in the certification program actually requires users to provide electronic feedback because we had gotten a number of questions from both providers and developers around when this feedback opportunity has to present itself and whether providers actually have to provide feedback to all the alerts that they may be receiving, and the answers to those are no.

We also highlight key terms that are discussed in the rules, such as what it means for certified health IT developers to supply predictive DSIs that are included as part of its health IT module, and we highlight important functionalities of (b)(11) modules. As an example, we note that health IT modules must support four capabilities related to DSI source attribute content. Specifically, through their health IT modules, developers have to enable a limited set of identified users to access complete and up-to-date descriptions of source attributes, record source attribute information, as well as change source attribute information.

Finally, modules have to indicate when source attribute information is not available for some of those source attributes related to external validation, local testing for validity and fairness, and continued assessments of validity and fairness. So, if you have not had a chance to thumb through it, we highly recommend you download and bookmark it. I would note that this is Version 1, so we will plan to update this resource guide, much like we have done with the real-world testing resource guide, as we start to get additional questions in that we think would warrant additional publication. Go to the next slide.

I think this will be our last slide before we take questions. I do want to note that we are going to do a summer educational series deep dive on DSI where we will go through the resource guide and answer questions over the course of about an hour. I would anticipate that the first of these happens sometime in July, and we will try to do another one in August and potentially one in September, and this really meant to try and help developers answer those complex questions that they are starting to uncover as they think about how to respond to and comply with our requirements within the context of their own systems. Again, I would just say thanks to all of the developers out there in internet-land who are listening. We have gotten a lot of really good questions, and we look forward to more questions. So, with that, I think the next is our last slide and our question slide, so we are happy to entertain questions. I will take a quick look at the comment box here.

Sarah DeSilvey
Thank you so, so much for all of these wonderful slides and updates. Hans, you posted a question in the chat. Did Avinash answer that for you? I see your hand is raised.

Hans Buitendijk
Thank you. I first want to thank the update and particularly want to highlight Jeff's update to DSI. They are very helpful, and I really appreciate the ongoing discussions and clarities that we are providing through the process. Avinash answered the question as well. As these tools become available, it is extremely helpful to have them, but it is also good to recognize that as we are all trying to figure out how these different pieces fit together in prior authorization, the work needs to happen as more and more parties are attempting to implement that, learning how to distribute some of the efforts across multiple IT. There is not going to be a single one that does it.

On the one hand, having that insight into how it compares with the implementation guides is good, yet we all need to continuously recognize that if somebody "fails" against such tests, then they are not yet in certification, but besides that, that does not mean that they failed, it is just that we are still learning. It might be a purposeful deviation from the implementation guide because of the new things we are trying to do. I think we are going to learn a little bit more about how to interact between these testing tools that are good and how we evolve the process and application of that, so I really appreciate that they are becoming available so that hey become another tool in figuring out how to make that progress. Thank you.

Rob Anthony
This is Rob Anthony. I just wanted to say yes, 100% to all of that. We thoroughly recognize that there is a state of flux, and we hope the test iterates as more feedback happens. These are certainly meant for self-assessment. They are not, as Avinash pointed out, part of the certification program. I think we have some plans to actually look at some opportunities to also work at some of the connectathons with some of these test kits all to get some feedback. It may not be necessarily just the IG that needs some iteration, but the test kit itself may need some tweaking.

Hans Buitendijk
Absolutely. I appreciate that.

Sarah DeSilvey
Thank you so much. Medell?

Medell Briggs-Malonson
Thank you, Sarah, and thank you so much for this presentation and all these wonderful updates as well. I also want to extend my gratitude for the DSI resource guide. While working with many different health systems, many people have wanted a distilled version to understand what exactly is in the HTI-1 final rule as it pertains to the DSI certification, so this is wonderful in order to guide us all that are doing this work, so thank you for that. My next question may be more of an administrative question or more of a naïve question, but I truly am curious about the answer, especially as we are trying to make sure we do not have broadening gaps between those that have been able to incorporate some of these recommended technologies and those that have not.

And so, in the background, do we actually look at which organizations are really adopting some of these toolkits and other forms of technology, and have we seen a difference in those under-resourced health systems or other organizations versus more that are more well-resourced, and if so, has there been any thought about how we can increase awareness as well as support for actually using more of these test kits, as well as really engaging in all of these different forms of technology?

Rob Anthony
That is a really good question. This is Rob Anthony again. I think it somewhat depends on where we are in the development and adoption cycle for things with certification, but on an ongoing basis, we try to look pretty closely at adoption rates where certain things are represented within the program as far as whether they are being sourced by larger developers or whether they are being offered by some of the smaller developers, who often certify to a single criterion or a couple of more focused criteria. I think one of the things that we generally look at is the different education needs among both developers and end users for engaging with the different aspects, especially when we do new functionalities that are required within the certification program, and that is not just the test kits that are available out there, but I think just certification functionalities in general.

I think there is probably always an opportunity for ONC to do some additional and better outreach, especially to end users. Most end users do not necessarily know exactly what ONC does or what the requirements are, but the functionalities sort of trickle down to them ultimately, and I think that is where we get some questions and, as Jeff was pointing out, sometimes some confusion about when you are required to put this feedback in. If we have insights from anybody as to where we might better deliver some of that education, I think that is probably a crucial part of what we do.

One of the other areas where we do try to get together with industry is we do a pretty regularly quarterly developer roundtable on different aspects of what we have done in the certification program, whether that is releasing new test kits, new requirements that are related to certification program that come to regulation, give everybody both a 101 and a 102 education, as we describe it internally, very basic, but also a little bit

of a deeper dive for those who are further along, and give people an opportunity to ask us some really pointed questions as well. Hopefully, for developers, that gives them an avenue, and obviously, many of them have us on speed dial and reach out to us regularly. Between all of those things, I think we do engage pretty regularly with folks, but like I said, I do think there is always an opportunity for ONC to do more and better education generally.

Medell Briggs-Malonson
Thank you so much, Rob, and I will send you a private message about some ideas, too.

Rob Anthony
That would be absolutely great.

Sarah DeSilvey
Medell's ideas are always good ones. Deven?

Deven McGraw
Great, thanks. This is probably a stupid question and a result of me not keeping up recently with some of the changes in the certification program from when it was first instituted, but what happens in a self-testing situation where someone does their self-test, which is completely on their own, but then markets their product as being certified, and it turns out that it does not work so well? That might have an impact on immediate customers, but I am also thinking in particular about some of the patient-facing APIs, for which those of us on the individual access service provider side have had some challenges, with some locations using tech where the standards have not been implemented properly. I just wonder what the outcome is when someone self-tests without any objective evaluation of whether that is right. What is the outcome of that, if any?

Rob Anthony
I would draw a distinction between some of the test kits that ONC is beginning to make available, like some of the Da Vinci IG test kits that we are beginning to make available that are purely for industry self-assessment and continued industry development versus the test kits that we make available for the certification program. Most of the test kits we make available for the certification program are available publicly and can be used as a lead-up to certification to do some of these self-assessments, but at the end of the day, if you are going to get certified to a new product, you also will go through one of the authorized certification bodies, usually one of the authorized testing laboratories, to demonstrate the results from that test kit. I think that is point No. 1 at which people can look at that, and it is not really possible to fail the test with a test laboratory and go on to get certified.

I think we also have ongoing conformance with the program. There are a number of requirements in the program that require that developers to meet the functionalities and standards supported within regulation, they have to make that available on an ongoing basis with the conditions and maintenance of certification, and if there is a potential nonconformity, there is an opportunity, both from our end and with consumers directly, whether they are end users or others, to report that to us or one of the Authorized Certification Bodies (ACBs). At the end of the day, developers are required to support the standards as required, and I should say that the vast majority of developers do.

There is one thing that I think is a little bit of a challenge and where we sort of drift outside of what is within ONC's sphere of control versus what happens in the end implementation. ONC oversees regulatorily and policy-wise what goes into health IT. We look at the functionalities and electronic standards that must be supported, but there is a lot of flexibility that is really left up to what end users actually implement onsite. Obviously, some of the CMS programs have some hooks as to what has to be used in particular ways, but the area of APIs is a great of example of where we regulate what needs to be supported and what functionalities need to be available, but how those are implemented is pretty widely left up to the end users in many ways, and I think that is sometimes where we see a little bit of a drift, where an end user may not necessarily choose to implement all of the functionality that is available, like, for example, a patient-facing API. I think that is where we drift out of the sphere of what ONC can do. We are obviously more focused on what we can make sure that the industry supports.

Sarah DeSilvey
That was an incredibly helpful answer. Thank you, gentlemen, for that answer. It was very, very helpful. Michael?

Michael F. Chiang
Rob, Jeff, and Ashley, I have a similar question to Deven's, which is really basic. Can you say a little bit about where test kits come from? I am specifically wondering if they are all developed and maintained by ONC. The reason I am asking is that I have been hearing about some privately developed, if you will, conformance testers out there to look at different standards, and I am wondering if you use those or whether you have to make your own.

Rob Anthony
Good question. So, anybody can develop a test kit, of course, and as an architecture, Inferno is something that ONC makes publicly available, and it is possible, and we are beginning to see some limited use, which is encouraging, of people doing some separate test kits that are not privately developed, but more of a private-public collaboration in that space, which is great, and that is part of what Inferno is there for. At the end of the day, though, virtually all of the test kits that are part of ONC's certification program that are actually used for certification are things that ONC develops or ONC contracts to develop with other entities to make available.

There are and there have been, in the past, a limited number of test kits, which we call alternate approved testing methods, that other organizations can do that functionally assure the same certification requirements as our authorized testing tools and test kits do. In order for people to get approved for that under the program, they actually have to go through a pretty rigorous process of demonstrating to us that their tool actually does the same things that our testing tool does. So, it is possible for people to participate in the program and have an approved alternate test method that they privately develop, but for the most part, most of the test kits that are available through ONC for the certification program are things that we developed on our own.

Sarah DeSilvey
Wonderful. Again, that is a really helpful, basic question and a really thorough and wonderful answer. Are there any other questions on this section of our meeting? Otherwise, we will be moving on to the next topic of our agenda, the presentation on TEFCA. It looks like not, and I want to give a sincere thank you to our

ONC colleagues for their presentation. Again, these are really helpful, practical presentations, questions, and answers, and it is very helpful information for those of us who are not so technically inclined. Thank you, Rob, Jeffery, and Ashley for your presentation. It is now my honor to segue to the next section of our presentation, welcoming Mark Knee and Zoe Barber to present an update on TEFCA. Thank you so much, Mark and Zoe, and we are passing off the presentation to you.

Trusted Exchange Framework and Common Agreement (TEFCA) (01:25:11)

Mark Knee

Great. Thanks, Sarah. I hope everyone can hear me okay. It is an honor to be here, presenting to you guys on updates to TEFCA with my colleague Zoe Barber from the Recognized Coordinating Entity (RCE). My name is Mark Knee. I am the Director of the Interoperability Division at the Office of Policy at ONC, and my team leads the policy work related to TEFCA implementation and all of the policy work related to TEFCA. So, we have been really busy, needless to say, and it is exciting to be here to give you guys some updates. I think it has been a little while since we have talked to you all about TEFCA. Next slide, please.

All right, here is the agenda. I am going to be really quick in going through the background because I know that you all are probably quite familiar with TEFCA and have seen these slides many times, but I know there are some new members, and it might be helpful to frame the rest of the conversation, so I will do the background pretty quickly, and then we will move on to all the newer stuff, which I think is probably much more interesting for you all. So, how is TEFCA being operationalized, especially now that TEFCA has been live since the end of 2023? And then, we will talk about what is next. We have a lot going on, and it will be great to provide the details to you all. And then, we obviously want to leave time for Q&A because it will be great to hear your thoughts on everything that is going on. Next slide, please.

Before I jump into what is on this slide, just to give some background and context for HITAC's involvement with TEFCA previously, to recap, in 2018 and 2019, HITAC had specific TEFCA task forces, and since then, we have presented updates, but have not specifically charged HITAC to make TEFCA-focused recommendations. But, your role is always extremely important, especially within the TEFCA context. HITAC provides recommendations annually on USCDI versions and our proposed rules, and, as you all know, within ONC, there is a lot of matrix work, and there is a lot of overlap there. The final USCDI versions of rules really flow into the TEFCA requirements, and there is a lot of overlap. Even if you are not commenting directly on TEFCA, your voices are being heard in the TEFCA context. I will also note that TEFCA was referenced in one of the HITAC recommendations on public health data systems. I am actually going to go off camera just for this presentation, and I will come back on for Q&A.

So, really quickly, why do we need TEFCA? What you can see on the right-hand side of this picture is not great. There are too many agreements, and even though there has been a lot of great work done on the federal, state, and local levels, as you can see bolded on the bottom, health data exchange has to be simplified in order to scale, and that is what we are trying to do with TEFCA. Next slide, please. You guys are all aware that TEFCA is being formed out of the 21st Century Cures Act language, which said that the national coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks, so that is really what spurred our work that has been going on since Cures was passed in 2016. Next slide.

This is really straightforward here. TEFCA has many goals, but these are the three overarching, big-picture goals. First, to establish a universal policy and technical floor for nationwide interoperability, second, to simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate healthcare value, and third, to enable individuals to gather their healthcare information. Next slide.

As this slide shows, we view the benefits of TEFCA as very far reaching, and really impacting everyone in the country, hopefully: The effects on individuals, providers, public health, payers, health information networks, technology developers, and also research down the road, which I will talk about and which is not one of the current exchange purposes, but Micky has been very clear. I believe he has even referenced it as the seventh exchange purpose, and we are already doing our due diligence to understand what it will take to implement research in the very near future, so there is more to come there. The impacts obviously will be greater as more and more entities join TEFCA, but we think there is not really a ceiling for the benefits. The impacts can be felt across the healthcare system and amongst these stakeholders and others as well. Next slide, please.

This is the umbrella slide, which I am guessing you all are pretty familiar with. As a recap of the overall structure of TEFCA, ONC, at the top left, sets the overall policy and governance requirements for TEFCA, and we work closely with the RCE. Zoe is here today as the policy director for the RCE. The RCE, the recognized coordinating entity, which is the Sequoia Project, provides oversight and the governing approach for Qualified Health Information Networks (QHINs).

Then we have these QHINs, which are super-nodes, as we call them colloquially, on the network, but they are entities that are high-functioning and able to support nationwide health information exchange at scale, which is what is needed for TEFCA, and then, they have agreements with participants and their customers, and their customers' participants can have relationships with sub-participants to enable exchange, and one of the great things about TEFCA is you are able to get the same access to the information regardless of how you connect, whether it is as a QHIN, a participant, or a sub-participant, because there is this base level of trust in the agreements you are signing that everyone is playing by the same rules, which is extremely important. Next slide.

TEFCA has a number of components, which you see listed here. There is the Trusted Exchange Framework, which was published with the Common Agreement Version 1, and it lays out the high-level policy goals and approach for health information exchange. Then, you have the Common Agreement, which is the agreement that is signed between the QHINs and the RCE. The standard operating procedures are documents that we are putting out on a rolling basis to provide additional details and color for the requirements that are included in the common agreement. Then, you have the QHIN technical framework, which includes all the technical requirements and specifications for TEFCA exchange. QHIN onboarding is a really important process that takes upwards of a year for entities to go through this rigorous testing and onboarding to make sure that they are able to support TEFCA exchange, connect to other QHINs, and support all the technical specs as well.

Metrics is going to be really important moving forward. There is not much to report now, given how new TEFCA exchange is, but in the future, we are really leaning into understanding the metrics and being able to see where TEFCA is succeeding and where there is work to do, so there is more to come there. Last is

the governing approach. This is an ever-evolving governance approach, and we are working on different aspects right now that we will be providing more information on in upcoming Standard Operating Procedures (SOPs), but it is a really important aspect of TEFCA that there is participatory governance and all the QHINs, participants, and sub-participants have a say in how the governance approach works. Next slide.

Here, you have the six exchange purposes: Treatment, payment, healthcare operations, public health, government benefits determination, and individual access services. As I noted, a seventh exchange purpose that we will be building out soon is research. Next slide. All right, I am going to pass it over now to Zoe to really dig into the details of how we are operationalizing TEFCA, and I will come back later on in the presentation to talk about the next steps for TEFCA. Zoe, over to you.

Zoe Barber
Thank you so much, Mark. Hopefully everybody can hear me okay. I am actually going to ask whoever is driving the slides to please move up two slides, and then we will come back. I also want to say what a pleasure it is to be here with you all today. It has been a little while since I have presented to the HITAC, so it is wonderful to see so many faces and names on the panel. So, here, you can see the timeline of the TEFCA evolution, and this is a very high-level timeline, dating all the way back to 2016, which, as Mark noted, the 21st Century Cures Act established TEFCA and directed ONC to develop or support a trusted exchange framework and common agreement. Many of you on this call will remember when ONC was drafting those first two initial drafts of TEFCA back in 2018 and 2019, like Mark said, we actually had the HITAC very involved in helping to inform those initial drafts of TEFCA through the various task groups.

Later on, in 2019, ONC selected the **[inaudible] [01:35:59]** to serve as the recognized coordinating entity as that neutral convener to help oversee and operationalize implementation of the common agreement. Fast forward to January of 2022, when the RCE and ONC, working together with industry, released Common Agreement Version 1 and the QHIN Technical Framework Version 1, and we actually began accepting initial applications in February of 2023, and then, in December of 2023, we had a huge milestone and went live on Common Agreement Version 1 with the initial set of qualified health information networks.

So, now we are in Q2 of 2024, and we have actually released Common Agreement Version 2, which is what we are mostly going to be focusing in on today. We have a few organizations that are live on exchange today, and we are actively working on getting out a new set of materials to support the go-live of Common Agreement Version 2.

So now, if you would not mind backtracking two slides, as we said, TEFCA is operational, and we have seven organizations that you can see on this slide that have officially been designated as qualified health information networks after completing the onboarding and testing process. We actually have two other organizations that are currently going through that testing process. We call those candidate QHINs. And then, we do have one organization that is actively submitting their application and is in progress towards getting towards that testing phase.

So, as the RCE and ONC, we work with these organizations on a weekly, if not daily, basis to help inform the progress of the common agreement. We have one-on-ones with these organizations, and we have also created a policy technical advisory group that consists of the seven organizations on the screen, plus the

two that are in that candidate testing phase, as well as several of their participants and sub-participants, so it is a pretty diverse and representative group of organizations that we meet with every single week. We have had a few in-person all-day meetings as well to help us inform the development of Common Agreement Version 2 and all of the standard operating procedures that we are working on towards publishing in the coming months.

Exchange is also occurring today, so we do have some exchange happening live on the network today. We have certainly seen several organizations being listed in the RCE directory service, and so, that is really fun to see that RCE directory service build as time goes on. I think several of the organization are waiting to see how the common agreement matures and grows, especially with the new requirements and flexibilities that we are creating under Common Agreement Version 2, so we really expect to see that exchange grow and mature throughout the rest of this year. Next slide.

Okay, great. So, as I mentioned, we released the Common Agreement Version 2, it was published on May 1st of 2024, and it has an official implementation date of June 30th, so that is in just a few short weeks. Right now, the organizations that you saw on the screen previously are currently operating under Common Agreement Version 1.1, and Common Agreement Version 2, as it says here, includes several enhancements and updates to support a more dynamic and flexible exchange environment, including for FHIR-based exchange. The Common Agreement Version 2 also includes brand-new static terms of participation that all participants and sub-participants in TEFCA sign without modification. This was something that was asked for widely by the participants in the network because it really gives more comfort and trust to know that everyone across TEFCA is agreeing to and complying with the same terms.

This version of the common agreement also **[inaudible] [01:41:09]** adding more details. It **[inaudible]** several of the specific implementation details that had been in previous versions in favor of placing them into the standard operating procedures, which we are developing today, so this really helps to support the more operational environment in which we find ourselves today. Again, we are working on creating those various SOPs, which we hope to release by July 1st, just in time for that implementation date of June 30th, so those SOPs will be released. There are about 10 SOPs, plus the QHIN technical framework and a brand-new FHIR SOP, that will be released on July 1st.

Next, I want to talk a little bit about FHIR and the FHIR roadmap. The Common Agreement Version 2, as we mentioned, supports the environment and provides that framework for FHIR-based exchange to happen, and in particular, it breaks the mold of what is currently happening, which only allows for exchange to occur between two QHINs, and now, it allows for transactions to occur directly between participants and sub-participants using FHIR-based APIs. We call that facilitated FHIR. Back in December of 2023, we released a FHIR roadmap that provides more **[inaudible] [01:42:50]** and guidance for the future, and it describes the long-term goal, which we are currently working towards, of moving from where we are now, where we support the exchange of FHIR content and FHIR resources using IHE transport protocols, to the next stage that we are working on, which is that facilitated FHIR exchange, the exchange between point-to-point APIs, and then, eventually, to a long-term goal where we have QHINs themselves actually **[inaudible] [01:43:25]** FHIR exchange across the network.

Seth Pazinski

Hi, Zoe, this is Seth. You are cutting out a little bit. You might want to try going off camera and see if that holds up.

Zoe Barber
I can do that.

Seth Pazinski
All right, thank you.

Zoe Barber
Okay, hopefully this is a little bit better. Let me know again if I am cutting out. Thank you, Seth. So, back to some of the specifics on facilitated FHIR-based exchange and what we are working on today. We are creating a new SOP for FHIR adopters, which, again, will be published on July 1st, along with the QHIN technical framework, and this SOP provides another roadmap for network-wide adoption of a common method for registration, authentication, and authorization of FHIR protocols. So, what we are doing is allowing some flexibility in the next year and a half or two years to allow participants and sub-participants in the network to use different types of frameworks and protocols like SMART, HL7 FAST security IG, otherwise known as UDAP, or what I think we are calling SARAH now, as well as other types of frameworks that they may be currently using today that may be based on out-of-band agreements.

And then, what we are doing is providing a roadmap to get to that common network-wide approach for facilitated FHIR, and we have established a FHIR implementation advisory group with a number of subject matter experts from the industry and from the QHINs and their participants and sub-participants that have been tasked with collecting and documenting learnings and progress towards that goal of adoption of the network-wide approach, which we anticipate will use that HL7 FAST security IG.

Next, I want to talk about several of the new and updated standard operating procedures that we are working on releasing on July 1st and soon after that date that will facilitate the official go-live of the Common Agreement Version 2, so I will just try to give some of the highlights. We are working on a lot of different things, but in particular, we have a couple of standard operating procedures that will be providing more specifications on the individual access services exchange purpose, so that includes some more specifics around proper identity proofing and authentication for IAS transactions. It also has requirements for IAS providers, which are the third-party apps or other types of platforms, that are actually providing services to individuals to allow them to exchange on the network and requires them to develop things like a written privacy and security notice that individuals have to agree to in order to use those services.

We have also created several new SOPs that have the goal of adding more granularity to the RCE directory services. So, as I mentioned, with Common Agreement Version 2, we are really trying to break the mold in a couple of different ways and allow for more dynamic, more flexible exchange that better mimics what we actually see happening in the industry today. So, these new standard operating procedures will, first of all, help us to differentiate between the legal organizations that are actually signing the common agreement, so those are your QHINs, participants, and sub-participants, versus the technical systems, which we are calling nodes, that each legal entity in TEFCA uses to conduct TEFCA exchange, so they actually use these systems to initiate and respond to transactions.

We have created some new terminology to describe the systems. Again, we would call these systems nodes, and we also have new terminology to differentiate between types of participants and sub-participants in the network, so we have principals and delegates. “Principal” describes types of participants that have the primary authority, for lack of a better term, to conduct TEFCA exchange for a specified purpose, so this would include your covered entities, public health agencies, or those individuals **[inaudible] [01:48:42]** IAS provider to exchange on the network. And then we also have delegates, which are a type of participant or sub-participant that has a written agreement with a principal to conduct TEFCA exchange on behalf of that principal, so that includes your business associates or others that have some kind of written data use agreement to initiate transactions on behalf of a principal.

So, again, our intention here is to allow for more flexibility to match what we are seeing and what we have heard from those exchanging in different networks today, and in particular, it allows for participants to sign only one framework agreement with one QHIN, but still have the ability to initiate transactions from multiple systems across TEFCA. And then, we have a whole new set of SOPs that then further describe the requirements in the specifications for tracking all of these principals and delegates, and so, we have created a chain for making sure that principals are identifying who their delegates are that they are working with in TEFCA, and also, delegates, in turn, have to identify in each of the transactions that they make which principal they are making the transaction for, so this creates kind of a reciprocal handshake, if you will, so that there is that sort of mutual trust in tracking to know exactly what these relationships are and who these relationships are between.

We also have a set of exchange purpose implementation SOPs for some of the different exchange purposes in TEFCA. So, you may have heard over the past several months or even years that we have been working on and even released several proposed implementation SOPs for some of the purposes in TEFCA, like healthcare operations and public health.

I know Micky often refers to these implementation SOPs as the paved pathways for exchanging information for a specific reason underneath each of these purposes, so, while participants are allowed to or permitted to exchange under these broader terms, like “treatment,” “payment,” and “healthcare operations,” we then create sort of a subset of use cases underneath these that provide for more specification around what is included in a transaction, what needs to be included, what is the specific code that identifies what the use case is for, and what should be included in a response, and the goal of these is to, again, enhance trust and comfort with the transaction, and hopefully create a higher likelihood of response, particularly for those purposes that do not have a required response right now, like healthcare operations or public health.

So, some of the use cases that we are working on right now, and on which we have worked with many of those on this call, and many subject matter experts in the industry, and within the federal agencies for public health, we are working on implementing electronic case reporting and electronic lab reporting, and with healthcare operations, we are looking at some of the use cases, such as care coordination, case management, population health management, and quality measure reporting.

One thing that is brand-new that I do not think we have talked to this group about previously is that we are now working on an implementation SOP for the treatment exchange purpose. So, the common agreement, like many networks, relies on the HIPAA definition of treatment, and just like healthcare operations and payment, that is a very broad definition. Both the definition of treatment and the definition of healthcare

provider are quite broad. And so, we have heard from many of our stakeholders that there is interest in being a bit more precise in our definition of treatment, and perhaps even creating some of those paved pathways for the use cases that occur under treatment.

So, in order to inform the development of this new SOP, the RCE has actually created a feedback form. There are about 50 scenarios on that form. It is quite complex, and it really goes across the spectrum of your most basic treatment use case, "I am going into my primary care doctor's office for my routine scheduled visit, and I see that doctor every six months," to some of your really more complex use cases like using a medical device or some kind of application where perhaps you do not have a license or you do not have a traditional doctor directly involved, but you have an application that is pulling data, pulling your records, and using those records to provide you with specific medical advice and guidance.

So, we are actually asking for quite a bit of feedback, and I am going to put that form in the chat. The form is due on June 20th, so I know that that is pretty soon, but we are looking to get as much feedback from the industry as possible from a wide variety of stakeholders to help us inform our treatment implementation SOP, and we are really excited to see what the responses to this form and **[inaudible] [01:55:33]** is to identify and analyze some of the areas of both commonality and also of disagreement, so we ask things like, "Is this treatment? Is this being performed by a healthcare provider? If it is treatment, should it fall under the umbrella treatment exchange purpose?" Or perhaps it is something that requires one of those more paved pathways with more specific sub-exchange purpose use cases and codes to better identify what the use case is. So, please feel free to share that feedback form and work with your stakeholders, staff, and compliance officers to provide thoughtful feedback in that form.

Finally, the last thing that I want to mention before I turn things back over to Mark is some of our work on governance. Back in February, we convened the transitional council, which is the body that is responsible for overseeing governance in the first 12 months of TEFCA-based exchange, and this is a body that is made up of QHINs and representatives from QHIN participants and sub-participants, and they have the responsibility of creating the transition plan and describing more details for how the permanent governance body, which is the governing council, will operate once the governing council after the transitional council's tenure.

So, right now, the transitional council is working on better defining the roles and responsibilities for that governance council, but they are also working to better define the composition, roles, and responsibilities for what is known as advisory groups, and we have two of these advisory groups today, which I think I mentioned, that policy technical advisory group, where we are working with the QHINs and their participants, and then we have that FHIR implementation advisory group that we are just establishing to help us with our roadmap for facilitated FHIR, and we anticipate that we will establish many more advisory groups as things progress. In particular, we want to make sure to have a wide variety of representation from across the spectrum of the industry making sure that we have specific rules for everybody involved in tech exchange, including for public health officials, payers, providers, and consumers to really get an array and diversity of voices in the mix to help us with governance.

So, again, the transitional council is working really thoughtfully to better define what those roles will look like, what the responsibilities are, and what the various composition of each of those groups will look like. So, those are the highlights of what you will see coming on July 1st and in some of the weeks following July

1st. There is a lot going on, and we are still just beginning. I think Mark is now going to talk about our next steps.

Mark Knee
Yes. Amazing, thank you, Zoe. Great job. I saw a lot of the chat during Zoe's presentation, and I put the list of SOPs that are being updated for July 1st as well as the list of SOPs that will be updated on a rolling basis after that, and I think, as Zoe mentioned, just to highlight the reasoning there, there are certain SOPs, for instance, ones where we pulled information from the common agreement into the SOP, that need to be released by July 1st. Obviously, all of the SOPs are extremely important, but those have specific July 1st deadline, and then, we have additional SOPs on the way. I apologize for not having a more detailed list in our slides. It is just that everything is really kind of a moving target at this point, so it felt like it would be easier just to talk through it.

That said, I want to highlight the link that some of my colleagues have put in to the RCE's website that has all of the resources that are publicly available, and if you have any questions about where to find things or questions about the documents that are on the website, feel free to reach out to me and Zoe directly. There are a lot of really great resources, and I just want to echo what Zoe said as well about the treatment form that she shared. Input that you all could provide would be amazingly valuable for the ongoing thought process we have on how to think about treatment and all the different exchange purposes. Next slide, please, and then probably two ahead.

As you probably got a sense from what Zoe was saying, we have a ton going on, and it is happening very quickly, which is great. You all know Micky very well, and he has been really driving the progress for TEFCA, and really creating the foundations and the relationships that are necessary for TEFCA to succeed. So, here are the next steps. There are more than are on this list, but these are really what we are doing now at a high level to make sure TEFCA is successful and hit the ground running. The first one here is advancing additional exchange purposes and use cases, including early demonstrations, which essentially means pilots. That is what we are talking about there.

I just want to highlight a few of those really quickly. One is the work we are doing on public health. You heard in the previous presentation that Katie provided as well as in Micky's remarks that public health is a priority for our office, and we have been doing amazing work with CDC, Dr. Jirjis, who I know is on, and other CDC colleagues to work together to reach out to the different public health stakeholders, such as Dr. Karras, who I see on as well, who I have spoken with many times on these topics, to try to make sure we are making great progress in addressing public health issues through TEFCA. The early demonstration work there is going to get started, as Micky said, in July, maybe on July 1st, but very soon, which is extremely exciting.

I was at one of Micky's talks yesterday. It was our public health informatics and technology program, which, as an aside, is a really exciting program that addresses public health as well to create curriculum for universities to help advance the next level of leaders in public health informatics and technology, and what Micky was saying was that there was a lot of skepticism about public health and how we would do it, and it is amazing that right now, public health is one of the exchange purposes that is moving the quickest, and we are seeing the most progress immediately, and that is really a testament, again, to Micky, our colleagues at the CDC, and all of the work from our public health team at ONC with Katie, Rachel Abbey, and Molly

Prieto, so, a big thank you to all of them. It is really exciting to see what comes from those early demonstrations and the lessons we can learn moving forward with public health and TEFCA.

Another one I want to highlight that is a high priority for us is healthcare operations. We are currently developing what we are calling a 10 by 10. The idea is that we are going to have at least 10 providers and 10 payers to test out exchange for healthcare operations. The details are still being worked out, but it is extremely exciting, and I think there are going to be more updates in the coming months on that. Obviously, healthcare operations has been a challenging exchange purpose to create the parameters for, but we have made amazing progress, and I think we are at a point now, again, thanks in large part to the relationships we have with our colleagues at CMS and other agencies, to understand the landscape, understand the needs of our federal partners and stakeholders, and then to start working on pilots or early demonstrations to start implementing these types of TEFCA exchange. So, it is really amazing work and collaboration there.

Another key piece here is the research exchange purpose. I have mentioned it a couple times in my earlier remarks, but that is the next exchange purpose that we are going to be looking at. We are trying right now to develop the framing for it and to understand the legal landscape for research and any of the challenges we might see, but we are going to be moving fast, and I think you will be seeing much more to come in the back half of this year on research, and we are hoping to really get started in implementation aspects of research early in next year at the latest.

The next bullet here is expansion of TEFCA participation. We just had an interesting meeting, which I think Zoe mentioned, with all the QHINs and the RCE, and a representative from one of the QHINs made the point that TEFCA reaches its goals if every provider is participating in TEFCA across the country. That is the goal. The goal is that everyone is participating in TEFCA, trusts TEFCA, and believes that, through TEFCA, they can have more seamless exchange of information in a safe and secure way, and so, after we get all these SOPs out, and we already have Version 2 of the common agreement out, we are really shifting our efforts to implementation, education, outreach, and expansion of the TEFCA program, and that means reaching out to stakeholder groups. Right now, we are focusing a lot of our efforts on patients and providers, and we are also going to expand out to how we reach the public health communities, the payer communities, and everyone that may have questions about how you become connected to TEFCA and what the implications are for becoming a participant or sub-participant in TEFCA.

I saw some comments and questions in the chat about the calculation for whether you want to be a QHIN versus a participant or sub-participant, and maybe I will tackle that right now in some of my remarks. It is really a business decision. We hope that we have a robust group of QHINs, and we are extremely excited about the initial crop of QHINs. Seven to start is really amazing, and we have two on the way. We are extremely excited to have these organizations on board, and they also represent a very diverse group of stakeholders, and the entities include a company like Epic, which is obviously a huge health IT developer, and KONZA, which is a smaller health information network, and they come with different experience, different customers, and different services, and really, that is part of the calculation.

Like I said, you can get the same access to the information whether you are a participant, a sub-participant, or a QHIN, so you really have to think about the benefit to your organization to become a QHIN versus a participant or sub-participant. Are there QHINs offering the services that you want? If there are, compare the different QHIN options and try to decide, based on cost, value-add services, and other calculations what

makes the most sense for you and your organization and how you will be able to maximize health information exchange in the use cases that are most important to you and your organization. So, I know that is a very vague answer, but that is part of the thinking there.

The next bullet here is further adoption of FHIR exchange. I often say I am just a lawyer, not a tech person, but I have learned enough about FHIR to at least convince people that I might know something about it. Obviously, you have heard Micky and other leadership with ONC talk about it over the years. FHIR is essential for the success of TEFCA, and we have heard that loud and clear from industry and the different partners we have in the market, and we are really focused on not only implementing FHIR-based exchange through the updates we have made to the Common Agreement Version 2, but also by expanding FHIR use and adoption in TEFCA moving forward. Just because we put out Version 2 of the common agreement does not mean that is the end. As Zoe said, that is just the beginning, and we are trying to find more and more ways to help industry and meet them where they are, but also help guide them along to make sure they are adopting FHIR as quickly as possible.

Medell Briggs-Malonson
Mark, I know we are heading onto the last dot that is actually here on the slide, but I just wanted to make sure we have enough time for questions from the HITAC members. We only have about 20 minutes left.

Mark Knee
Okay, I will close it out, Medell. Sorry about that. I appreciate it. So, the last thing I want to highlight is something I already mentioned, but it takes a village. I have three kids, and raising kids takes a village, but it also takes a village to make TEFCA successful and to meet our goals. The collaboration we have had is with many of the partners we have on the call today. I mentioned CDC, but I saw CMS. Alex Mugge and all of her team have been great partners in all of this. We are working closely with VA, DOD, and SSA. You name it, we are talking to them, and my team is working out individually with all those different federal partners to understand how they can become a part of TEFCA, but also having broader conversations with groups of federal partners to understand if there are common issues they are dealing with and how we can help them address them.

So, all of these pieces of next steps are just to say that there is a lot coming down the pike, and we are really excited to see where this all takes us, and we encourage you all to be as involved as possible and help us along the way. I will stop there. I see a lot of questions, and Medell, over to you for the questions.

Medell Briggs-Malonson
Thank you so much, Mark and Zoe, for this incredibly comprehensive update on TEFCA. We are very passionate about it as well, which is why I think there are so many questions for you. So, everyone, we have about 20 minutes, so please keep your questions very concise and to the point so we can get through as many questions and comments as possible. Hannah, I see your hand up first.

Hannah Galvin
Thanks so much, Medell. Thank you for this really excellent presentation and all the hard work on this. My question is about how Version 2 of the common agreement and governance in general is going to handle bad actors, having been an organization impact by Particle Health and all the Carequality issues around

that and Carequality governing looking at potential bad actors in that space. I am very interested in how TEFCA and TEFCA governing is looking to improve those processes as we expand outward from there.

Mark Knee
That is a really great question. The way we are looking at it, there are a lot of lessons learned. We worked very closely with Carequality and other national networks, and I think first, it is really understanding what happened, and then trying to figure out how we can make sure that TEFCA is different and TEFCA addresses issues in a way that can build trust amongst everyone who is participating. In the details there is that we are currently working on updates to our dispute resolution SOP, which would provide details about how, if there is a dispute, it would be handled, and we are making sure that there are really strong protections and processes in place, and we are getting feedback from industry and all these partners to make sure, as we are sometimes insulated in the government, that we are hearing from the people like yourself that are actually affected by these types of situations, and I would love to get feedback from you as well if you have thoughts.

But also, we are trying to make sure we are being very clear and think through what is a dispute and what are other types of situations that may be handled in a different way, and obviously, it is really essential that situations like you mentioned are dealt with quickly, so we are trying to figure out how to make it a quick process, but also a thorough process, that has the right processes in place to make sure that experts are reviewing the use cases in question, understanding the specifics, because with health IT, there is just so much variability, as you all know, in what types of use cases are happening, and also just working, again, to not jump to conclusions.

I understand the bad actor reference, and maybe I am taking too optimistic of a view, but I do think the majority of folks are, a lot of times, good actors, but they may be doing things the wrong way, and I think that is part of the value of TEFCA, that by creating these six doors for exchange with the six exchange purposes, I think there are a lot of situations where entities may be trying to cram other exchange purposes into the treatment exchange because that is really what is available right now. And so, I think that will be a way that, down the road, TEFCA will be able to help with that problem, but for right now, we are just trying to dig into the specific use cases and come up with a process that is thorough and robust. Zoe, I do not know if you have any other thoughts as well. I know you have been working closely with us.

Zoe Barber
That was really comprehensive, Mark. The only thing that I would highlight, like Mark said, is that it is not just about disputes, it is about ensuring that we do not have to get to the actual formal dispute resolution process so that we have a process for handling informal grievances and complaints, and the governance body that I mentioned, the transitional council, and will ultimately have a role in helping to inform the RCE and ONC in those matters.

Medell Briggs-Malonson
Excellent question.

Mark Knee
Sorry, Medell, just one more thought. I was going to say exactly what Zoe said. We are trying to be really proactive, and that is part of that link about treatments. I am guessing you probably connected the dots, but

one of the questions is how are we defining treatment, so that is something we are trying to figure out immediately and implement in our processes.

Medell Briggs-Malonson
Wonderful. Again, that was an excellent question and excellent responses. I appreciate you all. Anna, you are up next.

Anna McCollister
I have a couple quick things. I put this in the chat, but are there plans to include patients or consumers on the governance council? I will just throw that out there and let you address it. Secondly, I was very encouraged that you added research as a use case for trusted exchange. I think that is absolutely critical. It has been part of the "plan" from the beginning as it relates to health IT and a potential secondary use of data for health research, so I am glad we are acknowledging it.

One important question that I have from that perspective is are there mechanisms through TEFCA to actually require transparency about data uses, what it is being used for, and what types of research is being conducted? Because "research" can mean many different things. It can mean market research, it can mean clinical research into diseases or potential treatments, it can be for pharma companies, it can be for academic research organizations, and there is not necessarily that big of a distinction there, and it can be for patient groups. Research is absolutely essential, but from a trust perspective, if we are serious about trust, we have to be transparent about what exactly is being done and allowing individuals to be able to see how their data is being used and potentially monetized and how their data ultimately contributes to the advancement of science.

Mark Knee
Thank you, Anna. I can start with both of them, and Zoe, jump in at any time. The first question I think you had was about the governing council and representation for patients and providers. I think I put on the list that one of the SOPs we are currently updating is governance, and we have heard that from a lot of folks, both from providers and patients, but also from the public health perspective, and I think payers as well, that we should look into representation based on the type of partner you are versus just having representation based on the QHIN, participant, or sub-participant. So, there is nothing finalized yet, but I think it is a great suggestion, and I have heard it from others, and we are really looking into that and how we can implement those types of changes, so I really appreciate that comment.

I think your second one was about mechanisms for transparency for data use. It sounds like some of that is secondary use that you are talking about, for which I think there are limitations on what we can do regarding secondary use, just because the way that we define TEFCA exchange is that it is when the data is in transit, and once it reaches a system of record, it becomes part of that system of record, and other laws like HIPAA would apply to it. That said, I think we need to be very proactive in thinking through the research exchange purpose, and your points are very well taken. We need to be transparent about how we can give as much detail as possible in the SOP about how the research exchange purpose is going to work and how we can build in these protections that we are talking about. I think there are different ways, but I just wanted to level set on the secondary use aspect, that that is a little bit trickier, just from the way TEFCA is structured. Zoe, any other thoughts?

Zoe Barber
No, that was great.

Medell Briggs-Malonson
Excellent. Thank you so much. Katrina?

Katrina Miller Parrish
All right, thanks. I will also say thank you so much. This is just an amazing amount of work, or prolific, as I said in the chat, and my head keeps spinning, trying to track with all of the details and where I go to find information, but these meetings are terrific to get that summary. My question, which is similar to what Ike just added in the chat, is about metrics. First of all, what are they? Where are they? I think I am a consumer in this whole mix. Will I be able to see metrics? I will just add anecdotally on here in all kinds of things about how data is not being exchanged correctly yet, pieces of data are coming through, it is not successful because the wrong data is in the wrong field, we are getting a lot of text jargon in places where it should be coded, etc. So, could you tell us more about metrics now and/or later? Who will have access to them? Thank you very much.

Mark Knee
First, I will just start by saying metrics are going to be so important to TEFCA, and creating the right foundation for transparency that we all want, and understanding, like I said earlier, where TEFCA is succeeding and where we can continue to grow. With metrics, we are working very closely with the ONC's Office of Technology Data Analysis Branch, DAB, so they have lots of experts who have been working closely. I know there is a survey that asks questions about participation in TEFCA, but also looks at how HIEs are functioning and interest in TEFCA, so that is some of the initial work that we were trying to use and leverage to understand where the gaps are in participation in and understanding of TEFCA, but I will say that though I do not have the details of what types of metrics we are going to be looking at, the team is working very closely with the RCE as well as the QHINs to make sure that we are getting the most up-to-date information.

To your question about what will be made public, we are going to try to make as much public as possible. There is some stuff that will fall under confidentiality or trade secrets that we cannot share, but we are going to share as much as we possibly can because, again, we want TEFCA to be trusted by the country, by all of you, by the experts, by the participants, and everybody, so there is more to come there, but if you want to have a more focused conversation on metrics, I would be happy to loop in our data analysis branch and have a separate call, if you would like that.

Katrina Miller Parrish
Please do. Thank you.

Medell Briggs-Malonson
Thank you, Katrina, and thank you, Mark. So, we have about 11 more minutes, and there are lots of questions in the chat, so if you do want to ask your question live, please raise your hand, and thank you so much, Jim. We will start off with you.

Jim Jirjis

Hi, Mark. I do not know if you and I talked about this before, but the current model is a push model, so somebody actually needs info from the network that pinged the network, and then, whatever the source decided to send is what happens, right? I am guessing that one day, when we get to FHIR, it will be more that the requester will be able to ask for specific data and how far back it goes, but my question is about how far back it goes. So, when I was back in healthcare with CommonWell, where we were receiving these CDAs, what we found was that when some people were sending two years' worth of payload when they got a request, like the VA, some people were sending 90 days, and a lot of people were just sending content from the very last encounter, even if it was just a skin tag removal.

So, part of the value of TEFCA is Metcalf's law of getting everyone to participate, but part of it is the richness of the data. Are there any mechanism plans or provisions to try to define in the current state so that the receiver has an expectation of how far back people are going? Even when we get to FHIR, though, won't we have to address how far back the data exist? I will just end with one sentence. One great use case in public health, for example, is tuberculosis. If somebody gets a positive skin test, you are either going to get one medicine for prevention treatment, or if they are active TB, they get three meds for nine months, and if there is an abnormality in the chest X-ray, knowing that there was an abnormality three years ago means that it is not active, so there are real reasons for the recipient. So, are there any mechanisms or plans to address the expectations around how far back the data goes?

Mark Knee
I saw Zoe come on, so she might have some thoughts. I was going to give an answer that is probably not the most satisfying, but Jim, given your experience, I know how much you have been involved in this type of stuff and how important it is. One of the benefits of ONC leading TEFCA is that we have experts in a lot of different fields. So, I think what you are talking about bleeds into some of the stuff that our team that works on information blocking and information sharing may be working on because it seems like it is an issue that is perhaps a bit broader than TEFCA. TEFCA can create rules for the network, but we also want to leverage the appropriate practice more broadly. And so, for that question, I do not have a clear answer yet, but I think it is something we should definitely look at, and we will, and I think we will, and I think we will also pull in the experience of the folks who have been working on information blocking and some of the doctors on our staff as well to understand how we create the right guardrails there. Zoe, do you have other thoughts?

Zoe Barber
Thank you so much, Jim, for the question. My computer does not to have me on video these days. First, I just want to address what you mentioned at the top of your question. Currently, you said that TEFCA is a push model, and I just want to make sure to correct that statement because currently, TEFCA allows for both query requests and push-based exchange. So, to your point, FHIR will allow for more granularity in terms of the data that is being asked for, but the standards and the protocols in TEFCA today do absolutely allow for requesting documents across the network and responding with those documents.

Jim Jirjis
Good.

Zoe Barber

Now, as far as your question about how far back the data goes and if there is a way to specify that, there absolutely is. I do think the QHIN technical framework has a default which I believe is five years, though I can double-check it, but I do know for sure that in several of the implementation SOPs that we mentioned, where we are defining and specifying those specific use cases and paved pathways, we do specifically state what the default look-back period is for the information requested, and the requester also has the ability to specify in their request how far back they are looking for data, and if they do not specify, then it actually defaults to the standard that is specified either in the QTF or the implementation SOP.

Jim Jirjis
Really quickly, I realize it is push and pull. What I meant was that even in the push-and-pull model, you are constrained by what the source has decided they are going to send. That is what I meant, but thanks for clarifying.

Medell Briggs-Malonson
Wonderful. Thank you for those answers, and also for that very important clinically relevant case scenario as well. Rochelle, you are next.

Rochelle Prosser
Hello. This is for either one of you. Mel, just as a note, my prior comment is applicable to this presentation. Thank you for bringing up the definition of what "treatment" means in the context of what we are looking at in the data. It can have many meanings, which is why we have so many conversations on how far back we should go, what it should involve, and what pieces of paper we should include in this. My question is in terms of the method you are using to define what treatment means within the context of trifecta and QHINs, etc., are you using a methodology, are you using a clinical determination, or are you using a healthcare determination? For a layperson, I just wanted to understand a bit more if you have that, and if you do not, does ONC have a better definition of "treatment" that we can then assist in moving this initiative forward?

Mark Knee
Thanks for your question. The starting point for us is really the HIPAA definition of "treatment," and that is where we are starting the foundations of our understanding of treatment, but, that said, we are open to the possibility that TEFCA's definition could, not will, as I do not want to get people too upset… We are analyzing whether there should be a narrower definition of "treatment" within TEFCA versus HIPAA. That said, we understand the value of leveraging existing laws that everyone knows and is comfortable with, like HIPAA, and so, it really needs to be a balanced kind of analysis of what would be the benefit, the value, and the risk of limiting TEFCA exchange to something narrower than HIPAA's definition of "treatment." We want to make sure that the right type of information is being exchanged, and we are still just digging into some of these use cases and making sure we are striking the right balance.

Medell Briggs-Malonson
Thank you. We have time for one last question. Bryant?

Bryant Thomas Karras
Thanks so much. I think this is a quick one, but one I feel like I have brought up many times, and I would love it, Mark and Zoe, if it could make its way into the master slide deck because language does truly matter. I left this in the chat. On Slide 29, you refer in the public health use case to "improve quality, reduce cost,

and expand public health interoperability." I think "reduce cost" is not just hypothetical, it has been proven not to be the case. We need to change that language to "improved return on investment" because unless you are exclusively looking at it from the healthcare provider lens, I believe this is going to cost the public health part of the ecosystem a tremendous investment in reengineering and transforming our surveillance and public health response ecosystem. So, legislators read these words carefully, and we need to have ONC make sure to convey an expectation that it is not going to cost less, we are just going to get a heck of a lot more out of it, so, that is a friendly amendment.

Jim Jirjis
My hand is up.

Mark Knee
Go ahead, Jim.

Medell Briggs-Malonson
Okay, very quickly, Jim, because we have to move to public comment, so, thank you.

Jim Jirjis
Really quickly, instead of "remove cost," I would say "reduce complexity." Avoid the word "cost" because it is loaded. There are a thousand ways STLTs report to the CDC, for example, so I recommend "reduce complexity."

Mark Knee
One thought that will be very quick, Medell, is that that is a great point, Dr. Karras, but I want to note that, initially with TEFCA, there will obviously be some implementation costs that do raise costs, but we do think that, over the long term, once this becomes the standard practice, there is the possibility for reduced costs for everybody, but your point is really well taken.

Bryant Thomas Karras
I am looking forward to that.

Medell Briggs-Malonson
Wonderful. Obviously, we still have so many questions and so many ideas about TEFCA, so, hopefully we can extend this conversation sometime in the near future. Thank you so much, Mark and Zoe, for this wonderful presentation. Thank you for all of the input from HITAC. At this time, I am going to transition to Seth for public comment.

Public Comment (02:33:49)

Seth Pazinski
All right, thank you, Medell. We are going to open things up for public comment. If you are on the Zoom and would like to make a comment, please use the raise hand function, which is located on your Zoom toolbar at the bottom of your screen. If you are participating only on the phone today, you can press *9 to raise your hand, and once called upon, you can press *6 to mute and unmute your line. I have a couple of administrative announcements while we give folks from the public a chance to queue up. Just a reminder that our next HITAC meeting is going to be on July 11th, and also, just a reminder that all of the HITAC

materials can be found on HealthIT.gov, including all the presentations from today's meeting. With that, I am going to do a check of hands here to see if we have any hands raised. I am not seeing any raised hands. Accel, do we have anyone queued up on the line? Okay, there are no comments at this time. I will turn it back to Medell and Sarah for their closing remarks.

Final Remarks and Adjourn (02:35:07)

Medell Briggs-Malonson
Thank you, Seth, and again, thank you to all of our speakers and presenters today. This was just an amazing meeting, as always, with so much knowledge, and again, we look forward to continuing these conversations on behalf of HITAC, so thank you so much. Sarah?

Sarah DeSilvey
I was going to reiterate what Medell said. Thank you so much. This is like one of those instances where our conversation ranges from the whys to the whats, the USCDI+ Public Health use cases into the very granular details, over our last two presentations. I am very grateful for all of your expertise and for responding to the thoughtfulness of these presentations, and we hope you have a lovely rest of your day. Thank you all so much, and we will see you next month.

Anna McCollister
Thank you.

Medell Briggs-Malonson
Bye.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Rochelle Prosser: Good - Morning Everyone!

Bryant Thomas Karras: Hear hear

Bryant Thomas Karras: 🤟

Jim Jirjis: Bryant Karras and Washington State are one of those early jurisdictions who are connecting to TEFCA in a couple of weeks!

Jim Jirjis: Bryannt is Also on the call

Rochelle Prosser: Congratulations and wish the companies well as the begin the TEFCA journey.

Bryant Thomas Karras: July 1… don't Jinx me

Sarah DeSilvey: Thank you, Micky! Exciting news as always!

Medell K. Briggs-Malonson: All amazing updates!

Deven McGraw: Great work, ONC!

Rochelle Prosser: Please send the LEEP link.

Meg Marshall: Apologies for joining late

Rochelle Prosser: Thank - you Seth.

Desiree Mustaquim, CDC/OPHDST/DPSD: This is the report that Katie mentioned that is driving the MDN work. See recommendation #1: https://www.cdc.gov/about/pdf/advisory/DSW-Recommendations-Report.pdf

Seth Pazinski: ONC LEAP link...https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information

Seth Pazinski: USCDI+ link for more info...https://uscdiplus.healthit.gov/uscdi

Eliel Oliveira: Do we have a vision/strategy on the collection of results of at home tests?

Katrina Miller Parrish: +1 @Eliel!

Bryant Thomas Karras: For true on the ground public health practice we need to look beyond CDC

Bryant Thomas Karras: Thank you for recognizing this Katie

Desiree Mustaquim, CDC/OPHDST/DPSD: Correct @Bryant - this is why the open comment period is so important and valuable.

Jim Jirjis: Would not have it any other way Standards is a team-based sport

Bryant Thomas Karras: Eliezer is think NIH RadX was working on that but not sure that continued after the emergency status ended

Bryant Thomas Karras: @Eliel

Eliel Oliveira: Thanks, Bryant!

Desiree Mustaquim, CDC/OPHDST/DPSD: For USCDI+, it was mentioned for the lab use case: "The exchange of reportable laboratory order and result data necessary for the investigation and treatment of reportable diseases. Includes electronic ordering and reporting of suspect cases, reporting point of care and at-home testing results to public health, and other more traditional lab data exchange with immunization & vital records systems."

Desiree Mustaquim, CDC/OPHDST/DPSD: Many of the lab data elements needed for home testing would likely overlap, as the scope for lab data exchange was very wide,

Desiree Mustaquim, CDC/OPHDST/DPSD: Home-based testing is a huge gap for many of us.

Jim Jirjis: point of care testing kits

Jim Jirjis: whetehr at home or in office.

Desiree Mustaquim, CDC/OPHDST/DPSD: yes

Jim Jirjis: Isnt it a matter of those test kits using the USCDI and USCDI+ applications using current terminologies in their app;lications/her systems

Desiree Mustaquim, CDC/OPHDST/DPSD: Yes! Thank yo, Bryant - these are the "nontraditional testing sites" I was referring to.

Keith E. Campbell to Hosts and panelists: Current terminologies (LOINC + SNOMED) don't have the necessary granularity to track effectiveness of test devices.

Desiree Mustaquim, CDC/OPHDST/DPSD: I think the home testing issue is far more than the technology.

Hans Buitendijk: At home test data sharing seems less of a USCDI(+) challenge, more an infrastructure question on how to share with the provider/others and associate with a patient's record.

Desiree Mustaquim, CDC/OPHDST/DPSD: agree, @Hans. Also, @Keith - UDI is included currently in the USCDI+ use case for lab data exchange.

Hans Buitendijk: UDI is in for Implantable Devices, but not yet for test kits, etc.

Desiree Mustaquim, CDC/OPHDST/DPSD: Thank you, everyone!

Hans Buitendijk: As the Da Vinci guides are recommended, thus one can deviate as we are still learning/maturing, I would assume the test results are all informational beyond the test itself, correct?

Medell K. Briggs-Malonson: https://www.healthit.gov/sites/default/files/page/2024-05/DSI-Criterion-Resource-Guide_508.pdf

Avinash Shanbhag: @Hans. These testing capabilities toolkits are available to developers and test the conformance requirements in the balloted standard published by HL7. Da Vinci IGs are not currently part of certification.

Robert Anthony: I would add to Avinash's comments that we definitely understand that the Da Vinci IGs are continuing to develop, and we're certainly looking at how these available test kits can iterate as the IGs themselves develop

Katrina Miller Parrish: Thanks so much - great info and detail!

Jim Jirjis: thank you for the presentation. One question: I know initially it was said that it was anticipated that we would end up with only a handful of QHIN's. Do we still think that will end up being true? also what is driving and entity to decide to become a QHIN instead of staying a participant?

Deven McGraw: Jim, I have wondered that myself - I think that some of the QHIN business models are not just based on membership fees but also monetization of de-identified data passing through their pipes (which can be done legally as long as their BAAs with their provider customers allow it). Don't know this for sure - this is based on some things I have heard and some documentation I have seen from at least one QHIN.

Kim Lundberg: Another good high level TEFCA resource, the 2023 HITECH Report to Congress: https://www.healthit.gov/sites/default/files/page/2024-04/2023-HITECH_Report_to_Congress.pdf

Eliel Oliveira: Where would be the endpoints for FHIR exchange? QHINs, EHRs, HIEs, all of the above?

Bryant Thomas Karras: @Mark Knee: Slide 29, not sure PH goal is to reduce costs. Just to improve return on investment. It may cost us [Public Health] more to modernize and migrate to be interoperable and maintain in the cloud… agree improved response and better service but can't promise lower costs to PHAs. Maybe from providers respect, better standardized may result in savings to them [us Healthcare].

Jim Jirjis: Another question: early discussions had on the roadmap both facilitated FHIR and brokered FHIR. is the latter still in play?

Christopher Muir: @Eliel For Facilitated FHIR, it would be systems at the participants or subparticipant level to allow them do point-to-point FHIR API exchange. Usually, those would likely be EHRs.

Jim Jirjis: seems we are stuck on slide 35

Bryant Thomas Karras: Think this is all under the 3rd dot pointNew and Updated SOPs

Eliel Oliveira: Thanks, Chris!

Medell K. Briggs-Malonson: We are on the correct slide. Zoe is discussing the SOPs under bullet 3

Kim Lundberg: https://rce.sequoiaproject.org/tefca-and-rce-resources/ to find the SOPs, RCE updated website is so helpful!

Zoe Barber: https://forms.microsoft.com/r/ZZicptZs1W

Mark Knee:

The SOPs being released on July 1 include the following:

a. QTF

b. FHIR SOP

c. Exchange Purposes (XPs)

d. Delegation of Authority

e. RCE Directory Services Requirements Policy

f. Security Incident SOP

g. Expectations for Cooperation

h. Governance Approach

i. IAS Provider Requirements

Additional SOPs being worked on for release post July 1 include Treatment Implementation XP, Health Care Operations Implementation XP, Public Health Implementation XP, IAS Implementation XP, Dispute Resolution, and QHIN Security for the Protection of TI.

Christopher Muir: @Jim Jurgis - we replaced "brokered" exchange as Stage 3 in the original roadmap to an updated roadmap with stage 3 being QHIN-to-QHN FHIR API exchange and then added phase 4 which will be end-to-end FHIR exchange to follow exchange patterns much like the IHE exchange. Essentially, both stage 3 and stage 4 were the old stage 3 "brokered exchange"

Katrina Miller Parrish: Prolific!

Rochelle Prosser: +1 Katriina

Elisabeth Myers: And here's the link to the RCE resource page which has the current SOPs grouped by type. https://rce.sequoiaproject.org/tefca-and-rce-resources/

Adele Stewart: Where is the feedback form?

Christopher Muir: Here is a link to the updated FHIR Roadmap v.2 https://rce.sequoiaproject.org/wp-content/uploads/2023/12/FHIR-Roadmap-for-TEFCA-Exchange.pdf

Rochelle Prosser: Fantastic presentation Zoe

Zoe Barber: https://forms.microsoft.com/r/ZZicptZs1W

Jim Jirjis: @ Mark. public health early demonstrations do not get started in July...the GO LIVE in July! :) Woot Woot

Jim Jirjis: Metcalf's law!

Katrina Miller Parrish: Appreciate all your explanations Mark!

Bryant Thomas Karras: Will handle my concern in chat @Medell so we can save time

Bryant Thomas Karras: Lowered my hand

Steven Eichner: What are the plans for a public health advisory group? For a state Medicaid group? For patients, especially with focus on both research and treatment?

Jim Jirjis: will you cover some of the chat questions?

Medell K. Briggs-Malonson: Let's see if we can get to the chat questions live after Katrina.

Steven Eichner: Can you speak to how data quality will be addresses, to include accuracy, timeliness, and completeness?

Steven Eichner: +1 Anna

Jim Jirjis: and some only send limited data (like the very last encounter)

Keith E. Campbell: Data quality metrics will be a really important, and trying to answer “why should I trust this data” with metrics…

Keith E. Campbell: And a challenge for TEFCA will be to “Build Trust in Data”

Rochelle Prosser: I am very glad you mentioned the definition of what 'Treatment" means according to this project and Process. That was my Question. What are the methods you are using to define what Treatment means within this context for TEFCA, QHIM etc.?

Rochelle Prosser: +1 Katrina

Keith E. Campbell: I would like a focus session on data quality metrics… Thanks!

Naresh Sundar Rajan: +1 Keith!

Steven Eichner: A better understanding of TEFCA metrics would be very helpful.

Rochelle Prosser: +1 Keith

Jim Jirjis: the value of tefca will be muted if everyone is just sending the last encoutner's worth of data

Jim Jirjis: i realize it is push and pull, but what is pulled is constrained by what the source decides to send (or push) to the query requestor

Hans Buitendijk: We have to be very considerate on how to scope queries to avoid sharing everything always. How can we right-size data sharing, yet get the relevant data for the purpose at hand? Having a uniform look-back period will yield its own unintended consequences.

Derek De Young: +1 Hans

Keith E. Campbell: Different data types have periods of relevance. Having a one size/uniform look back period for all types of data can lead to patient harm.

Hans Buitendijk: As well as more data to de-dup and reconcile by the receiver. It will be a balancing act.

Deven McGraw: Fwiw, minimum necessary would apply to any query (at least where data covered by HIPAA is being sought) other than a treatment or individual access query.

Keith E. Campbell: Jim's example about cxr abnormality is one.

Keith E. Campbell: Another are medications that have lifetime dose implications, such as Bisphosphonates.

Deven McGraw: But minimum necessary (at least the policy) is intended to be flexible based on the circumstances, not just the use case, so it's difficult to hardwire a set of rules or expectations....

Keith E. Campbell: Certain titers have lifelong implications and similar.

Hans Buitendijk: FHIR has the promise to be more surgical about requesting data of interest. But that will yield its own complexity. We have lot to learn here.

Bryant Thomas Karras: Return on investment may take 15 years. Like it did with Meaningful use

Seth Pazinski: Next HITAC meeting is 7/11

Jim Jirjis: I say reduce complexity because ultimately complexity of current datra exchange contributes significantly to cost. over time as TEFCA reduces complexity, costs should come down

Seth Pazinski: All HITAC materials at HealthIT.gov

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HITAC Webpage
HITAC - June 13, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO on 8/20/2024.