Health Information Technology Advisory Committee (HITAC) Virtual and In-Person Meeting

Transcript | October 17, 2024, 9:30 AM – 2:45 PM ET

Attendance

Members

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

Members Not in Attendance

Trudi Matthews, UK HealthCare
Mark Sendak, Duke Institute for Health Innovation

Federal Representatives

Keith E. Campbell, Food and Drug Administration *(Absent)*
Jim Jirjis, Centers for Disease Control and Prevention *(Absent)*
Kyle Cobb, Centers for Disease Control and Prevention *(attending on behalf of Jim Jirjis)*
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology *(Absent)*

ASTP Staff

Micky Tripathi, Assistant Secretary for Technology Policy and National Coordinator for Health IT
Steve Posnack, Deputy National Coordinator for Health Information Technology
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Designated Federal Officer

Presenters

Stephanie Lee, Branch Chief, Strategic Planning Branch, ASTP
Wesley Barker, Branch Chief, Data Analysis Branch, ASTP
Jordan Everson, Public Health Analyst, Data Analysis Branch, ASTP
Liz Turi, Care Coordination and Collaboration Branch Chief, Office of Standards, Certification, and Analysis, ASTP
Adam Wong, Senior Innovation Analyst, ASTP

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

Seth Pazinski
Good morning, everyone. Welcome to the October HITAC meeting. I am Seth Pazinski with the Assistant Secretary for Technology Policy (ASTP), and I will be serving as your designated federal officer for today. As a reminder, this meeting is open to the public and public feedback is welcome throughout. If you are participating on the Zoom webinar today, you can use the chat feature throughout the meeting, and we will also have an opportunity for verbal comments at the end of our agenda today for the public who have joined us in the room as well as for those of you joining us virtually. I am going to start by welcoming our ASTP executive leadership. I want to welcome Steve Posnack, our Principal Deputy Assistant Secretary for Technology Policy, and I will also welcome Avinash Shanbhag, our Executive Director for the Office of Standards Certification and Analysis. And now, I will begin the call with a roll call, and I will start with our co-chairs, so when I call your name, please indicate that you are present. Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Sarah DeSilvey?

Sarah DeSilvey
Good morning, everybody.

Seth Pazinski
Shila Blend?

Shila Blend
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk? Michael Chiang?

Michael F. Chiang
Good morning.

Seth Pazinski
Derek De Young?

Derek De Young
Good morning.

Seth Pazinski
Good morning. Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Lee Fleisher?

Lee Fleisher
Good morning.

Seth Pazinski
Good morning. 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
Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Seth Pazinski
Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
Good morning. Trudi Matthews? Anna McCollister? 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?

Aaron Neinstein
Good morning.

Seth Pazinski
Good morning. Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning, all.

Seth Pazinski
Good morning. Randa Perkins?

Randa Perkins
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser? 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 call our federal representatives on HITAC. I did get a message that Keith Campbell will not be able to join us today. Kyle Cobb?

Kyle Cobb
Good morning.

Seth Pazinski
Meg Marshall?

Meg Marshall
Good morning.

Seth Pazinski
Alex Mugge? I did get a message that Alex may be joining us a little late this morning. Ram Sriram? All right, thank you. Is there anyone online that I missed? Sorry, Eliel Oliveria?

Eliel Oliveira
I am here.

Seth Pazinski
Thank you. Sorry about that. And now, please join me in welcoming Medell Briggs-Malonson and Sarah DeSilvey for their opening remarks.

Opening Remarks and Review of the Agenda (00:03:36)

Medell Briggs-Malonson
Thank you so much, Seth, and good morning, everyone, both everyone here within the room with us as well as everyone that is on the Zoom. It is always such a pleasure to be in the same space as the entire HITAC committee, and we have a wonderful, wonderful meeting ahead of us today. One of the first things I want to bring up before I transition to Sarah is that we have a couple of housekeeping items, specifically for everyone that is in the room. All of you all have a sheet of paper that is right in front of you that we are going to go over very, very briefly.

First of all, when you are speaking, you press the button right here on the microphone. Please say your name first before you either ask your question or provide your comment. The reason why is that we want to make sure that your name is actually provided for the record. In addition to that, as we all know, the public can make comments in the Zoom, and you all can also log into our Zoom if you would like to make additional comments without saying anything audibly at that point in time. If you do have your Zoom on, please make sure your camera is off, as well as your microphones, and our Accel team will also be able to assist us with that. Everyone should be able to see all the different Wi-Fi on the various different screens around us, so please make sure to sign into Wireless Fidelity (Wi-Fi).

The other thing is that, if you are on virtual, the same way that we normally do conduct business with HITAC, please raise your emoji hand if you have a question or comment. For those of you in the room, as a nice reminder, we have physical placards, so if you have a question or a comment, you are going to move your placard upright, and that way, Sarah and I can see, and we are going to scan the room as well as the virtual Zoom in order to try to go in order. Last but not least, and this will be a reminder that will be provided numerous times, as some of you

already know, you all cannot leave this room without a chaperone. Again, you cannot leave this room without a chaperone, but we do have restrooms right behind us, and there is a filter for fresh water behind us as well. All right, so, those are all of the housekeeping items. We will continue to reiterate those. Again, I am so excited to be with all of you all today, and so excited to jump into the meeting. And now that I have finished the housekeeping roles, I will turn it on over to Sarah.

Sarah DeSilvey
I just want to extend a similar welcome to everybody who is here in person and everybody who is on a Zoom in this meeting. It is really lovely to be back with all of you. I have the honor of going through the agenda, so if we can go to the next slide, just so people at home can follow through, the task for today is quite large. There are several significant things that we have to address over the course of our time together. We are going to be going into the charge for the ever so critical and very thought out Health Equity by Design Task Force, then we are going to be going into ASTP objectives, benchmarks, and data updates from our friends at ASTP. We will then have the United States Core Data for Interoperability (USCDI) + Cancer presentation from Liz Turi, and then we will break for lunch for an hour. After that, we will come back, and Micky will join us for remarks from the Assistant Secretary for Technology Policy and the National Coordinator for Health IT. He is triple-booked today.

And then, after Micky's presentation and his speech, we will go into the draft HITAC annual report and the extensive work of that workgroup. They will be presenting in the first part of the afternoon. After that, we will have the draft federal Fast Healthcare Interoperability Resources (FHIR) action plan, and then we will have a period of public comment, and we hope to close slightly before 3:00 to allow people who have to catch planes to catch them and fly home. It does look like a really powerful and impactful day, and we are very grateful that all of you can be here with us today. Now I have the honor of passing off to Seth.

Health Equity by Design Task Force 2024 Charge (00:07:50)

Seth Pazinski
All right. Thank you, Sarah and Medell. I am going to go over the Health Equity by Design Task Force charge, roster, and timeline. I think we are both happy to be finished with the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule review, and also happy to kick off this important work, so we are excited to get this Task Force going. We can go to the next slide. So, I will just go over the charge, which is to provide ASTP with recommendations on promising practices, challenges, and resources to support health and human services organizations to incorporate Health Equity by Design principles into the design, build, implementation, use, and monitoring of health IT. The recommendation should include both considerations that health and human services organizations can use to begin their work on including Health Equity by Design into health IT, as well as recommendations to ASTP for potential next steps to continue to advance implementation of Health Equity by Design principles into the design, build, implementation, use, and monitoring of health IT. We have asked for those recommendations to be completed by May 2025. Go to the next slide.

So, this is the roster for the Task Force. I want to thank both Hannah Galvin and Hung Luu for agreeing to step up and serve as the co-chairs for this important work and the rests of the folks on HITAC, as well as our federal partners and outside experts who are joining the Task Force as well. Go to the next slide. This is the list that will be shared here with HITAC, as well as with the Task Force as they start their work. These are considerations for HITAC to think about as they work on their recommendations related to the charge. These have come from your feedback from when we talked about this earlier this year, as well as the public feedback that we got on the Health Equity by Design concept paper that ASTP put out for public comment. And so, this includes things to think about as you work through the HEBD Task Force work and recommendations. It includes things like how to incorporate accountability into health IT HEBD efforts. Go to the next slide.

And then, lastly, I just want to go over the timeline. So, we are syncing up with our co-chairs next week to go over all of the plans for the Task Force, including what the weekly schedule is going to be, and then we anticipate weekly meetings of the Task Force. We will start by taking a look at the public feedback that ASTP received on our concept paper, and then we will start with discussing and focusing on the recommendations to support health and human services organizations, and then move on to the recommendations for ASTP on potential next steps. So, we would expect that the HITAC would be reviewing the draft work of the Task Force at the April HITAC meeting, and then, final recommendations and vote at the May HITAC meeting. So, that goes over our charge, our roster, and our timeline, so I welcome any feedback or questions that folks have at this point.

Medell Briggs-Malonson
Thank you so much, Seth, and yes, congratulations to both Hannah and Hung for being the co-chairs of this incredibly important Task Force. I think so many of us in the entire HITAC committee thank you for your leadership, and we are very excited to kick this work off. Are there any questions for Seth about the Health Equity by Design Task Force charge and the kickoff that is going to begin in about a week? Any questions or comments at all? All right. Yes, Sarah?

Sarah DeSilvey
I am going to quickly comment and say it is such a critical thing, of course, from a Gravity Project perspective. Health equity is part of everything that we focus on in our work, and we are very grateful to ASTP for convening this meeting that has been well thought of and planned for quite some time to address this critical topic. I am looking forward to the work, and thank you to ASTP for giving it a forum.

Medell Briggs-Malonson
Thank you so much, Sarah. I completely agree. Any other comments? Yes, Derek?

Derek De Young
Is it too late to join the workgroup? Never too late? That is what I like to hear. Otherwise, Sarah would be very, disappointed in me.

Medell Briggs-Malonson
Well, Derek, you saw me. I was like, “It is definitely not too late,” but I had to confirm it with Seth. This is very important as well because you do see exactly where our roster is, but when it comes to Health Equity by Design, especially thinking about incorporating the principles of equity and justice into our health IT systems, so many of us around this table and beyond have a large amount of expertise, and we are looking at this from all the different directions in order to ensure that we are providing recommendations that are inclusive when thinking about how to execute this work when it comes to health IT structures and policies. So, please, if there is anyone else that would like to join this very important Task Force, we welcome you. Good morning, Anna. There are already some people that are being volunteered for it as well. Any other questions or comments?

Seth Pazinski
Thank you, Derek. We have you down. If anyone else is interested, please reach out to us.

ASTP Objectives, Benchmarks, and Data Updates (00:13:40)

Medell Briggs-Malonson
Thank you so much, Seth. Well, we will go directly right on into the next topic on our agenda this morning, and that is actually going over our ASTP objectives benchmarks and data updates. This is always such an incredibly

exciting portion of all of our HITAC meetings in order to see a bit more about all the amazing work that ASTP is conducting. Seth, I will turn it on over directly to you, and then the rest of the team after you.

Seth Pazinski
Thank you, Medell. Unfortunately, you get more of me this morning, but you will at least get the benefit from the best of my colleagues. I just want to start by saying that we are going to cover a lot of topics today, so please refer to these slides in the future, too, as a handout, so we will be quickly touching on various topics. We can go to the next slide. So, this presentation fulfills a statutory requirement on behalf of ASTP to present our objectives and benchmarks to the HITAC. The presentation that you are seeing here today will be incorporated into the HITAC annual report draft that you will be discussing later in the meeting today.

This also serves as information on how we are implementing the 2024-2030 federal health IT strategic plan that was recently released and incorporates the objectives that you will see later in the slides, and we welcome your feedback on the objectives benchmarks as well as your discussion and feedback on the data updates as well. I also wanted to acknowledge the HITAC for their input on the draft federal health IT strategy back in the May HITAC meeting, so I really appreciated your feedback, and that did help inform the final version of the strategy, including a greater emphasis on data quality, which was a key part of the discussion back in May at the HITAC meeting. Go to the next slide.

So, these are the HITAC priority target areas. You will also see this later today in the Annual Report Workgroup, including the discussion of potentially adding an additional priority target area to this list, but this is from the FY 23 HITAC annual report, and again, the presentation here today will be incorporated into that annual report. We can go to the next slide. Before I get into the specific activities, I just want to give an overview of how we group our activities at ASTP, how those feed into our objectives, and ultimately what the intended impacts of our work are on the agency. Go to the next slide.

Generally, the work of ASTP can be bucketed into four things: Standards, certification exchange, which gets into the expectations on data sharing, like our work on Trusted Exchange Framework and Common Agreement (TEFCA) or information blocking, regulations, and coordination, which incorporates both the government and industry coordination. That feeds into our two objectives, which are to advance the development and use of health IT capabilities, as well as set expectations for data sharing. The intention there is all feeding into what the impacts are from the agency on our work, and these are actually laid out in statute for us in the HITAC Act, which was to make improvements in healthcare, public health, health research, health equity, patient access, and competition and choice within healthcare. Go to the next slide.

And now, I will go through the activities from the past year to recap them. Go to the next slide. This is our regulatory work. You all are intimately familiar with this, having given us 143 recommendations on HTI-2 at the last HITAC meeting, and we also published the final rule for Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule at the beginning of this calendar year. Go to the next slide. So, the latest version of USCDI, Version 5, also benefited from HITAC's recommendations and feedback, and included a number of new data classes and data elements, including those that support equity-related standards. Go to the next slide.

So, we began our work in engaging with HITAC and with the public on a number of USCDI+ domains over the past fiscal year. Today, we are going to hear about the USCDI+ Cancer domain, and then we will conclude our initial engagement with HITAC on these domains with a presentation and discussion on USCDI+ Behavioral Health in the November HITAC meeting. Go to the next slide.

So, we also completed the latest turn of the crank on our Standards Version Advancement Process (SVAP) with 10 approved standards in 2024. These included USCDI v4 and the USCDI Core FHIR Implementation Guide Version 7. We also continued supporting work related to advancing the FHIR standard, and we released a 2024 draft federal FHIR action plan, which we will be discussing with you all later in the meeting agenda today. Next slide.

In the public health space, we continue the work on the Helios public health FHIR accelerator with some work done in testing some use cases for prior queries, and that work can ultimately support some future TEFCA functionality. Go to the next slide. Lastly, in the standards space, we presented with our colleagues from the United States Department of Health and Human Services (HHS) Assistant Secretary for Financial Resources on the proposed rule that focuses on acquisition requirements related to the adoption of HHS adopted standards, and that work aims to advance the overall authorities and investment power of the HHS in helping to drive forward HHS-adopted standards within the market. Go to the next slide.

Moving into the certification program, the main emphasis here is focused on implementing the HTI-1 final rule that went into effect earlier this year. This will work on USCDI v3 as well as a number of different certification companion guides and educational resources, including those on the Decision Support Interventions (DSI) resource guide and DSI roadshow webinars that are under way. And then, we also continued to build out the Inferno framework with a number of new test kits that were put in place over the past year. Next slide.

So, this was a big year for TEFCA, as you all are familiar with. Seven-plus Qualified Health Information Networks (QHIN) went live with data-exchanging capabilities, and we also put forward the Common Agreement Version 2.0 and related publications and documents to support FHIR-based exchange through the TEFCA umbrella. Go to the next slide. In information blocking, we continued to put the regulatory framework in place, with HHS publishing its final rule, which became effective back in July, with provider disincentives related to information blocking. Go to the next slide. We also continued to monitor information-blocking claims that come through the information-blocking portal. We have received over a thousand complaints to date since we put that portal in place back in 2021. Next slide.

For Health Equity by Design, I mentioned continuing to support data elements that support equity-related standards through the USCDI process. We also published the Health Equity by Design concept paper that we hope will help inform the work of the HEBD Task Force for HITAC, and also made good progress through the Public Health Informatics & Technology (PHIT) workforce development program, which aims to bring informatics expertise into the public health workforce, and we have trained over 3,700 students through that program, with a target of reaching 5,000 by the end of next year. With that, I am going to turn it over to Stephanie Lee, who is going to talk about what we have coming up in the year ahead.

Stephanie Lee
Go ahead and go to the next slide, please. So, starting off with the standards work, we plan to continue working on SVAP and USCDI, which, as you all know, run in annual cycles. We anticipate HITAC reconvening the Interoperability Standards Workgroup in a couple months this upcoming January for the release of the draft USCDI Version 6. Also, engagement with HITAC on the USCDI+ domains will continue as the existing initiatives progress. That being said, we do anticipate engaging on the USCDI+ Sickle Cell Disease domain next year.

So, this is just a snapshot of the work around FHIR. We will continue support for aligning US Core FHIR implementation guides (IG) with the latest USCDI versions. We will also look to finalize the federal FHIR action plan and continue leading the Global Digital Health Partnership (GDHP) program. Support for FHIR advancement in the public health space will also continue. This will be through the support of Standard Development Organization (SDO) activities and FHIR profile development in the USCDI+ Public Health domain. We will also be

initiating production pilots and testing use cases as we go. Next slide, please. We also recently announced our latest investments on Leading Edge Acceleration Projects (LEAP). The work of these most recent awardees will focus on artificial intelligence (AI) as well as the adoption of health IT in behavioral health settings. So, with the Health IT Alignment Policy, we will continue to take additional steps for implementation. This includes the advancement of technical assistance on health IT adoption and use as well as supporting finalization of the HHS Acquisition Regulation (HHSAR) Proposed Rule.

Shifting over to the certification program, we just wanted to highlight some technical conformance requirements coming up in 2025. These are some of the implementation pieces of the HTI-1 final rule, such as view, download, & transmit (VDT), e-case reporting, and standardized application programming interface (API) for patient and population services. We also plan to continue implementing test tool updates and certification programs. So, this slide is just showing ongoing plans to support Inferno test kids in FY 25. We will be supporting testing tools for the industry on standardized APIs, prior auth, and other capabilities.

So, as you all know, TEFCA operations are in full swing. We do expect to release multiple standard operating procedures (SOP) in the coming year, and we will look to increase FHIR-based exchange via TEFCA as well. As Seth said, with information blocking, now that we have the initial regulatory framework in place, oversight of information blocking will continue, as well as the analysis. Last but not least, we are also looking to advance equity-related standards through our USCDI, USCDI+, and certification program efforts. Through the HITAC, as was mentioned earlier during this meeting, through the Health Equity by Design Task Force, the committee will have the opportunity to support this by providing recommendations on resources to help healthcare organizations in building these principles into their organizations' practices, and we will also continue to train **[inaudible] [00:25:53]** help, and now I will turn it over to Wes and Jordan.

Wesley Barker
Thank you, Stephanie. I am Wesley Barker, the branch chief for data analysis here at ASTP. I am going to do a brief overview of the accomplishments at ASTP on our data analysis team over the past year, and then hand it off to my colleague, Jordan Everson, who will provide a presentation on new findings from a cooperative agreement with the American Board of Family Medicine. Next slide.

So, as a sort of year in review, ASTP is mission-focused to put out as much as we can related to our research findings, putting out in the public space the things that we find out through the research that is done annually by the team. You can find much of the published work on HealthIT.gov/data, where we self-publish our data briefs as well as other analyses. We have also published extensively in academic literature, and you can find many of our papers there, and often communicated through our listserv as well as our social media channels. We covered a plethora of topics in the past year. We will not go through them all here, but given the breadth of ASTP's mission and the broad focus of our policy work, the research work focuses as well on a broad set of topics, and much of the research we published in the past year covers that breadth of topics. Next slide.

Here are upcoming activities, looking ahead now that we are in FY 25. We have upcoming data coming our way that is either ongoing or completed and in our hands. The annual health IT supplement to the American Hospital Association annual survey, which we collaborate with AHA on, will cover a number of topics related to APIs, machine learning, and artificial intelligence, as well as ongoing tracking of hospitals' awareness of and plans to participate in TEFCA. We also are looking forward to new results from the National Electronic Health Records Survey, which is a collaboration between the CDC's National Center for Health Statistics and ASTP. Next slide.

We also look forward to the next set of results from the Health Information National Trend Survey, which is a survey done every two years by the National Cancer Institute, and ASTP is a champion of and contributor to that survey, particularly focused on patient access to online medical records, and we look forward to updates from that

survey very soon. Finally, as a lead-in to Jordan's presentation, we will also be looking at new data collected through this cooperative agreement with the American Board of Family Medicine, looking particularly at family medicine providers' experience with their technology in respect to interoperability burden, public health reporting, and social needs documentation and use. Over to Jordan.

Jordan Everson
Hi, everyone. As Wes said, I will be walking through results from our cooperative agreement with the American Board of Family Medicine. Next slide. So, as you may know, ASTP has supported surveys of physicians' use of health IT for over a decade, going back initially to the National Ambulatory Medical Care Survey, and later through the National Electronic Health Record Survey, both of which were collaborations with the National Center for Health Statistics within the CDC. Beginning in 2021, we launched a cooperative agreement with the American Board of Family Medicine with the idea of moving away from an adoption and "do you use/do you not use" style of survey towards a survey directly aimed at measuring physician experience using health IT, how well it was going, and where there were friction points for more of a subjective understanding of this as a way to understand the impact of ONC/ASTP's policies as well as where the industry stands as a whole.

And so, as part of this cooperative agreement, we have been able to partner with physician leaders at the American Board of Family Medicine (ABFM), and then get really exceptional access to practicing physicians to design effective research questions because it is substantially hard to design questions that match how doctors experience their technology. The cooperative agreement also has a unique design that ensures high response rates, which I will describe on the next slide. Go ahead.

So, as a quick context setter, there are over 100,000 family medicine physicians, making them the largest primary care specialty. Primary care, of course, is essential to providing care continuity and coordination across patients' journeys, and so, it is a place where interoperability can have a high impact because they have interest and a role in gathering information from specialists from multiple sites and ensuring their patients are receiving coordinated care across those sites. These questions that we developed with the ABFM are included on the family medicine recertification questionnaire, and so, essentially, this is required on a recurring basis. When a family medicine doc goes to get board recertified, they are required to complete the questionnaire that we developed with ABFM.

This is really helpful because surveying anyone is very hard these days. Physicians in particular have very low response rates, and other survey efforts can suffer from response bias, where the folks who respond do so for a reason and may not represent the overall population. Here, these folks have to respond, so we avoid that really difficult problem of response bias. We are also able to get a very large sample of respondents, over 7,000, in the data that I will be presenting today, which is large for a survey of this nature.

I will be presenting questions and data from 2024 because we went through a really thorough redesign of these questions in 2024, but over a pretty long process that included two expert panels, one to inform the approach and one to finalize the content and make sure we were capturing what we needed to. We then did 20 interviews with family physicians to try to understand how they thought about interoperability and how they thought about gathering information from outside sources. Once we had a survey instrument in place, we did four focus groups to cognitively test the questions and make sure they were well written and well understood.

Really, the overall goal of this was to match respondents' mental models by focusing on specifically how they think about information that they need, what is missing, and what is important to care for their patients, and also focusing on where substantial exchange is occurring today. A challenge here is that it is very hard to ask questions around the exchange of things like behavioral health data because, in interviews, physicians said, "Well, I have never received anything like that," so it is very hard to structure good questions and expect to see a signal for

things that are forward-looking in nature, and in some cases, they are not where the industry is at today. Next slide.

This is just a very quick overview of who these respondents were. Sixty percent were over age 50, 52% were male, 47% were female, 34% practiced in a health system, 29% practiced in independent practice, 16% in rural locations, and over 22% of respondents said that over 50% of their patient panel were part of a vulnerable group. So, this is a self-reported number of who treats patients from a vulnerable group. So, there was a pretty wide slice, and again, this should look a lot like the population of family medicine physicians because it is not a voluntary survey, it is something that they take as part of certification. Next slide.

So, I am going to walk through findings in two pieces, first focused on clinical information exchange and interoperability, and then focused on physician burden. I will give you a preview of these results before walking through some charts, and fundamentally here, we find that relatively few family physicians are very satisfied with their electronic health records (EHR) support for interoperability despite support of policy in a lot of work by industry in this direction. Maybe unsurprisingly, we see a substantial difference in how physicians experience accessing information from organizations that use an EHR from the same developer versus those accessing information from organizations that use a different EHR. I think one way that we can think about this data is that parity in these measures could be a measure of success, that it does not matter if they are using the same EHR or a different one. Information flows.

The next highlight is that physicians report limited flow of core information, including laboratory results and imaging reports. I think it is relevant to continued work in lab interoperability and the interoperability of images themselves to understand where imaging reports sit today. And then we have this focus on ideal data flow or ideal interoperability, and few family physicians report experiencing ideal interoperability where they often automatically obtain information, that it is easy to find, and that it is easy to reconcile or otherwise use. I will walk through these charts in the coming slides. Next slide.

The first thing we asked is “How satisfied are you with how your primary outpatient EHR supports obtaining health information from outside organizations?”, and a lot of our physicians said that, overall, they are very satisfied, 24% said they are somewhat satisfied, so that was about a third, and the remainder said they were not satisfied, dissatisfied, or even the 16% that said their EHR does not have this capability at all. Next slide.

We then split this into “How satisfied are you with your ability to access information from those organizations that use the same EHR vendor as you versus those that use a different EHR vendor?”, and 24% of physicians said they are very satisfied with accessing information from organizations that use the same EHR, and just five percent said the same about accessing information from organizations using a different EHR. Similarly, there were higher rates of saying they were somewhat satisfied about accessing information from organizations using the same EHR, and you see almost 40% of family physicians said their EHR has no ability to currently electronically access information from organizations using a different electronic health record. Next slide.

From here, we dove into specific types of data, and because physicians told us in interviews that it was hard to think about information in a very broad sense, and rather wanted to think about how you gather specific types of information, given that this can come from very different places. Even from there, looking at lab results, particularly test results in particular, they wanted to separate out test results from commercial labs and health systems, as they are very different experiences, so there is really a necessary level of granularity here. I will not run through all of this, but we will dive into some of this in the next slide.

The general takeaway here is that about a quarter to a third responded to each question saying that they often automatically obtained this information and that they are able to find it in their EHR, and then, 16% said that their

EHR makes it easy to compare the results from outside organizations and internal results. For the vast majority of these, the most common response was “sometimes,” so a sense that this sometimes works and sometimes does not is pervasive here, and there is an unevenness. I would point to this last item around being easy to compare results from outside organizations and internal results as a sign of challenges related to data quality or semantic interoperability, making it hard to say that these are the same things and compare them in meaningful ways. Next slide.

This is another view of a similar set of questions. These are focused on medications. I apologize to folks in the room, as I realize this is hard to read, but this is really intended to depict ideal data flow or ideal interoperability. Where we first asked folks, “How often do you automatically obtain medications in your primary outpatient EHR?”, 32% said they did it often. Of those, we then asked them if it was easy to find those medications in their EHR, and 33% said no, it is often not easy to find that information. Just 21% overall say that they often obtain it and that it is often easy to find.

From there, another third say that, even when they can find it, it is not often easy to reconcile those medications to use them to make a single reconciled medication list. And so here, in the end, here in that brown box, you have 13% of physicians in this ideal interoperability state where they are often automatically obtaining it, they can easily find it, and they can easily reconcile the medications, so there is a clear minority. In the analysis we have done to try to understand this, I would say there are really challenging patterns to understand who is happy and who is not, and it varies by data type and document type that we ask about, because we do ask about a number of different types of data. Next slide.

I said we asked about a number of different types of data. We asked about a number of different types of documents as well. This is focused on imaging reports from independent imaging centers and how family physicians report obtaining those. I think of relevance to thinking about interoperability of images is where we are with imaging reports to just the text-based results from those. About a quarter of family physicians say that they often automatically obtain imaging reports from independent centers in their EHR, and then, if you follow along the top line, about 17% say that they often automatically obtain them and it is easy to find the reports, and just 15% are in this ideal interoperability flow, where they say they often obtain them, it is easy to find the reports, and it is easy to find information they are looking for within the report. I think that last category differs a lot by document type, with some things like encounters. We lose more folks saying that it is not easy to find information in the document here. They do pretty well on the last one. Next slide.

So, as a review of what I just walked through around family physicians’ experience with interoperability, first, we saw that foundational exchange of information remains a challenge, and I think there is the hope or the goal that that will be improved as TEFCA achieves scale, but today, given the various networks in place, family physicians still report that it is not often the case that they automatically obtain that information. I think the challenges we saw to easily finding and using information may support data quality initiatives to ensure that when information is obtained, it is semantically interoperable and has enough quality to use. And then, I made this point earlier, but to reiterate, equal experience as reported by physicians in obtaining information from organizations using the same or a different developer may be one way to think about success in interoperability. Next slide.

So, shifting focus on this data from clinical interoperability to understanding provider burden and how that interacts with the EHR, here are a few key findings. First, about half of physicians indicate that information gathering from other organizations is a substantial burden on them or their practice staff. I think when we think about provider burden, we often do not focus on that as a particular statistic, but it came up in interviews, and we sought to capture it here. We also saw that those who are happy with how their EHR supports interoperability reported lower burden gathering that information, so this is a signal that technology is helping here. We also heard that about half of physicians indicated prior authorization is a substantial burden on them or their practice staff, and here, we saw

that current EHR-based tools to support prior authorization were not associated with reduced burden, and I will show you that in subsequent charts. Next slide.

So, here is how physicians reported on the question around time and effort that they and their staff spend trying to track down information from outside organizations, and you see about 44% said that they spend substantial time on this, about 38% said moderate, and very few said minimal or not applicable. I would say we tried to ask this in a more concrete way, but it is very hard to give time estimates to this sort of question. Next slide.

So, we then cross-tabulated that prior slide on whether there was high time and effort spent gathering information with a question around satisfaction with how your EHR supports accessing information from outside organizations. And so, the farthest to the left is the group of folks who are very satisfied with what their EHR does to support interoperability, and just 28% reported substantial burden gathering information as opposed to, on the far right, the very dissatisfied group. Sixty-five percent of those folks said that there was substantial burden from gathering information, so the takeaway here is that the technology can reduce burden. Unfortunately, only 11% of physicians are in that very satisfied, and moving more folks into it could be a way to think about progress here. Next slide.

We also asked about prior authorization, and here, 55% of physicians, about 10 percentage points more, reported substantial burden from prior authorizations, and again, this is family physicians. The rest reported moderate, with a few saying minimal or that they did not know. So, there was substantial burden from prior authorization, and that is probably not news to anyone in the room. Next slide. We also asked about how often they are able to complete required components of their prior authorization from within their primary outpatient EHR, and a quarter of respondents said that they are often able to complete prior authorization within the EHR, 35% said somewhat, and 17% said not at all. Next slide.

We then did a similar cross-tabulation to ask how burdensome prior authorizations were and whether they were able to do them in the EHR, and the key takeaway from this slide is that folks who do more work around prior authorizations in the EHR are more able to complete these there and report no different burden than those who are working outside of the EHR. So, I think the takeaway here is that current EHR-based workflows around prior authorizations may not be reducing burden. Next slide.

So, to recap the key findings here, we saw lower burden when physicians were satisfied with how their EHR supported interoperability, and again, the idea there would be that ensuring that more physicians are satisfied could really reduce burden from gathering information. For prior authorization, we did not see that same trend, and so, the takeaway might be motivation for ongoing rulemaking and other work to ensure that technology is there to actually have the capability to ease prior authorization where it exists and is used today. Even using technology does not impact burden from prior authorization. Next slide. I think that concludes our presentation here. I am going to hand it back to Seth to manage discussion.

Sarah DeSilvey
Hello. Actually, I have the honor of moderating. Thank you so much for the presentation. It was really wonderful. We have a host of questions. I have tried to get the order in. We do have 30 minutes for discussion. Again, we are very, very grateful, and first of all, this was just an incredible year in general. I just want to note that that presentation was profound. There is an incredible number of accomplishments. All of us on the committee are grateful to work with you all daily, and it is exceptional to see it all on a set of slides on an October morning. I believe Bryant was the first person with a question.

Bryant Thomas Karras
Not surprisingly, most of my questions center around public health, but there are multiple different angles to take here. Back to Seth's or Stephanie's original presentation, which talked about Helios's current successes and plans

for 2025, do we have to wait for HTI-2's final rule to determine that the Helios accelerator needs to be accelerated more? I do not think we have to wait for the final rule to be established to recognize that there are still gaps in what needs to be invested in for Health Level 7 (HL7) adoption and FHIR transformation for the public health space, so I would love it if you could speak a little bit to what additional Helios accelerator, investment, or expansion might be planned.

My second question is about the PHIT program. You mentioned it is winding down in its fourth year and will be graduating a number of graduates, hopefully 5,000. Is there any kind of report yet on how many of those are actually making it into the public health space as opposed to the clinical space that has a public health bent? It is a very different hiring market and workforce development, and I encourage you to coordinate with CDC's workforce development and infrastructure grant recipient to make sure we find a home for that skilled workforce. And, why is it sunsetting? The need is not going away. We need to find another four years of funding for that program.

If I remember, when the awards came out, there were 20 historically Black university or minority-serving universities awarded. There were 20 applications from those types of institutions that scored above the pay line, but there was not enough funding. There is definitely a need and a gap that could be filled there. My last question in the two minutes is about the data-blocking dashboard. You showed some data. Is that a publicly accessible dashboard, or is that only in slide decks? How can we dig into it by jurisdiction and find out what is happening in our neck of the woods?

Sarah DeSilvey
Seth, you are first, I believe, with the first Helios question, but we want to make sure to keep our first round of questions simple so we can let everyone have a chance, and then we will circle back around. Thank you.

Bryant Thomas Karras
If you only answer one of those, Helios would be my top priority.

Avinash Shanbhag
I will begin, but actually, I see Kyle is here, and I would like to mention that Helios is really a joint effort supported by CDC substantially. Beyond a lot of standards work around wider records and improving data access for both parties, there is lots of engagement that we do with CDC with respect to what they forecast as potential improvements and modernization of activities like electronic case reporting (eCR) and other sets of activities. So, again, we could do more, but obviously, there is a finite resource, both from government and industry support. I think what we also do see when we talk to vendors is that they also need time to digest all those changes to be able to give thoughtful responses. So, again, I agree and acknowledge. We need to do a lot. I think HTI-2 and Notice of Proposed Rulemaking (NPRM) did highlight a lot of areas where public health is leaning in, APIs being potentially a huge area for us to modernize on that we will certainly lean on. With that non-answer, I am going to go to Kyle to see if she has any specifics that CDC is interested in.

Kyle Cobb
Thanks, Avinash. CDC is working on providing additional funding for Helios for FY 25. In addition, we just put out a significant cooperative agreement for the additional pilot testing. There is the Public Health FHIR Implementation Collaborative (PHFIC), which comes after the Helios accelerator, but it is for testing in the real world, and as you know, Bryant, we have had continued conversations across PHFIC, Helios, HL7, CDC, and ONC/ASTP for the last months to really tighten that so that we are making sure that whatever is going through the FHIR accelerator is connected to what is happening in real-world testing, which is aligned to HTI-2.

Bryant Thomas Karras

Thanks, and as full disclosure, I am the co-chair of the Public Health FHIR Implementation Collaborative, but it is a pipeline. It is the implementation of things that are developed in Helios to make sure they work in the real world before they are scaled up through implementation centers to the whole country, but there is a supply chain problem. We need those FHIR standards to be accelerated in the areas that are a gap.

Seth Pazinski
I just have a couple quick responses. On the PHIT workforce program that was CARES Act-funded, that was a onetime funding, so there is not funding beyond the current program at this point. And then, I will also bring back the question on the public health versus clinical workforce as far as where folks are landing. I will bring that back to HITAC and circle back on that question. On the information-blocking claims, that is not a public data set. There is some more information available on HealthIT.gov beyond what was presented on the slides today, but that also could be something we could bring back if there is interest amongst the HITAC members to have a deeper discussion on it.

Sarah DeSilvey
Thank you so much, Seth. Because everyone raised their things at the same time, we are going to go to Michael next, and then just go down the row. Michael, thank you.

Michael F. Chiang
Sure, thank you. Stephanie, Wes, and Jordan, I thought that was awesome survey data. My simplistic interpretation of it was that EHRs are passing the granular-level certification and MIPS, and yet, on the high level, something is not working with interoperability, and doctors are not satisfied. That is obviously an uncomfortable thing for me to hear about. My first question along those lines is the way that doctors are evaluated is by Press-Gainey surveys that are very high-level, 1-to-5, Yelp-style surveys. Is this working at a granular level or not? I am wondering if there is any consideration to use some of those high-level criteria for evaluating interoperability.
My second comment is just about imaging reports in the EHR. As someone who does a lot of imaging in their practice, that is a really low bar because the real issue is if they can actually see the images, not the report on the images. My comment is about the slide with information-blocking submissions. I just wanted to ask if you have data because the numbers seemed relatively low to me, in the hundreds. It sounds like these are at the case level. Are these the same people? Are they the same EHRs? What I am really getting at is that I just wonder if more people need to know that they are able to file complaints about information blocking. **[inaudible] [00:56:50]**

Jordan Everson
To the first point about the sense that, despite passing certification, EHRs are not working in some ways, I think the data supports that in some ways, but we have also set a relatively high bar here around a pretty ideal state, where you are routinely getting this information, it is easy to find, and it is easy to use. In contrast to prior surveys and prior ways we have monitored this, it is “do you sometimes or do you ever,” and I think we could analyze this data and set a lower bar and tell a story that we are in the middle, but we have chosen to take away where we are headed towards an ideal and how close we are to getting there. Things like health information exchange (HIE) portals and other ways we exchange things would not count with these measures, so I agree, but it is important to put into context.

I also think you are right that there is something breaking down here, and I think an important role is to understand the root cause analysis of where things fall down in data quality, semantic interoperability, usability, and how things are documented. There are so many potential causes that our data cannot point towards very precisely that there is a lot more to do. To the question about information blocking, I do not create that data, but I will say that we do provide information about who appears to be reporting the complaints, which is primarily patients and patient representatives, and who the complaints appear to be about, which is primarily providers. Also, in the American Hospital Association survey we do of health information organizations, we ask them how often they have reported

information blocking if they have experienced it, and over 95% of hospitals and EEOs that have experienced information blocking said that they have never reported it, so I think we understand that the complaints received are not a perfect representation of the activities out there. I may have missed a question in the middle, and I apologize.

Sarah DeSilvey
That was excellent, actually. I think you did a very good job responding. Dan?

Dan Riskin
Thank you. I would like to echo Sarah's comment. There is a huge amount of work in these very clear presentations, and I thank you. My question and comment are to Jordan. So, this is a really powerful survey that you are requiring answers to. It feels a bit grounded in early ONC, totally focused on EHR, and I wonder whether there might be an avenue to feel more like ASTP/all of health IT to speak to other issues in point of care, like consumer-facing and enterprise-facing applications, and other issues outside of point-of-care, like population health, real-world evidence, and these kinds of areas.

Jordan Everson
I think that is fair. One thing I will point out is that I went through how we developed the survey through interviews and focus groups with family physicians. My take on this survey data is the old Henry Ford line, "If I asked my customers what they wanted, they would have told me a faster horse," and I think what this survey data really reflects is what physicians think they want as ideal, and I think physicians are very EHR-centric. At least as things exist today, if something is outside their EHR, it is hard to get them to look at it. I was just at the Civitas conference where the HIEs were discussing the challenges of getting folks to look at HIE data if it is not really well integrated or there are not clear hooks to the EHR, and I think that remains the case. So, I think it is a challenge for this type of work and for the field as a whole of how we open up the box as well as ASTP would like it to be in terms of the type of applications you are talking about. I have also presented only some of the data that we collected, so I think it is worth noting that I tried to focus on some of the core issues, but we do have some things, so there is a mix.

Dan Riskin
Thank you.

Sarah DeSilvey
Seth, are you all good?

Steve Posnack
Steve.

Sarah DeSilvey
Oh, sorry.

Steve Posnack
We are interchangeable.

Sarah DeSilvey
I know. No, not really!

Steve Posnack

We both have the same abbreviation. So, as Jordan was just alluding to, there are a number of other collaborative surveys that we have with other components of HHS, Dan, that get to some of the other data that is out there, like Health Information National Trends Survey (HINTS). We could talk about that really briefly.

Wesley Barker
I mentioned the Health Information National Trend Survey in the brief year-in-review slides, but that is a survey that the National Cancer Institute has put together for many years to get an understanding of individual Americans' perspectives and experiences using technology as well as their experiences in healthcare. And so, we collaborate with National Cancer Institute (NCI) to add questions to that survey that is fielded every two years. We will be getting the newest data very soon in the next few months for questions that were fielded in 2024, and that provides insights into individual Americans' access to their medical records online. We have published extensively on individual Americans' experiences both getting access to their records and actually going the next step and accessing those records, and also looking at newer topics related to going beyond just the EHR-centric patient portal access and if they are also interested in using apps and other applications to engage with the health information and receive healthcare.

So, that survey covers the gamut in terms of **[inaudible] [01:03:07]**. In addition, we work with the California Healthcare Foundation and University of California San Francisco on a survey of digital health companies. We published a paper earlier this year looking at the results of that survey, which kind of dove into digital health companies' experiences using APIs to integrate with EHRs, so it was those digital health companies' experiences using APIs that have been in place for a number of years or are newer and standards-based, or their experiences integrating other technology EHRs for end user, provider, and patient use.

Sarah DeSilvey
Thank you so much. I just want to keep on moving, if it is okay, and we can circle back around. Katrina?

Katrina Miller Parrish
Hello, I am Katrina Miller Parrish, a family physician. Thank you for adding more questions to my recertification process! But seriously, again, thank you, everyone for all the amazing work and research. Obviously, we all want data-driven, evidence-based reasons as to why we are doing what we are doing, even if it is difficult to see, even if there are a lot of opinions that we have already done it and everything is fine. With this kind of research, we realize there is still so much more to do, and so much more research to do, so, thank you for that.

When we get these answers and we know that it is really a mix of if the data is available or not, and really, the way I see it as a family physician is either it is not, or it is so much that it is a deluge of wading through what I can actually use, but when it is not, I want to know why it is not. Locally, I can see the connections in my local system or the HIE in my area, but I have not been able to figure out the connectivity of the QHIN network yet, and I am not sure exactly who might be able to answer this, but is there some tracking, and maybe it is Sequoia that might be doing this, of the actual national QHIN connectivity that we would be able to see so that, when we get the answers from certain areas, and definitely certain locales or regions, especially the more rural ones, that there really is not connectivity? That should be a major area of focus as opposed to other places. Is there a mapping that we can refer to? Thanks.

Sarah DeSilvey
Who feels best able to answer that question?

Jordan Everson
I think it is useful insight. Thank you for filling out the survey, I suppose. You can thank Bob Philips for making it long. One of the insights from talking with physicians is how different information flowed for each piece of data we

talked about. Medications are different. Are you talking about from the pharmacy or from the hospital? I showed you test results from commercial labs, and they said, “Well, that works totally different from test results from health systems,” so I think the idea that while this remains fractured, that there is not one source, it gives emphasis and hope in some ways on the potential value of TEFCA, which maybe can make this feel less different if we get participation from these many stakeholders.

In terms of the question on mapping participation, right now, in the QHIN technical framework, they are required to report some very high-level metrics around how many of certain providers participate and how many individuals have requested information, but that is the level of information that we have right now. We are working and talking with Recognized Coordinating Entity® (RCE™) and the QHINs about ways to get more granular information through, potentially, the RCE directory or other means, but it remains a conversation.

Sarah DeSilvey
Thank you so much. Hans?

Hans Buitendijk
Thank you. My name is Hans Buitendijk. I actually had the same kind of question as Katrina had with why is this, and building a little bit further on her question, do you have further insights when you go deeper in the stratification on some of this information around ownership, location, as well as the underserved community in the demographics to get a little bit more of a breakdown there, as well as the connectivity part? But I would not focus just on the TEFCA, as it is still very nascent, but on regional and national networks so that we can see if, of the ones that are satisfied or dissatisfied, wherever they are, there is a concentration around one of those stratifications. I would be very curious to see what it is.

The other part, which is probably much more difficult, but with the perspective that I am frequently thinking about it, is the same/different EHRs. What is actually the distribution, not specifically by name, and is the community reflective of the EHRs that are certified and what they serve? That might identify as well when we are talking about the same/different areas, more or less. I really like the direction and the level of the survey that you started with, but I am really interested in the stratification below it to see where the pain points are. If we can address those, is it really the EHR in its function? I am sure there is, but is it really the connectivity that is not lacking, and therefore, we have these questions coming up? One could wonder if they are certified or not, because not everybody uses certified software. So, I am really curious whether there is an opportunity to get insight into that.

Jordan Everson
There is a lot there. One thing I will say is that it is a survey of physicians, and if you ask physicians, as we have, if they use certified health IT, they really do not know. Two percent say no, 80% say yes, and 18% say they do not know. We can give a range of who is using certified health IT or not, but we have actually stopped asking that question. Similarly, when you ask about connectivity on a physician survey, they do not know. They cannot provide that information. So, it is really a challenge of needing multiple data sources and trying to combine folks with the technical knowledge to tell you something about that infrastructure with physicians or other clinicians telling you how it is going.

Hans Buitendijk
I appreciate that. That may put the first ones where we already asked for identification distribution across rural, etc. We might get a direction there.

Jordan Everson
We can look at that, and one of the key insights looking there is actually that it varied a lot by the type of data you were asking, such that the patterns were not as robust as you might think, and that is why I did not dive into

various regression models here. I would say generally, the EHR you are using is one of the most predictive things, particularly for discrete data, like medications, problems, and allergies, and the type of health system you are in is a second predictor, and when you include both of those things, independent physicians are actually associated with better reported experience than health systems, controlling for the EHR vendor. In rural, there is some signal, but it is quite weak. So, we have that data, we can look into it, but it is a complex story without a clear answer.

Sarah DeSilvey
Thank you so much. Medell?

Medell Briggs-Malonson
Thank you all so much for this presentation. I am going to keep my comments very brief. I want to add onto what Katrina and Hans have already mentioned and ask another question. Without a doubt, I think that this is very important to stratify this data based off of the demographics and the characteristics of the various different clinical settings that the physicians are coming from. My other portion of this is that as a practicing physician that has interoperability and is able to interface with everything from other larger academic medical centers, to other large health systems, all the way to Federally Qualified Health Centers (FQHC), I would recommend taking a look at that survey. There is a difference between just saying that the data is there and that the data is usable. Especially when it comes to comparison of various different results or even notes, just because the data may be there, if it takes all of the physicians and the clinicians a significant amount of time to dig through the Common Core of Data (CCD) or dig through whatever data comes over, it gets to be an additional significant burden.

So, there is that minimal floor that the data is there, but where we really need to go is if it is displayed and all coming through in a way that is easily accessible and usable for that clinician in that point in time. I think getting down to the roots of that is going to be key, as well as envisioning where we need to go with interoperability, and especially allowing to bring in that physician voice and that clinical voice to help inform the interoperability processes more. Thank you all so much for this amazing presentation, but I just wanted to add that point in.

Jordan Everson
I will say something really quickly. Looking at that ideal interoperability flow, a third of folks said that they often got the information, and of that third, one third of them, 13% overall, said that they get it, it is easy to find, and it is easy to reconcile. So, I think that gets some of the way toward what you are describing, but digging in more to understand that breakdown is absolutely an implication.

Sarah DeSilvey
Thank you so much. That is another one of those examples that not all the data that exists is the data that we need to see in the slides, so thank you so much for all the thoughtfulness in this study. Let's move on to Eliel.

Eliel Oliveira
Thank you, Sarah. This is a terrific report. I loved it for so many reasons. I started my career in healthcare and family medicine, so I really love that crowd, so it is great to see this report for many reasons. I was wondering one very simple thing about demographics. If you have collected them all the time, it would be great to see how things are shifting from rural to urban, from private practices to large health systems, and the composition of those physicians, but my major comment was related to what we have coming up later with the annual report and the alignment that I can see on what you just describes when you are talking about labs, meds, imaging, and a few others that we are going to talk about. Without necessarily communicating about that, the findings are very related to the work that we did in the Annual Report Workgroup.

On that note, one of the things that I think is important to mention as well, such as Civitas, which you mentioned, and Micky was presenting there yesterday, and we had some other colleagues there as well, is the importance of

TEFCA and the QHINs. I see them as the supernodes of data exchange nationally, but I would not discredit the fact that the local view is still very important for those reconciliations to support the local teams. I mention that because, as many of you know, I lead one of the health information networks in central Texas, in Austin, and it requires on-the-ground relationships. We say that data moves at the speed of trust, and what that means for us is that I have to work with my District Attorney (DA), with my sheriff, with the mayor's office, with the hospital tax authority, and with everyone to coordinate certain activities that just delivering data does not solve much. We need that level of understanding and coordination to flow across the agencies that are collaborating.

I guess my point there is to say that one of the key things that I keep hearing from some of my work with The United States Food and Drug Administration (FDA), at the Harvard program, and the Sentinel network of drug surveillance is that other folks do not even know that those networks exist. It is important for TEFCA to bring forth these other networks that basically connect to the national network, which I believe is ultimately the goal of TEFCA, and there are still challenges there. I think the fact that we need to connect post-acute care, long-term facilities, behavioral health, and many others that are not even certified and currently plugged in is on-the-ground work that still needs to happen, and then it needs to be plugged into the national network. If we are advertising how that comes together, it becomes very important for primary care physicians and rural providers to get plugged in and have that more complete data. That was a lot. Thank you.

Sarah DeSilvey
Thank you so much. Just because there was a sense of order afterwards, I am going to skip over the timestamp of where people raised their flags and then come back again. Rochelle, I believe you are next.

Rochelle Prosser
Thank you, Sarah. Very briefly, I agree with everyone here, but the question that really stuck out to me was that 16% that do not have access or do not even know what that access is and that distinct disconnect between rural and urban centers. The urban centers were saying they had somewhat of an understanding, it is also understandable that there are deserts within urban centers in terms of interoperability. So, knowing that we need to dig and parse into the data a lot more, my question is this. What I did not see was the breakdown of who the family practitioners were based on licensure. As you know, there is a big push for nurse practitioners and Advanced Registered Nurse Practitioners (ARNP) to go in and be independent practitioners after three years. I live in Florida. That is a standard. After three years, you are your own family practitioner. I did not see that carve-out there, and in certain states, there are deserts where the nurse practitioner is the actual family practitioner and the general practitioner. Are you asking for that data as you are doing family resource? The next question is are you expanding to other medical bodies, like the American Medical Association (AMA), where you can get even more information?

Jordan Everson
That is a great question. This is in partnership with the American Board of Family Medicine, so this is board-certified family physicians that are responding, so there are no nurse practitioners or physician assistants (PA) within the American Board of Family Medicine by nature. In selecting this partner through a competitive process, one of the key challenges is we can get 100% responses here, we can get large survey results, but it is the family medicine physicians, who are an important group, but just one group, and there are many important groups. We are working with the ABFM to interface with the American Board of Medical Specialties and, through them, other physician specialties, like the American Board of Internal Medicine and the American College of Pediatrics, to reach other specialties through that, but that remains physician-focused.

Other groups are a challenge. If you work with the AMA or folks like that, they do not have this ability to require questions, so you get really small responses for a really expensive survey outreach in a lot of cases. Just given the nature of a voluntary survey of busy professionals, it is a hard thing to do. It is a goal to survey everyone, and we

have described some of the work we have done. We also had surveys of skilled nursing facilities and others, but this is a true boil-the-ocean problem to try to get everyone's experience, and it is a challenge.

Rochelle Prosser
Just to push a little…

Sarah DeSilvey
I am so sorry, we only have three more minutes, and I want to make sure we can hear multiple voices. We have a few more minutes. We are going by time now and whoever raised their thing first. Derek? And then, hopefully we will get a couple more. You can always put comments in the chat. My apologies.

Derek De Young
I am Derek De Young. Thank you so much for all the work that you are doing. This is very complicated and nuanced, and there are lots of layers of this onion, so I appreciate all the work. I am a very big believer that you cannot improve what you do not measure, so this is very critical. I think someone else mentioned that too. Hans asked most of my questions, but as you can imagine, coming from an EHR vendor, I have a lot of questions on how the questions were asked. Here is a quick one. Would it be possible for us to get the raw data and see it to try and figure out some of the stuff ourselves? Second, I think there has been a lot of input from this group on whether we asked this or that question. Next year, if we are looking to iterate on this, should we set up a workgroup with HITAC to iterate through those questions, potentially getting some of the EHR vendors involved in what questions we think would be valuable to ask? We, of course, want to improve this as well.

Jordan Everson
So, we do intend to continue the cooperative agreement. In fact, we just re-awarded it to ABFM, so there is an opportunity to think about what goes on with this in the future, and we certainly intend to track things over time. I guess we can explore if the HITAC has a role in that. In terms of accessing the data directly, there are limitations to what we can share, given our agreement with ABFM. I think we can share with contractors, but I would need to look back at the agreement. You can also request the data directly of the ABFM, and they are looking for research partners, so that is a possibility.

Sarah DeSilvey
Thank you. Zeynep, I believe you might be the last.

Zeynep Sumer-King
Yes, and I will keep it really short. I will actually just make it a comment, and I am sure there will be discussion later in the day. On the public health work and Helios, is there work being done with public health departments or could there be with ones that are not currently engaged? Just speaking for my own very large state, we are still collecting hospitals and other providers who are submitting over 80 data points manually on a daily basis since COVID in New York state, and when we speak to them about these initiatives, they are happy with the data they are getting, they would like to get more data, and they would like to design their own version of how and what to get. They are not engaged in Helios, for example, and I think there is a lack of real knowledge, which is not intended to be a criticism. I think there have been a lot of investments made in our public health infrastructure to capture that data and use it for what they want to use it for, but I think there is also a lack of knowledge or understanding of FHIR, for example, so if there was more education and outreach preemptive to the expansion of Helios, I think once you make this ubiquitous, there could be a rapid uptake.

Kyle Cobb
I agree. The CDC foundation just sponsored 50 State, Tribal, Local, and Territorial (STLT), the local jurisdictions and states, to attend the HL7 connectathon last month, and HL7 did a two-day training. For the most part, over

50% had no FHIR exposure, so we see this as a big adoption and learning curve to know what is possible. People are like, “Oh, this is similar to C-CDA,” and we are like, “Yes, but better.” We are continuing to fund that, and we are working with HL7 to continue doing these STLT-based trainings in conjunction with CDC Foundation as well, but there are also the implementation centers, which will be providing that level of learning and adoption support for states.

Sarah DeSilvey
Thank you so much, Kyle. Thank you, everyone, for your questions. If we did not get to you, please place your question in the chat so it can be part of the public record. I am going to move us along. I believe our colleague Liz is with us virtually to present on USCDI+ Cancer, and thank you so much for the presentation and work, ASTP friends, for 2024, and we are looking forward to 2025.

Liz Turi
Good morning, thank you. My name is Liz Turi, the branch chief for care coordination and collaboration. I lead USCDI+ program management as well as USCDI+ Cancer.

Steve Posnack
Hey, Liz? We have the ultra-*Star Wars* audio volume turned up to 11 right now, so we just need to turn it down a tiny bit.

Sarah DeSilvey
Can you test your mic, Liz?

Steve Posnack
Or you can back up. It is us, not you.

Liz Turi
Okay, let me see. Is this better?

Steve Posnack
We need 30 seconds to get the volume down.

Medell Briggs-Malonson
Liz, we will let you know in just a moment. The Accel team is working on the volume here in the room.

Seth Pazinski
We are always worried about people not being able to hear, so at least we overcompensated on this one.

Liz Turi
It is also the power of my mic on my computer.

Steve Posnack
Seth?

Seth Pazinski
We are working on it.

Anna McCollister

Sarah and Medell, I just wanted to note that I am having some vision issues now. I cannot see the chat, so it is not possible for me to… Just as an FYI, that is not a perfect alternative to not being able to do comments.

Medell Briggs-Malonson
Thank you in every single way for letting us know. In fact, we are waiting right now, so would you like to go ahead and ask your questions?

Steve Posnack
We have support here right now. Liz, do you want to try again?

Liz Turi
Testing, one, two, three. Is that better?

Steve Posnack
That is a little too low now.

Sarah DeSilvey
My apologies. Time is always the first…

Anna McCollister
No, I completely understand.

Sarah DeSilvey
Thank you for the access. It is really important. Thank you.

Medell Briggs-Malonson
We will make sure to take care of it, so, thank you.

Steve Posnack
We need it up a little bit.

Liz Turi
Is that any better?

Steve Posnack
Like all things bureaucracy-wise, we will get to the Goldilocks option in just a moment.

Medell Briggs-Malonson
Anna, while we are waiting, I know that the team is still in the room. Would you like to ask your question?

Anna McCollister
Basically, it is more of a request than anything. I would love to see the survey that was referenced. I think it was being led by the NCI, related to patient health IT things, because it feels to me like there is or has been a lack of focus from ASTP on documenting the burden on consumers and patients as it relates to health IT, and it is a significant point of frustration. I am leading a workgroup through the Sequoia Project, and we did a lot of documentation on significant burden still with data dysfunction as it relates to consumers, and there are a lot of portals, especially at smaller physician offices, where they say, “Well, legally, we have a portal, but we do not put anything in it, so you cannot expect to get any data.” These are people work in data, in some cases, who cannot get access to their data from their physician, even though they have “certified health IT.”

So, I think it would be helpful if ASTP, or maybe the NCI staff, documents it. There is still a significant amount of burden, and it feels to me as if it has been deprioritized by ASTP/ONC over the years, and I would like to see that advanced, as there are other ways of getting at this besides just getting surveys. You could do user experience testing or a variety of different things that could document it, but it is a significant need. I am dealing with these issues myself personally at the moment, particularly as it relates to imaging access. Anyway, it would be great to get an update on that.

Sarah DeSilvey
Thank you so much.

Medell Briggs-Malonson
Thank you, Anna. That is important. Thank you so much.

Liz Turi
All right, I have been asked to test.

Sarah DeSilvey
That is better, yes. Liz, take it away.

Liz Turi
All right. I will not reintroduce myself, but thank you for the sound check. Anyway, I will just jump right in. Next slide, please.

Seth Pazinski
Hold on, Liz. You were good for a second, and now you are back down again.

Medell Briggs-Malonson
Liz, you may have to move a little bit closer to your microphone again.

Liz Turi
Let's see. Does this work?

Medell Briggs-Malonson
No. You are a little low, and we want to make sure that everyone is able to hear. We are going to get to that sweet spot very soon.

Liz Turi
Sure, all right. I cannot boost my microphone.

Medell Briggs-Malonson
I know. You are okay. We are adjusting you in the room.

Liz Turi
Okay, good?

Medell Briggs-Malonson
We are good.

Seth Pazinski
Thank you.

USCDI+ Cancer (01:31:30)

Liz Turi
All right. So, what we are going to do today is give a little bit of background of USCDI+ and do some level-setting there, as well as some of the background of USCDI+ Cancer, because it has been a while since I have presented here. I also want to do a little bit of a Cancer Data Exchange Summit recap. We have had a lot of interest and heard a lot of requests for updates, and I want to share here what we did, what we set out to accomplish, and how that impacted the work over the summer and our work going forward. Then, we will give a use case update across all of our use cases and share next steps. Next slide, please.

So, usually, I start this conversation around level-setting on USCDI in general. For this particular audience, I figured I would not go over what USCDI is, but suffice to say, USCDI+ was designed to extend beyond the USCDI. What we have heard over the years and what we have seen in USCDI data submissions is a call for more nuanced data elements that are either not represented well or not demonstrated within USCDI. So, what we have done, starting with Quality, adding Public Health, and then Cancer, Maternal Health, and now Behavioral Health, is set out to provide a way to delve deep into those areas and look at use-case-specific data needs. We set out to both fill a gap that may be there and also to demonstrate how to implement data elements that are already represented in USCDI. So, this helps us work, both with our federal partners and industry partners, to build in what those nuanced program-specific needs are. So, we apply a lot of similar processes that are already established in USCDI, as well as establish unique processes for USCDI+. Next slide, please.

For USCDI+ Cancer specifically, we are partnering very closely with NCI, Centers for Medicare & Medicaid Services (CMS), CDC, and FDA, and we are looking to align with the White House Cancer Moonshot Initiative, with the Data Innovation Task Force, and to look to capture the data needs for cancer reporting that fall outside of the scope of USCDI. We are working towards a comprehensive list across all use cases, but we are starting within the narrow scope of each of our use cases to create lists of data elements that can address multiple partner needs and that can be harmonized across all of those use cases, and I will go through those in a second. We are looking to leverage existing processes and build out cancer reporting programs. Next slide.

I wanted to also introduce the lifecycle of a typical USCDI+ project. We go through a number of different phases. Not every USCDI+ project incorporates each of these phases. For example, some of our projects do not go through the use case drafting and refinement phase at the beginning because they are looking to look at the overarching data set and then refine through that data set. Cancer looks to use a methodology where we look at individual use cases, narrowly scoped in order to build from there. Our goal is to look to adoption and production, and so, we are looking at the most efficient process to get there to make it real so that we are not just stopping at a data element list. We have plans to get into production, and I will show you in a few minutes that we have done that already with one of our use cases.

So, just in general, we do an initial discovery phase prior to the launch of a project. At the launch of a project or concurrent with the launch, we do some high-level use case drafting. We then do a deep dive into the environmental scan. Some projects will do interested party interviews. Cancer in particular did a data summit because we were looking to accelerate our timeline. From that information, we refine our use cases. From that, we develop our data element lists going to implementation guide development, then into testing and piloting, and then adoption and production, so it very closely aligns with a fairly typical software development lifecycle, but we are applying it to data element development and refinement. Next slide, please.

As mentioned, we did things a little bit differently with USCDI+ Cancer by creating that data summit, and part of the reason for this is that we had some special considerations that we needed to take into account. We had White House commitments by EHR vendors that we needed to be able to support so that they had something to implement. We had ties to Cancer Moonshot and their aggressive and incredibly important goals that we wanted to be able to support, and as a result, we had to collect information on a very accelerated timeline. Next slide.

We also had to work with a wide variety of partners, both within the federal government and external to the federal government. We were working across four use cases that had some overlap, but not always. We wanted to make sure that we were working within existing standards as a starting point, leveraging USCDI where we could, leveraging Minimal Common Oncology Data Elements (mCODE), and leveraging the work that North American Association of Central Cancer Registries (NAACCR) and College of American Pathologists (CAP) have done. Again, we are so closely partnered with each of our federal partners engaged in this work, and it has been an absolutely tremendous partnership, where we have had really robust discussions, and we have been able to move quickly as a result. We have also partnered very closely with Vulcan, CodeX, and FAST in order to make sure that the framework and the foundation were there in order to reach our goals. And of course, we could not do it without the initiatives sponsored by the White House and by CancerX. Next slide.

So, with that in mind, we wanted to try and figure out how best to really represent all of the various perspectives that we had, and we decided to put together a Cancer Data Exchange Summit. Next slide. So, here, we set out to do a couple of things over a couple of days in May. First, we really wanted to set the stage. We wanted to make sure we established why this was important, why we wanted to do this from a leadership perspective, from a federal perspective, and from an industry perspective, and we really wanted to make sure that the patient perspective was included in this work.

As a result, we did a deep dive into the data journey and identified 10 different user perspectives, and we spent the first day deep diving into those user perspectives, looking at enablers and barriers and thinking about, regardless of the use case, what are the things that are common across those user perspectives. Then, on day two, we flipped it. We took all those user perspectives and mixed them across the use cases, and we had similar discussions, but really focused on the use cases and being able to connect dots, pull things together, and think about things in a way we had not thought about before, especially keeping in mind the grounding of our own user perspectives. Next slide.

So, you can see here what that data journey framework looked like, and I apologize for the small print. You will be able to see these in the slides afterwards. So, we wanted to make sure that we looked at the data journey, where different user perspectives lived within that data journey, including those perspectives that really have a broad view across the entire journey, where we had patients, caregivers, advocates, researchers, data scientists, regulators, policy and government, payers, public health, and senior executives like this. It was really important that we made sure to look at how these perspectives really work within the overall work. Next slide.

So, again, the things that we were looking at were key themes and challenges, both across the user perspectives and use cases, what those enablers were, and what the barriers were to really dig in to understand, of the work that we have done so far, of the use cases that we were presenting at the time, what is really ready to push forward and move forward, what needed more work, where we could do better work in establishing data element lists, and what that means for the long term. What are some things that we need to consider to make sure that it can be made real? Were there policy levers that we needed to discuss? Were there technical challenges that we needed to surmount? Were there education challenges that we needed to surmount? So, we really were able to put all of that together. So, more of the results of those conversations will come through as I go through my next slides, and at the end, I have links to where you can access all of the recordings that we had for all of the conversations that we had, both at the data summit and since the data summit.

So, with that, I will go into each of the use cases. We have four. The first is EOM, which is Enhancing Oncology Model, primarily partnered with CMS. We have Cancer Registry, primarily partnered with CDC and Surveillance, Epidemiology, and End Results (SEER), Clinical Trials Matching (CTM), Clinical Trials Matching, primarily partnered with NCI, and then, the real-world data Immunotherapy-Related Adverse Events, primarily coordinated with the FDA. In all use cases, all federal partners were engaged and at the table, and they still are, but depending on the use case, we needed to prioritize preparedness and readiness materials with the primary agency for that use case. So, here, you can see what our development process is. I am going to share the EOM story in a second. It is really exciting. We are in production. Not to get too ahead of myself, but I will just say that out loud. With Cancer Registry, we are in the publishing phase and wrapping up the data development phase. I have some news about CTM and Immune-related adverse events (irAEs). Next slide, please.

Again, this is an iChart, and you will have access to this afterwards, but I just wanted to give a broad scope of the timeline of what we are working towards as you think about the detail you are going to see. So, we have a lot of activities upcoming over the next year, and actually the next couple of months, so there is lots of opportunity for you to be engaged if you have not been already, and we are very excited to invite you into the overall process and look forward to your thoughts. Next slide.

I also wanted to give you a brief overview of what our disposition process is because it becomes important in the next conversation. We will come back to comment disposition a number of times. The first thing we do is make sure that we organize it, that we gather comments from the platform, we clean up, consolidate, and categorize them, and sort themes. Basically, we try to press the easy button as much as possible for our federal partners and people doing the review of the comments to be able to understand and assess the information quickly and easily so we spend less time on raw comments and more time on discussing what the impact of those comments are, although they do have access to all of the raw data. We look at harmonization, we identify data elements that have comments that impact other use cases, and we prioritize those to ensure harmonization to make sure we do not have to redo work as we move forward.

We identify data element comments that impact USCDI, and we have regular meetings with the USCDI team. We identify data element comments that impact or are impacted by USCDI+ domains, and we have mechanisms in order to coordinate with the other domains to make sure we are doing as much harmonization as possible, again, minimizing the rework. Then, we put it out to our partner agencies so that we do an initial review by a small group of federal partners leading the use case, we do weekly updates in that small group in advance of the larger federal partner group so that we can make sure, again, to make it as easy as possible to have these conversations and to make sure that we are making progress as efficiently as possible. And then, final review and decision-making is done through the wider group of federal partners engaged in USCDI+ Cancer. Lastly, we handle the disposition. It is all consensus-driven to determine whether we remove, replace, or update any of those definitions and look at what the impact of harmonization is.

So, with all of that stage-setting, let’s move on to the Enhancing Oncology Model. Next slide, please. Again, we worked closely with CMS for this. This was our initial use case for USCDI+ Cancer. We needed to align with CMS’s goal to drive transformation and improvement in care coordination oncology. In December of last year, as we were developing the concept of USCDI+ Cancer, it really seemed like EOM was the perfect case to start with. They had a discrete set of data models that they needed to be able to collect. Having it submitted via FHIR seemed to be a reasonable, achievable goal based on the work that they had already been doing in other areas of Capability Maturity Model Integration (CMMI), and we were able to establish a minimum set of cancer-related data for exchange.

By March, in working with mCODE, we had a demonstration model on how you could put together a fit-for-purpose IG based on the broad data model that is mCODE, and we were able to then have an EOM-specific IG ready and in place for testing at the May connectathon at HL7. We had McKesson Ontada at the table at the connectathon; we had Epic at the table at the connectathon actively testing and working through, looking for any challenges that they may have with retrieving information from CMMI on patient lists and submitting data for that attribution list.

Based on that and the CMS connectathon in FHIR, they were able to finalize everything and go into production for their submission period this month, and in fact, I have confirmation that McKesson is submitting data live and in production, and I am waiting to hear additional feedback. We will have more of that information by a little after October 29th, when the submission period ends, but it is really exciting to see something go from ideation to production in a little over nine months, so it just really demonstrates the commitment and the work that we have in all of the partners that we have, both internal to the federal government and external with standards bodies, provider organizations, and EHR vendors. It has been really incredible. Next slide.

Cancer registry: So, coming out of the data summit, what we heard was that there were a lot of challenges in cancer registry. The big challenge was that it could take six months to three years to compile a complete abstract for an incident of cancer that gets reported, and our federal partners were indicating that they wanted to rapidly shorten the timeline to collect those abstracts in order to really support both the public health use case as well as patient care. So, what we heard in May was that we needed to further refine the use case a little bit to really hone in on what aspect of cancer registry we really needed to focus on, and we heard loud and clear that the point which we should be working on is early incident reporting, and I will show you what that looks like in a second.

From that, we were able to very rapidly come to an agreement on what minimal data set was required for that early incident reporting, so we were able to get that draft data element list out on July 23rd for public feedback. That feedback period ended on September 23rd. We had a listening session on August 29th to really help make sure that people understood what the use case was and to hear any challenges or feedback that people who had already gone into the platform could see, and now, we are working on dispositioning those comments, and that is going to stretch through December so that we can make sure. We got about 84 comments back, and I will give you some metrics in a second. Next slide, please.

We worked really closely with the CDC to map out what early incident reporting looks like in the future state. Today, right now, there is early incident reporting being done from labs, both independent and hospitals. If you look at the upper left-hand corner of this diagram where the microscopes are, that is currently being done today via CAP protocols using the NAACCR and CAP protocol guidelines. We have a future state that we are considering with the cancer pathology data sharing IG, and those data are already going into central cancer registry. What we are focused on with USCDI+ Cancer is the ambulatory provider EHR- and hospital EHR-based early incident reporting so that we can make sure that we collect all early incidences. We will have radiology in the future, but today, we are really focused on what is coming out of the EHR.

The next step out of that is that early incident report triggers the next step, which is querying for information regardless of where it lives. You can see where it connects to other ASTP initiatives like TEFCA and also to ambulatory providers and hospital EHRs using FHIR-based query and response. The CDC was working on that at the September HL7 connectathon on the query response side, not the USCDI+ Cancer early incident reporting side, but this kind of gives you an idea of how these pieces fit together and why it is so important to make sure that we really truly understand what the use case is that USCDI+ Cancer is trying to fit into because in all of these use cases, there is a lot of work that is being done across the industry and across our federal partners, and we want to make sure we are not duplicating efforts, so we have identified here that we are working on that early incident reporting. Next slide, please.

So, as a result, like I said, we had our feedback period, we got 84 comments from 26 unique commenters, and consolidated, deduplicated, etc. We had 60 consolidated comments. We started off with 23 cancer registry data elements. We found that there were no changes in four, there are 19 with proposed changes, and we had submissions for 57 additional elements, so we will be reviewing those and seeing if any of them make sense to include within that early incident reporting focus. We also got comments on the EOM published data elements, and so, we are going to be working with CMS to identify if those are things that they want to or need to incorporate within their submission guidelines, but right now, we are focused on and prioritizing the cancer registry. Next slide, please.

So, the next two are not as detailed, but there is information here that you can look back to. So, clinical trials matching the area that we are looking at is, again, looking at that initial ping, if you will, to feed information to clinical trials database and get back all of the trials that are potential matches for a patient, so we are looking to make sure that the EHR data are there and that it is relevant to that early matching process. We have refined that use case. We have come together with our federal partners in order to identify what a draft data element list looks like, we are finalizing that, and we are looking to publish that for public feedback next week, so that will be going out and we wanted to introduce that. Next slide, please.

Again, that was based on feedback that we got during the data summit. The feedback was loud and clear that we needed to make sure that we refined it because there was a fair amount of discussion on what clinical trials matching means and where in the lifecycle we should focus on, and the feedback from there was that we needed to further refine it. So, we really narrowly defined it against that initial ping. Again, we have the draft data element list coming out next week, and we have plans to eventually do the implementation guide. IRAE is actually a very similar story. Coming out of the data summit, we heard that there was very little agreement on where we needed to focus in on, and so, we anticipated that we would not be ready to put together a draft data element list until January.

We expected there needed to be a significant amount of work and consensus-building in order to really, really understand the needs of the adverse event reporting, working with the FDA, working with NCI, and seeing where there were additional challenges and where there was overlap with clinical trials matching and clinical trials work in general. I am not sure what happened, but it was wonderful to see. I think we lit a fire, and we very rapidly came together with consensus and were able to refine the scope to look at specifically premarket surveillance for now. There were different challenges depending on whether we were looking at premarket or postmarket surveillance and which reports we needed to focus on, which reports were achievable, and which reports had levers and means by which to actually collect this information in a robust manner. So, we did decide to focus on that, and as a result, we were able to rapidly come up with a data element list, and that is also going through finalization, and we are preparing to release that on November 4th. Next slide.

So, we also looked at the challenges that there may be with public feedback for two different use cases, and we realize that there is a strong overlap between the needs of both the clinical trials community and the IRAE community and making sure that we anticipated that there are going to be responding to both, sometimes on the same element, and so, we wanted to make sure that we could be responsive to their time and concern, and through the platform, we are able to actually allow you to comment on multiple feedback periods at the same time, so we wanted to really leverage that capability and make sure that we had ample opportunity for harmonization and understanding the impact of how we are looking at these data. Next slide.

With that, not only did we have both the feedback sessions coming up, but what we are going to be doing is having a listening session that will go through the use cases in a little more detail, allowing people to have looked at the platform and the data element list for a few days before actually going into the deep dive on the listening session, and also walk through the platform and show people how they can submit their responses and how they can

comment on one, both, or neither, if they want to, but this is the timeline that we are looking at. You can see where all of the overlap is. Next slide, please.

Upcoming dates: Again, next week, we will have the clinical trials draft data element list published. The public feedback period will start the same day, November 4th. For IRAE, we have draft data element list published and the public feedback period starting, and then, on November 7th, we will have the public listening session, and you can see when the feedback periods close. In the overall timeline early in the presentation, you can see what the impact is downstream as far as what that means for dispositioning and IG development, etc. Next slide.

The other thing we have done is that all of our listening session recordings are available online on the site that NCI has put together for all of the sessions that we have done. It is all centrally located, it is easy to access, you can see all of the slides, all of the recordings for any plenary sessions, and all of the information related to the listening session. We also invite you to share feedback within the USCDI+ platform. The link is available here. We invite you to engage with us during the listening session and during the public feedback periods, and then, if you want to be on our mailing list or if you need to reach out to the USCDI+ Cancer team, please email our USCDI.Plus email address. This actually works for all of the USCDI+ domains and projects. That way, you can reach out to us directly, and we will respond to you. If you want to be on our mailing list so that you get direct email as to when each of these feedback periods are available, you can request that there. With that, next slide. We are at the end. I am sorry that was a lot of information really fast with a slow start, so I would like to open us up for questions and discussion.

Medell Briggs-Malonson
Thank you so much, Liz, for that incredibly comprehensive presentation. We really do appreciate all of the information you provided to us, and we do have some questions in the room. To our colleagues on Zoom, we have not forgotten about you, so if you do have a question, please ask it. Of note, since we did start about 10 minutes late, we are going to take time into lunch. I hope everybody is okay with that. We want to make sure we get everyone's questions and comments in. The very first one that I have on my list is Rochelle.

Rochelle Prosser
Thank you, Liz. Is she still there?

Liz Turi
I am here!

Rochelle Prosser
Okay, something happened on our screen in the room, so I apologize for that. Thank you, Liz, for that wonderful review of USCDI and USCDI+ Cancer. My question is mostly focused on cancer, and I was in the room in part of some of these listening processes. The question is regarding the cancer registries, particularly with children's cancers. They are rare, they are difficult to find, and they are usually scattered across America. Was there a particular reason you got to limiting where you decided to move in cancer registry rather than looking at rare diseases?

Liz Turi
I do not see that rare diseases are excluded from this. We did have input from Warren Kibbe, who is involved in CC-DIRECT, which is focused on childhood cancer, so I would not say that we excluded childhood cancer or rare diseases, but we did need to figure out where within that registry process we needed to focus in order to increase the timeline to get that full abstract, and that would include the pediatric population as well.

Medell Briggs-Malonson

Great. Thank you so much, Rochelle, for your question, and also Liz. Eliel?

Eliel Oliveira
Thank you. I was going to have a question earlier, and thank you, Liz. This was excellent to hear. I think you answered most of my questions throughout the presentation. I had the pleasure of working in a state cancer center for 10 years as the Chief Information Officer (CIO). I feel old saying this, but back then, probably about 20 years ago, there was cancer Biomedical Informatics Grid (caBIG), the big name in cancer centers that we were working on and building interoperable systems for, just to find out that it is so complex and wide in so many ways with proteomics systems, genomics, labs, clinical trials, and so on and so forth, so I can understand where the trial matching seemed pretty well defined, from your description, on how that could evolve.

But then, jumping to immunotherapy and the adverse event, it gets a little tricky with all the pieces of information that are necessary. I do not have a question anymore, but throughout the process, I was just thinking that I do have a recommendation, given my experience. The step after matching is screening, and it is very hard to do as well. It requires a lot of clinical data from EHRs to be able to allow the research coordinators and scientists to go through and define if someone can really be on this trial or not. I clearly remember working at Tulane Cancer Center and how that would be the holy grail to get folks in clinical trials. I will leave it at that.

Liz Turi
You are absolutely right, and we have been having those conversations, even before the summit, and that goes into a lot of the conversation around where we can focus right now, regardless of the use case, and at no point should it be considered that this is how we see the end state. All of these conversations, in our opinion, are iterative, so, just because we are focused on early incident reporting and cancer registry today, or that initial ping for a clinical trials matching, or the premarket surveillance in IRAE, these are ongoing discussions, and we are already thinking about what is next. So, we are not thinking of this as “Okay, once this is done, we are done.” We are always constantly thinking about what is next.

Medell Briggs-Malonson
Thank you both for your comments. Michael, you are next.

Michael F. Chiang
Liz, great presentation, and I loved the use cases that you had. My comment/question is that I think there are a lot of other professional organizations, and I loved that you worked with NCI on this, and I think there are a lot of other organizations and NIH institutes, including mine, who would love to be able to create USCDIs for their own fields, but I think the reality is that most other groups do not have a Cancer Moonshot or some enormous resource like that to support, so I am just wondering if there are things like what I learned from this that would lower the barrier to make it easier for other groups to create a USCDI+? As I looked at your slides, I almost wondered if it would be useful to have a playbook or a checklist about the things you need to do to be USCDI-ready, to talk to ASTP about this. For example, you need something like mCODE to be ready to go to Stage 2. I am just wondering if you have learned things that make it easier to create more in the future.

Liz Turi
I love that question, so I am going to put my program management hat on just for a moment. We are noticing that there is a desire and a need for more USCDI+, so we are looking at all of our projects and domains across USCDI+ in order to look at best practices and the things we really need in order to have the conversation. I will say that we are looking in other clinical areas as well. I did mention maternal health as one of the domain areas. We also have a couple of projects that are not incorporated within a domain. We are looking at sickle cell disease and respiratory illness, so we have been able to start engaging in some of these other clinical areas, and we are working with the appropriate clinical societies to make sure that we have proper clinical representation as well as

federal and industry partners, etc. I want to go back to the idea of that data journey framework that we took with cancer. We are looking at where else that can be applicable, and we are starting to have that conversation in some of the other projects as well. So, we are thinking about and looking at that, and I really appreciate that feedback.

Medell Briggs-Malonson
Wonderful, wonderful comments. We see Katrina there as well.

Katrina Miller Parrish
Thank you. Again, I am Katrina Miller Parrish. I was also wondering if a USCDI+ area could potentially be patient-entered data, which is a little less than the clinical side, obviously, but is so important. I see so much advancement when a USCDI+ area is identified, and I think the rate at which we are seeing patient-entered data elements coming into the base USCDI is quite slow, and there is quite a large list in Levels 0, 1, and 2, so I will just put it out there as an idea that that might be a better way to accelerate patient-entered data. Thank you.

Liz Turi
Yes, and I will definitely take that back and talk with the USCDI+ team. I probably should have mentioned this earlier. There is some relationship between those Level 0 and Level 1 data elements in USCDI. So many of them are very nuanced and very specific, so they do not necessarily meet the threshold of broad applicability. However, they are super important. So, again, this is where USCDI+ can really look at those data elements and see if this makes sense within our use cases. Speaking specifically of cancer, for example, I know there are genomics data elements that are listed in Level 0, and while that does not necessarily fit within our existing use cases, we are taking a look at them and considering how we look at them for next steps. To your comment about patient engagement and patient-entered data, the fact that we do make sure to include the patient voice within that data journey means that we are considering that as well. So, even if it is not its own domain, and I do not know what that looks like in the future, there may be other ways to consider it within the existing domains.

Medell Briggs-Malonson
Thank you, Katrina. I think that is a fascinating idea. We are talking about how we move towards the future and always incorporate the voice of our patients, and thank you, Liz, for that response. Ike, I believe you have a comment as well.

Steven Eichner
Yes, thank you. Really quickly **[inaudible] [02:14:01]**.

Liz Turi
Sorry, I cannot hear.

Medell Briggs-Malonson
Just one moment, Ike. We are going to…

Steven Eichner
Sorry. What is the involvement of the public health cancer registries in the work that you are doing, how do they engage, and what can they do to help you down the path?

Liz Turi
We did invite the local public health agencies into the process. They were in the room during the data summit. We have had engagement with Eric Durbin, who helped moderate the cancer registry public listening session, and we are always welcoming feedback from across the landscape. So, next steps for us are to finalize all of the feedback that we have received, including from local public health agencies, and then, we will be looking for ways to engage

as we develop the IG and look for testing, so there is definitely more to come, and we definitely want your involvement.

Medell Briggs-Malonson
Thank you, Ike, for that important question, and thank you, Liz. I am looking around, and I do not see any additional questions in the room, nor on the Zoom, so, once again, thank you, Liz, for this presentation on USCDI+ Cancer. This was incredibly informative, and thank you to all the HITAC members for all of your engagement during the first half of this meeting. We are now going to transition into lunch. I have a couple of housekeeping notes. This is what I love to do. So, No. 1, you already know the rule. If you are leaving the conference room, please make sure that you do have a chaperone. I have been told that they are all fully trained to escort us outside the room.

The other item here is that if you did order lunch, all of our lunch has already been delivered and has already been set up in our wonderful kitchenette that is right outside. There is a water foundation and, of course, restrooms behind us as well, and if you decide to go outside to get some sunshine because it is a beautiful Washington, DC day, then, of course, you know you need an escort. The other item is that we are running about 10 minutes late, but we want to start on time because we still have a very packed second half of our meeting, so please be back here in your seats, not just walking through the door, by 12:35 so that we can actually start on time. I think Seth has a couple more items as well.

Seth Pazinski
Please make sure your mics are muted for the lunch duration. We will pause the recording, but the audio will pick up if the mics are on, so please mute your mics. With that, Accel, I believe we can pause the recording, and we will break for lunch.

Remarks from the Assistant Secretary for Technology Policy/National Coordinator for Health IT (02:17:30)

Seth Pazinski
All right, thank you, everyone, and welcome back. We are going to get back into our agenda with some remarks from our Assistant Secretary for Technology Policy and National Coordinator Micky Tripathi.

Micky Tripathi
Thank you. Someone will teach me how to use the technology. Excellent. That is always a challenge. It is really, really great to see all of you, and I wish I could spend the day here, but I am really glad that all of you are here, and as always, I really want to thank you and acknowledge all the effort that you put into the meetings, especially coming here in person. I know it is not a small ask, and we all appreciate it and benefit from it.

I know I do not carry paper, but I want to make sure I do actually cover the things that Seth says I should cover. All right, I got that out of the way. Sorry I missed the meetings. I got that out of the way. Those are all sincere, though. He just put them there. I just want to thank you all for the hard work on the HTI proposed rule. In my experience, having been on your side of it for a while, any time a rule came around and we were in that, it was like, “Oh, man. This is real work. I thought I was just signing up to show up for meetings once in a while,” but that was real work, so I really appreciate the thoughtfulness, depth, and breadth of all your comments.

We did get 270 unique submissions that totaled over 2,200 pages. The team is now hard at work. One submission could be 100 pages, there are 270 of those, and the team now goes to work at parsing all that out into individual sections, categories, and all of that, so that is a lot of hard work and something that I observe from the inside now, but it is just a demonstration of how grateful we all ought to be that we have processes like this in place in a

democracy. Every single one of those comments gets looked at, adjudicated, and thoughtfully thought through. "What are we going to do with this one? Does it make sense or not? How do we think about that?" We go through every single one of those, which is partially why it takes so much time and is a big effort as well, and we all are pushing the team really hard to ask how we are going to use a large language model to be able to assist us in doing that because it is a ton of work at ONC, and we do not even get the kinds of numbers that Office for Civil Rights (OCR) or CMS get for theirs. Anyway, I just wanted to thank all of you for that.

The annual meeting is coming up really fast. It is in early December and I hope to see all of you there. There is more to come on that, but that is hopefully going to be a really great event. The federal health IT strategic plan has been released. I am really grateful to all of our federal partners and to everyone who contributed to that. We do have a draft federal FHIR action plan out, if you have not seen it. That was a bunch of work that the team did in working with our agency partners to ask where each of you are with respect to thinking about FHIR and your mission activities and how we consolidate that a little bit to be able to help our internal agency partners think about the roadmap or approach that we can take for this, but also to help everyone in the industry to be able to see where the federal government is, because there is a ton of activity now going on across our HHS agency partners, so there is a lot of great work there, and we welcome your feedback on that.

We did announce two new Leading Edge LEAP boards in 2024, one to improve data quality to support responsible development of AI tools and healthcare, and the other to accelerate adoption of health IT in behavioral health settings, so those should be getting under way soon, and we always look forward to the LEAP awards. Many of you may recall that, going all the way back, FHIR actually has its origin in an award originally from ONC to Boston Children's Hospital to think about this idea of substitutable apps that led in a direct line to all of the FHIR activity, with some others as well. A lot of these are Leading Edge bets. You are just sort of saying, "Let's place a bunch of bets out there on Leading Edge." You do not know which one might really pay off, but each of them offers value in and of itself, so we are very grateful for that.

The last thing I wanted to mention, which is off the script, sorry, is to just give you an update on where we are with TEFCA because there is a lot of great work happening with it. We now have seven QHINs, which have been in place for a while with active exchange going on, which I will describe in a second. Two more are just about to be announced there, candidate QHINs that I think were publicly announced that are soon going to be designated as QHINs once they complete the final steps there. One is Surescripts, which many of you may know as the nationwide e-prescribing network. They are also a health information exchange network across the country, and they facilitate a ton of exchange, so we are very excited about that. The second is eClinicalWorks, the EHR vendor. That will bring even more activity to TEFCA, and I think give it more of a firm foundation in the industry, which we are really excited about.

The second thing is just to give you some data, which is always hard to come by, but after about eight months now… There are about 10,000 organizations or directory entries, and this is always a hairy world when you start to say, "Is that an organization or a facility? What is it?" There are over 10,000 directory entries or correable points in the TEFCA directory, over 400 hospitals, over 5,000 physician offices, over 58 mental health centers, 150 LTPACs, over 50 public health jurisdictions now in TEFCA, and over 100,000 individual clinicians. Through August, there have been almost 5 million queries for documents and 2.5 million retrievals. In the context of overall network interoperability, that is a tiny drop in the bucket. Carequality facilitates something like 30-40 million a day and Care Everywhere does something like 10-15 million a day.

But again, this is just the first six months. In a model where no one is obligated to do this, these are organizations who are stepping forward, and with the number of other QHINs joining and QHINs like Epic, for example, who made announcements about their customer base and the goal of getting their customer base on, and CommonWell Health Alliance, which has their TEFCA platform now live, and a number of others who are moving

aggressively forward, we expect to see a lot more activity there as well. So, we are really grateful to all the TEFCA partners, and we will keep you updated on it, but, so far, so good, and we are excited about it. So, I will let you get back to the agenda. Thank you very much, Medell and Sarah, and let me turn it over to you.

Medell Briggs-Malonson
Wonderful. Micky, thank you so much for all those wonderful updates, especially about TEFCA, and thank you for your leadership because without your leadership, we would absolutely not be in this space, so we appreciate you for that. And so, now we are going to transition, everyone, into one of our favorite topics, which is the Annual Report Workgroup, or at least one of my favorite topics, as well as Eliel's, since he is my co-chair. We are going to give everyone a quick update on the Annual Report Workgroup and, most importantly, display the draft. Now, during this presentation, we want your feedback and your revisions. It is so incredibly important because the next time we meet, we will be reviewing the final draft, and we need to receive a HITAC vote on approval. So, this is the moment for us to really incorporate some of your thoughts as we have gone through this process for several months and to make sure that the voice of HITAC is fully represented in our Annual Report Workgroup. With that, I will turn it on over to my co-chair of the Annual Report Workgroup, Eliel.

Draft HITAC Annual Report for FY 2024 – Review and Discussion (02:26:00)

Eliel Oliveira
Thanks, Medell. Yes, it is not only my favorite topic as well, but it is very important at this stage, as Medell was saying. We are about to finalize it, so we really want you to look at what we presented today and be ready to provide some feedback because we are going to absorb all that and revise the report to then get to the finish line before December. With that said, next slide, please.

Here is the high-level overview. We are going to go over the scope and membership, the new schedules and next steps, and then we are going to do a deep dive into the report itself. Next. Here is our overarching charge. The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of HHS and to Congress each fiscal year, so it is very important. As part of that report, the workgroup will help track ongoing HITAC progress, and the specific charge is to provide feedback on the content of the report, as required in the 21st Century Cures Act, including analysis of HITAC progress and the related target areas, which we are going to cover quite a bit, assessment of health IT infrastructure and advancements in the target areas, the analysis of existing gaps in policies and resources for the target areas, and ideas for potential HITAC activities to address those identified gaps. Next.

I want to just recognize here for a second the amazing group that joined us throughout the year. It was an accelerated process this year because we are moving the schedule a little bit to be able to deliver the report by December. It was tremendous to work with all of you, and I just wanted to thank all of you for the time that you put into the committee and the report itself. Next.

And now, here is our next schedule. Let's go to the next slide. We met on October 7, we are here today, and in our next meeting, we are going to be reviewing all the comments that we received here from you today and making updates to the final version. In November, we will have the final report ready for transmittal. Next. Here, today, we are going to review, as you see, and, with fingers crossed, we are going to get your approval on November 7. Next. So, in summary, what I just covered are the reviews of the draft reports taking place and suggestion edits. We then vote on the revised report, we transmit that to Micky, our assistant secretary, for his review, and then ASTP forwards that report to Congress and to the secretary. Next.

So, at a high level, here is the outline of the annual report. One thing that I want to mention here is that we work in a very detailed report format, but we now have a version as well that is more like a slide deck format that is

compressed and much easier to follow, and we really believe this is going to be quite helpful for sharing the details of the report with everyone. So, in the report, we have a foreword, an “about HITAC,” the target areas, the Cures Act, and the IT landscape today, and then the progress that has been achieved by ASTP. Next.

So, here is a very important slide for what we are about to cover, and I want to note on the top that we have a new target area. There were five previously, and as you can imagine, artificial intelligence to improve health and healthcare is key to us today. I am going to take a moment here to walk us through this because we are going to see this multiple times. In terms of AI applying this emerging health IT by providers, patients, and interested parties safely, securely, and fairly to achieve better health outcomes, that is the focus of that target area, and then we have design and use of technology to advance health equity, applying health IT to help all people attain their full health potential regardless of social drivers of health.

Next, the use of technology to support public health, the facilitation of bidirectional information sharing between the clinical and public health communities, interoperability, which is a key one for all that we do, achieving a health IT infrastructure that allows for the electronic access, exchange, and use of health information, privacy and security, the promotion and protection of privacy and security of health information and health IT, and finally, patient access to information, the facilitation of secure access by individuals and their caregivers to such individuals’ protected health information. Now, this is not an order of priority. They are all priority areas and target areas. I just wanted to mention that last point. Next.

So, in the health IT landscape, the Cures Act requires annual assessment of health IT infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information. The landscape analysis considered the federal activities gaps, challenges, which is what we do, and opportunities to suggest recommended HITAC activities and key topics for each area, and that is what we are going to cover extensively in a bit. I want to highlight to you all, though, that we came up with a tiered approach of the opportunities that we want to target in the coming years, and we divided those into immediate opportunities and long-term opportunities, and just to say to those that were not part of the workgroup, this was really hard to define because everything was an immediate opportunity, so we really had to think for quite a bit to define what the long-term ones are. Next.

Here is our transition slide. We are going to open the actual report itself and share with you some steps and walk through the report, and we hope to get some feedback, thoughts, and comments. Next. So, as you can see here, this is a Portable Document Format (PDF), so you have received a copy of it, and like I shared in the outline, I think the key thing to keep in mind here is under the health IT infrastructure landscape, we have the activities across the target areas, but then we list all the target areas. The meat of the report is explaining each one of them. Next.

So, in the foreword, we have our co-chairs of HITAC giving the overview of where we are. Next. And then, this is a great slide to see the status and appointments. You can see here how each one of us was appointed, how many meetings we have had, committees, public hearings, and so on and so forth, so this is a great visual summary. Next slide, please. Here, again, are the target areas, and I am not going to cover that again, but I think you saw that this is really how the report is organized. Next slide. So, this is the landscape analysis of health IT that I highly recommend you all read, but we are now going to go over that quickly because we do not have a ton of time to cover the areas where we do want to hear feedback. Next, please.

This is one slide that is important for us to go over in a bit more detail. I want to highlight the colors of the target areas on the left side because the report is organized using those color schemes so you know which areas we are talking about, but on the right side are the topics that we discussed that are important for each target area. You see in the use of AI to improve health and healthcare that we identified three: AI for health and healthcare overall, provider use of AI, and patient impact and involvement in the use of AI. If we go down to advancing health equity, it

is Health Equity by Design, and that is just one, but it is a big topic, and we know there have been a lot of advancements led by ASTP.

Then comes the use of technology to support public health, which is the same, optimizing public health data exchange and infrastructure. We are going to get to the details there. But you see in interoperability, like I mentioned earlier, that there are quite a few things we still need to do, and that is a core aspect of what ONC or ASTP leads. So, we are talking about supporting interoperability for labs, pharmacy, image interoperability, Long-Term and Post-Acute Care (LTPAC), and behavioral health, and then to further quality and sharing, and standards for maternal health and diverse abilities. So, there is quite a bit there, but it is all very important to advance our work. In privacy and security, we have the sensitivity of health data, lack of disclosure accountability, and transparency in the use of deidentified data. Finally, in patient access, we have PGD, or patient-generated data, and reducing patient burden. Next.

This is a slide that was important to us. What are the federal activities across the target areas that are also out there that we need to highlight? It is not going to be very explicit on the report, but I will point your attention to the bottom left corner of the screen, which says the HITAC recognizes that it is important to align its work with significant initiatives already under way at HHS that address certain topics to some degree, and these topics are indicated with an asterisk. So, if you see an asterisk by one of those topics, that means that we have at least one of those key elements of the HHS strategy that links to that point, like the strategic plan, the TEFCA, and so on and so forth. Next. With that said, I turn it back to you, Medell, to take us into the details.

Medell Briggs-Malonson
Thank you so much, Eliel. As Eliel provided an overview of the structure of the annual report, there is one thing I wanted to bring to your attention. You probably noticed that the format is very different. First, it is has many more graphs and visuals, and the reason why is because ASTP, especially underneath Michelle Murray, really thought we needed to move more towards having more graphics and pictures because we know that people obtain information in different ways, both in the written format as well as through other types of visual content, so that is why this new format of the report is much more succinct and also has a very different layout. So now we are going to go into each one of the six target areas, and by the way, as HITAC, we have added on three target areas over the history of HITAC, so that shows, once again, the influence of this committee with really making sure that we are focusing on areas we think are incredibly important for ASTP as well as others to recognize.

And so, we will not read through all of this because there is a fair amount of content, but in each one of the sections, you will first have an introduction to that target area, and then, if we go to the next slide, you will see that there is an illustrative story that is associated with each one of the target areas. Now, the idea behind these stories is to outline the future state, and the reason why the recommendations from HITAC are so important is to try to get us to that future state of health technology, functioning policy, and other initiatives. To give an example of such, I am just going to read this story. I will not go too deep into the other stories, but this is just so everyone can understand the content of these.

So, this is the first target area of use of artificial intelligence that improves health and healthcare. This is the illustrative story of what the recommended HITAC activities can help advance. A network of rural federally qualified health centers all use electronic health record systems that are designed to incorporate best practices to collect and analyze their patients' demographics, medical conditions, and health-related social needs. Data dashboards and analytic tools are integrated with their EHR to identify and address inequities in clinical care and healthcare outcomes among their patient groups. The FQHCs desire a new AI clinical decision support tool, available across their EHRs, to identify worsening heart failure to enable early intervention and potential referral to the regional cardiac specialty center. They select a tool that is transparent and includes health equity principles in the design.

Via the EHR's patient portal, the tool also provides engaging education modules, assistance for their providers with shaping questions, and the capability to submit data generated at home. The FQHCs deploy the tool, along with staff training to appropriately assess for and mitigate potential bias. They also implement analytics to monitor for standardized tool use and equitable outcomes across their diverse populations. Patients can validate the data provided to the AI tool, and outputs are made available to them. The use of the AI tool leads to improved patient care and reduced inequities, including increased early heart failure interventions and specialty referrals, especially among patients of underrepresented ethno-racial groups, patients with limited English proficiency, and patients living with disabilities. The FQHC network submits its findings and data to the developers, who enhance their model and transparency documentation. So, that is an example of one of the stories. It is high-level and in the future. Go to the next slide.

You will see the various different recommendations from the Annual Report Workgroup as well as from you all as the full committee of HITAC where we have the topic, the key gaps we are trying to address, the key challenges, the key opportunities, and the recommended HITAC activities. For instance, for use of this topic of AI in health and healthcare, you also notice the asterisk that is there, as Eliel mentioned. What that asterisk means is that there is other work going on within HHS that also aligns with these recommendations that we as HITAC are putting forward. So, these are the same recommendations that were brought forward to the whole committee in the past. I will not go over them, but I wanted to make sure everyone saw the flow of the various different introductions into the story into the recommendations. Go to the next slide.

You will see the additional two topics, provider use of AI in health and healthcare and patient impact and involvement in the use of AI in health and healthcare. Next slide. And then we move on to design and use of technologies that advance health equity, in which, once again, you see the main topic that is going to be discussed on the left, which is implementing Health Equity by Design, as well as the introduction. Next slide. That is followed by the illustrative story of what we as the recommended HITAC activities should be in order to advance to a future state. Once again, unfortunately, we do not have time to read all of these stories, so, hopefully everyone read them beforehand, but you will see the progression. Next slide.

The topic is implementing Health Equity by Design with all the various gaps, challenges, opportunities, and recommended HITAC activities that are listed. Next slide. For the third topic, our target area is use of technologies that support public health. Once again, you see that huge topic of optimizing public health data exchange and infrastructure with the introduction. Next slide. And then, there is a story here that also talks about various different forms of surveillance, as well as the closed-loop circle of some of these various different forms of public health interoperability. Next slide. We also have the topics, gaps, challenges, opportunities, and activities. Next slide.

And then we get into the largest section by topic, which is interoperability. There is a lot that went into interoperability this year, and as we always know, it ebbs and flows when we put together the annual report, but as Eliel mentioned, the primary topics are on the left-hand side with the intro. Next slide. The interoperability is based in a clinical case regarding exchange of data information for a patient that received hip fracture surgery. Next slide. And then you have the various different immediate opportunities that are underneath each one of these various different topics, as you can see, and we have all four there on that page. Next slide. We also have additional immediate opportunities, with sharing data and data quality as well as other aspects focusing on mental health and diverse abilities with supporting data standards. Next slide.

This is one of our first longer-term opportunities. I just want to highlight that. We do have a few in there. We have supporting interoperability standards, not that information coming from pharmacies is less of a priority, but if you read what we have all looked at as a full committee, what it is saying is that we need some building blocks first before we put in and execute this recommended set of activities. Next slide. And then we have privacy and

security, which is another great topic, and thank you, Deven, for all your input on this one when coming and being one of our experts. Next slide.

Once again, this is an illustrative story of privacy and security, which talks about the various different forms of data from a patient perspective that the patient wants to be released to their providers or not. Next slide. Again, you can see some of these asterisks still because we know there is so much work that is going on in all of these areas, so you see some of the immediate opportunities here, especially with privacy of sensitive health data. Next slide. And then there are some longer-term opportunities. We are looking at lack of disclosure accountability and transparency and use of deidentified data. Next slide.

And then, last but definitely not least is patient access to information, which is really focused on PGHD, as well as reducing patient burden. The intro here actually provides more detail. Next slide. And then comes our illustrative story regarding the exchange or making sure there is coordination of the patient being able to receive all of their important data from multiple different settings and providers, again, decreasing the burden on the patient. Next slide. We have the immediate opportunities on how we need to ensure we reduce patient burden. Next slide. There are a few more focused on patient-generated health data and how we can continue to advance this very important topic forward, making sure we are doing everything needed for interoperability of this data, as well as decreasing patient burden on ensuring this information is transmitted. Next slide.

All right, I am still going over these. I am going to keep on going. We are almost at the very end, and then we are going to open it up for discussion. The other beautiful aspect about this is that we always put an overview of HITAC, and we wanted to acknowledge all the incredible work that our Task Force as well as our larger committee has been engaged in. We have the overall accomplishments for fiscal year 2024, as well as the list of the various different committees. Next slide. Here, you can see that each one of our various different workgroups and committees has its own slide, starting off with the Annual Report Workgroup with a summary of why we have this workgroup and its accomplishments. Next slide.

That is followed by the very important HTI-2 Proposed Rule Task Force. Yes, I see hand-clapping and finger snaps there. This talks about all the different accomplishments of the HTI-2 also accomplished during their time this fiscal year. Next slide. Of course, we cannot forget the Interoperability Standards Workgroup and all the amazing work that was put forward during that workgroup as well. Next slide. Here is the Pharmacy Interoperability and Emerging Therapeutics Task Force. This actually commenced in 2023, but it rolled over into 2024, so of course we have to give recognition for that as well, and all the amazing work this group put forth to guide ASTP's actions. Next slide. Here is the appendix. We will keep on going through. It has lots of different resources here. We can keep on going very quickly through all of these. And then, of course, there is special acknowledgement to the Annual Report Workgroup for all the members of the workgroup and all the many hours that were put in, as well as our ASTP team and Audacious Inquiry, which is always listening to us in the background, trying to decipher what we are trying to say, and putting it into the report in a concise way. We appreciate you, Audacious Inquiry. Next slide.

This is a full acknowledgement to all of you as a full HITAC committee. Again, your brilliance and expertise are what makes this committee go, and all your recommendations are so incredibly appreciated and valued. That is the end of the Annual Report Workgroup. Accel, let me make sure I am not jumping ahead. We will go back to our slide deck because I believe we have one more slide there. Excellent. Thank you so much. So, what we will do now is open it up for discussion, and the three primary areas we would love to know about are 1.) Do you have any questions or comments about the draft report, 2.) Do you have any suggested revisions to the draft report, and 3.) Do you have additional ideas that have been sparked?

What we have already started to create is a parking lot, and this is what we tend to do every year, where if there are new ideas or new visions that we cannot incorporate into this report, because again, we are on a very short

timeline, meaning we have to turn this around and get it approved next month when we meet, and it has to be submitted to Micky, and then to the Secretary and on to Congress, but there are always some really great ideas, and what we tend to do is put those in the parking lot for us to start on for our upcoming annual report. So, your ideas are never going to be lost, and if there is something that comes out, it should be in the parking lot. So, we have those three questions, and we will open it up for discussion, and Eliel and I are more than happy to answer any questions that the committee may have. Michael? Oh, sorry, I did not see Deven. Deven, and then Michael. That is always my blind spot.

Deven McGraw
That is okay, no worries. I am just here in the corner.

Medell Briggs-Malonson
We are going to move you next week. You are always in that corner.

Deven McGraw
This is amazing. Just reading the stories, I know those are our north stars. All of that should be 100% possible. We have lots of obstacles that get in the way, some of them technical, and I suspect most of them have to do with policy and culture, and we have lots of work to do, but this is still just an amazing report, and centering it around where we are headed is 100% the right thing to do. In terms of the future, patient access to data is always something, and that and privacy are the two things that probably wake me up more than other things, admittedly. In our last meeting, I brought up that the issue of patient access to data is not a solved problem, and one I would love for us to do in future work, though not necessarily to be included here because we had this discussion, to continue to do some check-ins on how things are going with respect to access to FHIR APIs and the status of access through TEFCA. Again, work is ongoing, and there are other venues where work is being done, but the most recent blog post from ONC/ASTP was a very pointed articulation of how we are not quite to where we should be in terms of how well that works for patients. But thank you, this was amazing, amazing work.

Medell Briggs-Malonson
Thank you so much, Deven, and again, thank you for all your contributions. We really appreciate it and note it for us to continue to work on that area. Michael? I am just going to turn this way for now.

Michael F. Chiang
I would just echo that to those of you who really led this. I thought this was an awesome report. I just had two minor comments and some parking lot suggestions. My first comment is that in one of the rows, there is one that is called “further improvement of data quality and data sharing,” and I just wonder if you would consider breaking that into two rows instead of one because I feel like data quality and data sharing are related, but I do not think they are exactly the same thing.

In terms of data sharing, my parking lot comment is that at NIH, coming from a researcher perspective, we hear the terms “data sharing” all the time, and we try to get people to do it, but really, nobody wants to do it because they feel like by sharing their data, they are helping their competitor because they are really incentivized by publishing their own papers with their own data. I feel like there is an analogy in the clinical world, where people are afraid to share data with who they perceive as their clinical competitors. One of the things we have been doing at NIH is trying to work on a data sharing index, and the idea is that every person would get their data sharing index, and the more you share and the more useful it is, the higher your index goes, and that could be used for incentivizing researchers in the future. I just wonder whether there is a similar way to make people feel like they are benefiting from sharing with other organizations.

My second minor comment is on the row that says “transparency in the use of deidentified data.” This is something that Deven and I were just talking a little bit about in the other corner here. To me, “deidentified” is a little bit of a funny term. Is there such a thing as really being deidentified? I just wonder whether you might consider calling it “legally deidentified” or something like that. I think we all suspect that these things can be reverse engineered, and you can kind of figure out sometimes who somebody really is based on their “deidentified” data.

For the parking lot items, in No. 1 here, it says “explore patient preferences,” and just to call this out, there was a group commissioned by the NIH called Novel and Exceptional Technology and Research Advisory Committee (NExTRAC). I think that stands for Novel and Exceptional Technology and Research Advisory Committee. They did some of what was No. 1, exploring patient preferences and how people would feel about their data being used for other purposes, for research in this case, and it just might be worth looking at some of their findings because I thought they were pretty interesting. Lastly, I just wonder whether there are any discussion items for the parking lot about working trans-HHS about questions like if informed consent is required, if there is some opt-in or opt-out way, or what the standard should be for dealing with this type of data moving forward. So, thanks and congratulations.

Eliel Oliveira
I can take some of them.

Medell Briggs-Malonson
I will take the others.

Eliel Oliveira
Walking back through your initial comments, Michael, I was going to comment on the one about deidentification. What was intended by that specific topic is exactly where you were going. Even though we consider data deidentified, if individuals do not have a say-so on that, as you know, it can be shared. That is what the legislation currently says. But then, we do not know where it goes and what is done with it. That line is to say that since that is that is the regulation, what do we do to trace it and make sure there is an account back to the source and the individuals? That is the way that we saw this, as opposed to trying to highlight what you said, which is that there is still a risk of deidentification here, which is another discussion in itself.

I totally agree on the quality and sharing split, “quality” meaning data is so complex and hard. In my view as well, everything we talk about with AI will not be possible until we achieve trust in our data, and it is not that simple, but we can leverage some initiatives that have already done some of that. I think some of our research networks, for instance, like the data quality process for The National Patient-Centered Clinical Research Network (PCORnet), Sentinel, and NCCC are very extensive, and with the amount of money that is continually spent to validate those data sets for research, that can be a place where we can learn quite a bit. I agree with you that sharing is another completely different line. I will stop there. Medell, I am sure you have some comments on that, but those are some reactions from me.

Medell Briggs-Malonson
I was going down my list, too, and I think you summarized it. Just for a little bit of context of where the data quality and sharing came up during the Annual Report Workgroup, it was very similar to the conversation we had earlier when we were discussing the physician survey. Yes, the data has to be high quality and not just riddled with excessive information that is not really helpful for making clinical decisions, but it is also talking about what should be shared. Oftentimes, we have these long C-CDAs. Do we need all of that?

We are also discussing the timeframes and having some levels of standardization. That is where some of the conversation started with thinking about how the data needs to be high quality, but also, what truly needs to be

shared, and what the standards of the amount of information or how you can query it going through that process. Separating it out to make sure that it is clear is helpful. And then, the only other thing I was going to say about sharing is that we do have information blocking in the clinical world, of course. Surely, to your point, while we know we have information-blocking rules and there are penalties to that, we know that sometimes institutions or clinicians may think twice or try to figure something else out, so that is something for us to continue to explore, but hopefully, information blocking, at least in the clinical setting, is helping to curb as much of that as possible. Those are all really great points, especially on the parking lot items. Thank you, Michael. We appreciate it.

Eliel Oliveira
If I may, I will add another thought for Michael on the data sharing aspect, which I would imagine, given the background that I know of you, maybe includes data sharing for surveillance, research, and other aspects, as opposed to the care, in which we have information blocking, which helps quite a bit. The thought process that I have is in each one of the data networks for research and surveillance, they have rules on data access, and we ourselves have our own information network, and the challenge is complex. Are you talking about identified or deidentified data, limited data sets, prospective or retrospective, or interventional? Not everyone understands that whole process. I have seen some of those networks summarize that really well. It is there, but it just takes time to educate folks on how to place the ask and what it takes to get the data reduced, but they do exist in some capacity.

Medell Briggs-Malonson
All right, we have Derek, and then Bryant.

Derek De Young
First off, congrats to everyone who worked on this. It is very impressive to get all your vision and ideas down to 40 pages. That is really hard to do. I do not know if it is a parking lot idea or potentially a suggested revision, probably more of a parking lot, but as I was reading through this, I had one other thing to note. I love seeing pharmacy on here. I think that is very important. There is one thing, which I am not saying has been overlooked, but I was just curious about why it was not on here, and that is lot of the work that CMS and HTI-2 is pushing with interoperability with payers. I do not see anything about payers on any of the interoperability stuff. Depending on what study you look at, 25-30% of every dollar in healthcare is administrative burden between payers and providers. I think that would be an incredible thing to focus on, and there is a lot of work happening in this space, and it would be interesting to see that in here, maybe in a future report.

Medell Briggs-Malonson
Gosh, I do not know if it was an oversight or not, but that is such an excellent point, and you are absolutely correct. As we move forward, I think that definitely needs to be a topic in our annual report for next year. Thinking about the complexities and bringing in health plans and the payers, that may be a little bit challenging for this report, but that absolutely should be a very clear topic for next year, so thank you for recommending that because you are right, there is so much work under way, and that tends to be the area we need to dive into. We know that is actually at the core of a lot of the various different aspects that were focused on, so, thank you for that. Even when we are talking about prior auth and everything else, it all comes down to a lot of the payers in every way, so, thank you, Derek. Bryant?

Bryant Thomas Karras
Thank you, and you have my congratulations as well. This is an amazing document, and I love, love, love the storytelling because I think that is what draws people in and helps them to realize what we are actually talking about here. I do have some friendly amendments to the public health storytelling. There is a little bit of a fiction included in there, and I guess my first question to the Annual Report Workgroup is was that storytelling meant to be what is current so that we can describe the gaps or what could be?

Medell Briggs-Malonson
The future. So, all of the stories were based upon how it should be and where we want to get to in order to try to support the recommendations that are being provided.

Bryant Thomas Karras
So, in that case, there is a reference to north star architecture, which is a concept that does not exist yet and has not been fully implemented, so I can accept that, but perhaps it does not go far enough. It still talks about some manual steps where staff at a healthcare facility are contacted by public health, and they work together to reach the individuals. In a fully automated vision of the future, we are actually saving staff time and avoiding taking them away from the clinical care of their current patients to talk about a patient that was there a few days ago when that data could have been teased out through an API and they would never even have been bothered. I will work with Jim Jirjis and Steve to get those edits in.

Medell Briggs-Malonson
Yes, and Ike was one of the primary authors there. Thank you so much for that.

Eliel Oliveira
I thought you were going to ask us to include Anakin Skywalker. That is what he said over breakfast.

Medell Briggs-Malonson
Oh, really? Okay.

Bryant Thomas Karras
We are working on a Death Czar.

Medell Briggs-Malonson
I am speechless on that. I do not even know what to say there. All right, very good. Any other thoughts or comments? I love all of these revisions, and again, we are still taking revisions, so this is not the last time, but with the caveat, to channel Michelle Murray right now, that the revisions really do need to be sent in to our ASTP colleagues within the next week because they are working very hard to finalize this on behalf of all of us as the committee. So, you still have time, and additional written comments and revisions are incredibly appreciated.

Seth Pazinski
Specifically, we asked if you could get your feedback in by October 23rd.

Medell Briggs-Malonson
Okay, that is next Wednesday, so, six days. Any other comments now, as we are capturing comments and revisions now? I am looking at all corners. Okay, Sarah, I do not think there is anyone on Zoom. Is there anyone from Zoom as well? Okay. Well then, Eliel, I think we have presented it.

Eliel Oliveira
That is a wrap.

Medell Briggs-Malonson
It is a wrap. Again, thank you so much to all of our Annual Report Workgroup members and all the revisions and comments that you all have made. Thank you so much to ASTP and Audacious Inquiry. Please get any comments or revisions in by Wednesday the 23rd at the end of the day, and honestly, it is kind of at the end of the day

Eastern Time. So, please try to do that, and then we will be able to incorporate everyone's comments, review them, and vote on them for our next HITAC committee meeting in November. Thank you all. Excellent.

Eliel Oliveira
I have one question, Seth, for others here. If you know, when do we start the next Annual Report Workgroup meetings? January, February, March?

Seth Pazinski
Let me follow up on that timeline. We are working on the draft of a work plan for the committee, which we do about this time every year, so, at the November meeting, we will have a presentation and a draft work plan to get all your feedback, and then we will come back with a final work plan and get things going in January.

Eliel Oliveira
Okay, great, thank you. Thank you again to everybody who contributed. When that announcement comes up next time, consider joining. We would love to have more of you involved.

Medell Briggs-Malonson
All right, thank you so much. We are going to move on to our next presentation, which is the draft federal FHIR action plan, and we have Adam here with us. Welcome, Adam.

Draft Federal FHIR Action Plan (03:10:06)

Adam Wong
Thank you. Good afternoon, everyone. I hope everybody can hear me. I think so. Again, my name is Adam Wong. I am a senior innovation analyst with ASTP's Office of Standards Certification and Analysis. Next slide, please. At the end of September, ASTP released a draft federal FHIR action plan to the public. Today, we will cover three main points: First, the development of the draft action plan and how it was a collaborative process, second, the intent to align federal agencies' adoption and use of FHIR, and finally, the fundamental areas of federal health IT activity that are covered in the action plan. Next slide, please.

The federal government's relationship with FHIR has been a journey. This graphic begins eight years ago, with the 21st Century Cures Act final rule, requiring certification program participants to implement a standardized API. In the years since, we have seen an increasing number of agencies developing and implementing FHIR, passing rules and regulations specifying FHIR, and the standard itself evolving. In 2019, a FHIR workgroup was convened under the Federal Health IT Coordinating Council to coordinate knowledge, implementation, and decision-making around the role and use of FHIR. This action plan builds off recommendations developed by this group and released in early '22. This document focused a bit more on the whys and hows of developing for and interacting with HL7 and FHIR and provided a foundation for this new plan.

The action plan owes a great deal to regulatory adoption and technical requirements of the past several years. With the releases over the past 10 months of CMS's interoperability and prior authorization final rule, ASTP's HTI-1 final rule, ASTP's HTI-2 proposed rule, and the specifications that were listed in those, the time was right to take the next step. The latest rules specified numerous long-in-development implementation guides that provide a foundation for use of FHIR by federal agencies. We have also recently seen a release of the HHS data strategy and continued development of the HHS health IT alignment policy, all of which will be mutually reinforcing steps for FHIR adoption and implementation. Additionally, ASTP engaged and consulted with several agencies, including CMS, CDC, FDA, and the VA to ensure that we are on the right track. That being said, this is a draft action plan, and we do seek further input. We want to make sure that the plan is as thorough as possible before releasing the final version. I will get into details on the commenting process at the end of this presentation. Next slide, please.

There are multiple goals and objectives with the action plan. The primary one is to align federal agencies' adoption and use of FHIR around a set of central components and capabilities that agencies have implemented or are planning to implement in the next two years, or by 2026. Many of these components are mature and being used in production. The action plan is intended to identify and address common needs, to coordinate efforts, and to emphasis the reuse of capabilities to avoid duplication of effort and investment. By cohering around the components specified, we can steer investment away from redundancies into areas that need new or additional investment, while we want to identify those areas in which additional investment and development are needed and to spur federal partners and the standards community to identify new areas for development.

Our hope is that this leads to additional benefits: Strengthening and expanding the federal use of FHIR APIs and related services to achieve both immediate impact and long-term success, making it easier for federal agencies to exchange information via FHIR so decision makers can act on it faster with higher confidence, encouraging agencies to identify which capabilities best support their needs so that they can be strategic in their investment and reduce duplication and effort, and equipping agencies with the knowledge and resources necessary to make informed choices on using FHIR to meet their needs.

So, who is this for? No. 1, of course, is the federal community, hence the federal FHIR action plan. Specifically, we feel it can be used primarily by program managers who make the actual choices from a variety of specifications and decision makers to decide what investments agencies will make. The latter will also go hand in hand with the HHS HIT health alignment policy, which, again, will have a role in unifying health IT requirements for investments. The standards development community and industry can also benefit from the action plan. It is designed to provide clarity, consistency, and predictability regarding the standards and implementation specifications that are being considered by federal agencies.

Interested parties who administer government programs with clinical health IT interoperability components would also be encouraged to look to the draft action plan to more fully inform their goals. Finally, this visibility, of course, applies to the HITAC membership and its community, giving insight into how agencies are implementing and aligning health IT. This is a window into what may be gaps or areas to improve, and HITAC advice would help spur agencies and the standards community to act on these types of areas. Next slide, please.

The heart of the draft action plan lies in the component tables in the FHIR ecosystem section. The individual components described in the tables are those that ASTP and our collaborators consider to be best suited to address current agency needs, factoring in the level of current implementation in industry, regulatory requirement, component maturity, and readiness for future adoption. These groupings do not align perfectly with or are owned solely by any given agency, but we do recommend that certain agencies be kept in the loop when developing and investing in those areas. First off, we have core components. These have been thoroughly tested and have been used broadly in production systems. They are the most foundational and have the flexibility suitable for multiple use cases. The most relevant agencies here are ASTP and CMS.

Next, we have network components. These are capabilities for exchanging and discovering data across large multimodal networks. At present, these are most apparent in TEFCA's progression to a FHIR-based system. They can play a role in future network applications. Again, the most relevant agencies here are ASTP and CMS, not to exclude anybody else. Next up we have payment and health quality components. These seek to reduce the reporting burden for clinicians, caregivers, patients, and payers, and enable the exchange of claims data. A relevant agency here is clearly CMS. The next category we have is care delivery engagement components. These ease patients' access to their health data and the healthcare system or reduce provider burden and assist providers in areas such as decision support in areas such as decision support. These issues touch multiple agencies, including CMS, Health Resources and Services Administration (HRSA), and CDC.

Next, we have the public health and emergency response components. These seek to modernize public health data infrastructure. Obviously, CDC is the key relevance here. Finally, we have research components. These seek to drive toward a fully digital health system that uses FHIR for research activities. Again, multiple agencies are of note here, with NIH and FDA being just two of those. The other section of primary note in the action plan is the early-stage capabilities. These are more general areas of interest. Our development has begun for the most part in one or several of these listed FHIR accelerators. The implementation guides being developed at these accelerators being developed at these accelerators will address current and future needs, but are earlier in the development process. FHIR Write is a good example of where there is additional development required where we know of interest, but there is not yet a scalable approach. Human services interoperability is also listed here, following its delegation of responsibility to ASTP in the HHS data strategy. Next slide, please.

So, just to recap, we covered three main points: The development of the draft action plan and how it was a collaborative process, or the how of it, the intent to align federal agencies' adoption and use of FHIR, or the why, and then, finally, the what, being fundamental areas of federal health IT activity that are covered in the action plan. Next slide, please.

So, the public comment period is open now, running through November 25th, or the Monday before Thanksgiving. That should be a decent road to provide some feedback by the public, generally speaking. We seek comment from federal agency partners, the FHIR development community, and subject matter experts. Commenting is available on the action plan pages located on ASTP's interoperability standards platform, and the final federal FHIR action plan is expected in April of next year. So, for HITAC specifically, we are happy to hear thoughts now or later through the comment process on the platform. We are interested to hear what those aforementioned gaps might be, where they have been improved, and what else could be good additions to the early-stage capabilities. And so, now, we have time for discussion.

Sarah DeSilvey
Eliel, are you the first one? Oh, sorry. Hans?

Medell Briggs-Malonson
Our corners…

Sarah DeSilvey
Our corner pockets, I know. You watch this side, and I will watch that side. My apologies.

Hans Buitendijk
I will scoot in a little bit further. I appreciate the update, and I am looking forward to diving into the report a little bit further as well. I have two questions, and as you were inviting some feedback on the early-stage capabilities, that is one of them. In one of the earlier slides, you provided a progression of FHIR r.4, r.5, and r.6, and I am curious if that is overall in the plan and the thoughts, not as much about r.4 and r.6, but what kind of plans there are within HHS to utilize r.5. The reason why I am asking that is because, at least in the various parts of the community, there is not a lot of attention on r.5, so I am really curious what those areas are to have a better sense of how that relates with work that is going on that may have to start to pay attention to that. Most of the focus is on r.6, and we should get ready for that.

So, that is one question, and the second is in response to your question about early-stage capabilities. I do not know exactly what is in the plan itself, but for presentation purposes, we should include some of the other FHIR accelerators as well. We are looking at Da Vinci, which is, first and foremost, in the payer-provider space, APIs that are being listed, Argonaut, which has provided substantial, fundamental foundation, Gravity, and Control,

Attitude, Reciprocity, Identity and Need (CARIN) with Blue Button, so I would urge you to recognize all those activities in the FHIR space to really help move it forward and contribute to rules, guides, and otherwise. But on the first part, the main question is about r.5. What are some of the thoughts there that you have?

Adam Wong
I appreciate the feedback. That was great to hear. I just have a quick comment on your second question. We do recognize all the work that has been done by all the accelerators, certainly. I am not sure if FAST was listed there, for example, but we are looking forward to seeing what other types of networking components can emerge from that accelerator, just as one example. As far as r.5 goes, yes, we have seen a lot of attention so far on r.4, obviously, and then continuing on to the future of r.6. I do not want to make a sweeping policy statement by any stretch or anything like that, but we do see r.5 as a little bit more of an iterative advance on r.4. One of the specifications that we have listed in the core components, I believe, is the use of r.5 to create a backwards implementable guide for implementing subscriptions, so that is just one instance of where we see that r.5 development going, using it as an interim space for building new technology that we seek to have compliance with other components.

Avinash Shanbhag
Hi, this is Avinash. Maybe I will put a finer point on it. Actually, the slide that you saw about r.5 is just a pictorial description of the progression of FHIR releases, but if you look at the plan, r.4 is more mature, so our recommendation is for all federal agencies that are currently working on FHIR-based APIs to look at r.4, not r.5. Just to put a finer point on it, r.4 is the recommended guidance from ASTP to federal agencies, and working with HL7, we intend to skip r.5 and move all the way to r.6 as the next floor where most of the industry will be going. Just to be very clear, that was the first point. And then, on the accelerators, maybe a broader point is that the goal of this FHIR action plan is not so much to broadly identify all the work that is happening because that is really variable. The Interoperability Standards Advisory, ISA, holds place.

This is more of a targeted network approach to showing all of you what government agencies are working on, and specifically, if there are activities within those accelerators that are of interest to federal agencies in particular, we highlight them. Particularly with Da Vinci, I think a lot of IGs have moved into the FHIR ecosystem. In the early capabilities, they are really use cases that are not yet baked, but Da Vinci are really into that implementation/testing phase, as we know, so a lot of those implementation guides are in the FHIR ecosystem. But again, we just released, so, take a look at it, but we would love to get feedback to hear if there are any specific areas that we either did not call out or we did call out but which are not mature yet and we need to work towards.

Sarah DeSilvey
Eliel?

Eliel Oliveira
Thank you so much. I am looking forward to reviewing the plan as well. I think this might fall under the core capabilities area. I am just imagining our ecosystem here. I would imagine that the goal here is eventually to make use of the FHIR endpoints that exist, and to me, that implies the need of a couple of core assets to make that work effectively, and to me, one of them is the deduplication or a master index of individuals and how we can get to not only the individuals, but also the endpoints to be able to reach. The second aspect is who is asking. Electronically, what is the validation of the identity of the organization, individual, or application that is trying to get to the piece of information? Anyways, I will do a deep dive into the report, but I was hoping to hear a little bit about that type of core asset that allows everything else to work. Thank you.

Adam Wong

Thank you. There is a bit of a survival-of-the-fittest nature in these competing core components, and the ones that have elevated themselves, at least partially through ASTP efforts, are what rose to the top in the core components. We are going to see that continue as we expand that list moving years into the future. I think the best solutions are going to win out, though not without a certain thumb on the scale, and that is how we will see some of these implementation guides get added to core and any other component tables, too.

Sarah DeSilvey
Bryant?

Bryant Thomas Karras
This is Bryant Karras, Washington State Department of Health. Adam, assuming this is not a *Federal Register* proposed rule, could you opine for a second on things that are not in the action plan, like activities that fall into the category "If it ain't broke, don't fix it," the use of v.2 HL7 messages that are so ubiquitous in a lot of the public health transactions that really could potentially benefit from a future FHIR implementation, but where we are not seeing any federal activity in those spaces?. Is its absence a signal that it is never going to happen, or is it just not happening yet?

Adam Wong
I think it is more the latter than the former. We really focus on just the FHIR specifications here, and the ones that, again, are mature and foundational are widely implemented. So, things that might be more…not speculative, but early in their development, are things that would likely belong more in the early-stage capabilities section that do not have a specific implementation guide or set of implementation guides that address the problem, but that are much earlier in their development. So, we are really trying to, again, focus federal effort around these certain capabilities that are available right now. Of course, there are some that are a little bit more baked than others. I think these are primarily in the core capabilities section, and some things in public health and research tables may require a little bit more baking, but it has been made clear to us that federal agencies are cohering around these particular ones. So, again, early-stage capabilities are where we want to go for certain specifications and capabilities, obviously, that we need to more coalescence around before we really start to call them out specifically for adoption by federal agencies.

Sarah DeSilvey
Thank you. I think I am actually next. I am not going to go last this time. I want to thank you for the draft report early reviewing, and I want to note and build off what Hans was saying insofar as the capability of health and human services interoperability goes, the work of social determinants of health and social care puts us firmly in exploring the use cases at Gravity of what that means because almost every single one of our use cases involves sharing information between clinical settings, core HHS, and all US programs, such as ACF, ACL, HUD, and United States Department of Agriculture (USDA), so that conversation between women, infants, and children (WIC) agencies, clinical agencies, community action agencies, and clinical entities about social care are all what we focus on on a daily basis. I just want to note that there is the Social Care Voice Codesign Report that Gravity put out last year that was an exploration of exactly those interoperability use cases that might be of aid for that purpose. But I am a big fan of that report, and, of course, of health and human services interoperability because at Gravity, that is what we try to lean into every single day. Hung?

Hung S. Luu
I am Hung Luu. Thank you for that presentation. Along the lines of what Bryant was talking about, there is a belief or concern in the laboratory community that the laboratory domain is not very well developed in FHIR. There are obviously workgroups that are working on that, but we do not feel that it is quite mature and up to the level of others. What would be the implications of certain things being carried by FHIR and certain things continuing to be used by HL7 v.2? Is there going to be a potential loss of information, and how do we mitigate that?

Avinash Shanbhag
Do you want me to address that?

Adam Wong
Sure!

Avinash Shanbhag
Hi, this is Avinash from ASTP again. This is great. This is really the kind of input we want for this activity because this is like a mirror where we watch where federal agents are currently investing funding. Again, having these gaps highlighted, having these areas where things currently may be working, but they need to be more organized, I am sure we can, in the future, put out sections where maybe we could **[inaudible] [03:32:46]** a section that says things are working, but need to be modernized. I can see that also as a potential area to highlight, and that might spur our federal agencies and the private sector to actually work on that. Thank you for that comment. Sorry, Adam. I did not mean to cut you off. Feel free to add on anything else you want to.

Adam Wong
I do not think I have anything to add there.

Sarah DeSilvey
I think we are going around. Ike?

Steven Eichner
Thank you, and thank you for a wonderful presentation. One thing I would like to add is there are some improvements that could be made in making the draft accessible. It is really hard to navigate through to actually get through the content, so if there could be some improvements to create a shorter path for people to be able to get to the content, that would be absolutely fantastic.

Adam Wong
I concur.

Sarah DeSilvey
Thank you, Ike. Rochelle, did you have your hand up?

Rochelle Prosser
Hi, I am Rochelle Prosser from Orchid Healthcare Solutions. First of all, thank you for all the work and all the predecessors that have put work into such a great endeavor. As I was listening to your presentation, a thought came across that I understand that we are doing the survival of the fittest, as you had mentioned. When they do not survive, but there is adoption in certain regions or areas, but that particular FHIR API goes away, what is the plan, strategy, or next step for those that have made those financial commitments and cannot commit to something else, so it is gone?

Adam Wong
I think that is a tough nut to crack. In an ideal world, all the specifications that we list here would be adopted and all the investments would serve the needs that were intended. It is possible that adoption could start in one place and then move in a different direction, and that would obviously be very unfortunate. I am not sure if ASTP is the entity that can really address that difficulty directly, other than trying to herd people in the right direction. If we see two paths diverging, then I would hope that we can identify those really early on in the process and try to steer things back into a singular direction.

Avinash Shanbhag
I will just add a few things. In ONC's previous role as coordinator, we have taken the role of engaging with our standards community when it seems that standards are getting upgraded and breaking. So, for example, when FHIR release 2 came in and the industry all decided that r.3 was not going to be a great place and r.4 was, through our standards activity and further regulation at that time, ONC navigated. I see that as our future role. If standards are moving forward more rapidly, where industry adoption may be at a different scale, perhaps this highlights that, and then, through our role as coordinators in the standards community, we can bring the industry and the standards community so that at least built and deployed investments have a way forward in a more deliberate manner. Again, this is our attempt at giving visibility to all of you on what government is doing, but also all of us where industry is going, and if there are gaps and/or areas of need, how do we align? Again, we are focused on FHIR because everybody is investing FHIR, and we want to make sure their investments are all aligned. Thank you.

Sarah DeSilvey
Thank you. Hung, is your card up for another question? Okay. Kyle?

Kyle Cobb
Recognizing that ASTP is the coordinator and the herder of a lot of this, maybe this is in the plan, but I would love to hear a little bit more about the sense of some of the FHIR standards like bulk FHIR, for example, that has been used in different use cases, and across CMS, CDC, and others, we have been trying to figure out how to use it effectively. It has been hard because they live in these siloed use cases, and we have had conversations with HL7 about how they can also be pushing out better to make sure that those standards that have multiple use cases are addressed in a more directive way, but I think that this is actually a role that ASTP can play with that. So, whether it is subscriptions or these advanced FHIR capabilities, it gets very weedy when we get down to the public health or the payer level, but I know there is this missing overarching area.

Adam Wong
I think it would be great if we had all the interested parties and the funds to run a pilot for a particular component in every single potential use case, especially something like bulk FHIR. I think we have to pick and choose where we can invest ourselves and encourage the wider agency community to also engage in these pilots and testing on a consistent basis across different things and not have 10 different pilots that are in one single overlapping use case. I think that ASTP can certainly help in those kinds of efforts, especially in our coordination role with all the other federal agencies.

Kyle Cobb
Sometimes it is not necessarily sponsoring the pilots, it is the information and getting it to the right people. I know HL7 struggles with that, and we are all looking for a central place to actually find this information. I do think that this is an opportunity for ASTP.

Adam Wong
Thank you.

Sarah DeSilvey
Are there other comments from either in-person HITAC members or folks on the line? Thank you so much for that wonderful presentation. It was a really great way to send us out. I believe our next topic is public comment.

Public Comment (03:40:20)

Seth Pazinski
Yes, thank you, Sarah. We are going to open up now for public comment. If you are present in the room today and a member of the public, there is a microphone in the back corner over there, sticking with the corner theme, so you are welcome to head up to the microphone there. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, please press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. While we wait for the public to raise their hands, I will just give a reminder that our last HITAC meeting of the calendar year is scheduled for November 7th from 10:00 a.m. to 3:00 p.m. Eastern Time, and that will be a virtual meeting, and a reminder that all the materials today are available on HealthIT.gov for anyone who is interested. I see we have no comments on the line at this time. Let me just check the Zoom. All right, there are no hands raised, and I see none in the room, so, Medell and Sarah, I will turn it back to you for any final remarks and to close us out.

Medell Briggs-Malonson
We have one comment from Bryant.

Bryant Thomas Karras
I just have a question. So, recognizing that the last official HITAC meeting would be in November, is there an opportunity for us to assemble in person at the annual meeting in December, or is that not allowed?

Seth Pazinski
Any meeting would have to be a fully structured HITAC meeting, which we have not scheduled at this point. We would also need to publish a notice in the *Federal Register* that we were planning to have that meeting.

Sarah DeSilvey
But we can have dinner!

Medell Briggs-Malonson
But you always know we can always informally get together. You know I love planning things.

Seth Pazinski
We would welcome the opportunity to informally connect with all of you, but there are no plans for a formal meeting at the end of the year.

Medell Briggs-Malonson
Rochelle?

Rochelle Prosser
I noticed that the last meeting actually overlaps with the USCDI+ Cancer listening session that Liz was bringing to the public, so I just wanted to let you know that our last meeting on November 7th will also overlap the listening session for the USCDI for about one hour, but I am not sure if we can structure our lunch break over the time to allow those that participate in USCDI+ Cancer to be able to attend.

Seth Pazinski
Thanks for flagging that. We can take a look at what our agenda will be for the day and do our best to work around any conflicts there.

Final Remarks and Adjourn (03:43:23)

Medell Briggs-Malonson
Any other questions or comments before we move into closing remarks? Okay, well, first, thank you, everyone, for an amazing day. We are ending early, which is always a treat, so that people can travel back, but thank you, everyone, for coming, and especially for traveling both the long distances and the shorter distances to get here. I appreciate all the participation and engagement. Yes, Seth, my heart dropped a little bit, since next month will be our last HITAC meeting of the year, and the reason why is because, as we all know, we as HITAC members are appointed for three-year periods, so there may be some people, and I already know one for sure, but especially at our November meeting, we will be acknowledging some of those members that have decided not to come back because they are off to so many other things as well, so that is one thing we will celebrate.

If you are going to the annual meeting, we will try to have an informal HITAC gathering, so we will discuss that, but we just really appreciate everyone. You always just brighten things up with all of your expertise and brilliance, and we really appreciate all of you all. A special thank you, as always, to our ASTP leadership, and also to our amazing Accel team that always keeps us moving and all the other teams that help to keep this committee going, especially all the logistics that go into this in-person meeting, which is not an easy task at all. So, thank you all for all of your kindness and all of your assistance.

Sarah DeSilvey
As always, Medell says it best, but finally, again, thank you so much for this day. I really appreciate the global view on what we have accomplished in 2024 from our friends at ASTP, and I am looking forward to 2025. The annual report is a stunning piece of work that really shows our vision, ethics, and principles, and we are closing out a lovely in-person session. It is always lovely to see you all in person, and we look forward to seeing you all in November. Go enjoy your precious hour in the sunshine.

Questions and Comments Received Via Zoom Webinar Chat

Bryant Thomas Karras: Testing the chat…

Hannah K. Galvin: We are very excited to start advancing this critically important work.

Sarah DeSilvey: Thank you, Hannah, for dropping in the charge and co-chairing this critical group.

Maria Moen: Health Equity by Design is the perfect touch point for all the work that ASTP (forever ONC to me) has put in to modernize our healthcare eco-system and enable people to be empowered in their own healthcare and right to equitable services. Thank you so much HITAC and ONC! Oops, ASTP. :0)

Medell K. Briggs-Malonson: We are all grateful to ASTP and its leadership for centering health equity, inclusivity, and accessibility for all.

Mark Savage: Amen!

Rochelle Prosser: Thank - you for this wonderful and insightful presentation.

Sarah DeSilvey: HITAC members, as a reminder we aim to keep first questions and comments brief to allow all members to raise thoughts. Then we can circle back around if time permits.

Maria Moen: Disagree completely. Your figures support that access is NOT there and that the majority of respondents are struggling. Period. Listen to what the users are saying, things are not working as they should.

Just my impressions, sorry about the tone of my comment, but there is a clear issue that exists which cannot be explained away.

Hannah K. Galvin: I do agree with Maria and experientially as well - interoperability and reconciliation of information are some of the major pain points CMIO's continue hear about on a daily basis. Glad ASTP has this data and that we will be continuing to focus on how to improve access to data and decrease burden here.

Rochelle Prosser: Thank you Maria for your comments. Bringing in the patient perspective there is indeed a large disconnect .

Sarah DeSilvey: Hans asked my question. Essentially, is there an ability to analyze data by practice type: hospital owned, FQHC, independent, etc. Then again practice location: rural, urban, suburban. Because these are where the differences lie. Says a rural FQHC primary care provider.

Sarah DeSilvey: +1, Medell

Hannah K. Galvin: +1

Rochelle Prosser: +1

Randa Perkins: +1 Usability, quality > quantity.

Bryant Thomas Karras: @Jordan @Stephanie Have you considered limiting the survey to CMIOs who might know if tech certified, and would understand the connectivity behind the EHR?

Rochelle Prosser: +1 Bryant and Epidemiology PHMD under the Area of Family PRactice. They are also key stakeholders of the data insights

Mark Savage: Following up on Medell's point, lifting up the work of NQF's Interoperability Committee outlining the domains and subdomains of interoperability--including usability. Key table at page 3.
https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85827

Bryant Thomas Karras: We found the results from UCSF study misleading in that Clinicians perspective were wrong on knowing if their system was reporting to PH.

Hannah K. Galvin: I like the table Mark references. I do think the definition "Accessibility" feature is key. In many cases, the data CAN be accessed, eventually, but with significant effort. Ultimately, we need to focus on Accessibility without significant additional effort.

Shila Blend: In the HIE space there is a push to not only to exchange data but become health data utilities which may result in more usability of data from outside sources over time. It would be interesting to see if these providers are connected and using their HIE/HIN at this time

Sarah DeSilvey: HITAC members, if we did not get to you, please place your comments/questions in the chat if possible so they can be part of the public record.

Rochelle Prosser: Thank - you for your response. in Rural and Urban centers where there is not available Family Medicine, NP, ARNP's are the resources answering a lot of those questions regarding interoperability and authorization specifically. Can those folks more proximal to the source might have better response rate. Definitely agree with more knowledge and awareness of different programs available.

Sarah DeSilvey: Amazing work, ASTP. Thank you, Liz!

Rochelle Prosser: +1 Eliel

Rochelle Prosser: Excellent presentation Liz.

Rochelle Prosser: How do we address areas of the country where decentralization of Clinical trials to ensure all members in need of clinical trials can be found and ping the network?

Rochelle Prosser: We are seeing increased incidences of over lap os WOmens health and Sickle cell and Kidney function within the diagnosis of Cancer involvement. Is there a plan to consider overlap within the separate areas displayed today and how Cancer can ad increase data capture within the mix?

Rochelle Prosser: Looking at increased complexity within the overlap.

Liz Turi: Hi, Rochelle, Thank you for your questions. The conversation around CTM is informed by concerns around access to clinical trials outside of NCI designated cancer centers, and is included in conversations as we work with our partners.

Liz Turi: Re: your comment about Maternal Health and Sickle Cell Disease - thank you for this feedback. I'll bring it back to both those areas as we consider and look at future opportunities and use cases.

Maggie Zeng: HTI-2 Proposed Rule: https://www.federalregister.gov/d/2024-14975

Maggie Zeng: 2024 ASTP Annual Meeting: https://www.healthit.gov/news/events/2024-astp-annual-meeting

Maggie Zeng: 2024-2030 Federal Health IT Strategic Plan: https://www.healthit.gov/topic/2024-2030-federal-health-it-strategic-plan

Maggie Zeng: About the Draft Federal FHIR® Action Plan: https://www.healthit.gov/isp/about-fhir-action-plan

Maggie Zeng: Health IT Buzz Blog: Introducing the 2024 Draft Federal FHIR® Action Plan: https://www.healthit.gov/buzz-blog/standards/introducing-the-2024-draft-federal-fhir-action-plan

Maggie Zeng: 2024 LEAP in Health IT Awardees: https://www.hhs.gov/about/news/2024/09/17/hhs-announces-2024-leap-health-awardees-focused-data-quality-responsible-ai-accelerating-adoption-behavioral-health.html

Pooja Babbrah: Great to see this on pharmacy interoperability - even if it's longer term. Work is being done on those building blocks you referenced!

Zeynep Sumer-King: Agree! Will Surescripts as a QHIN help with this goal?

Pooja Babbrah: yes. And the work we are doing at NCPDP to support more multi-directional data exchange between pharmacists and other caregivers

Mark Marcciante: The work CARIN Alliance is doing with Real-Time Pharmacy Benefits check will also ensure it's available in the app of the patient's choice

Pooja Babbrah: +1 deven - loved the stories wrapped into the report

Zeynep Sumer-King: Loved the stories!

Questions and Comments Received Via Email

No comments were received via email.

Resources

HITAC Webpage
HITAC - October 17, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 11/13/24.