ASTP | Health IT Advisory Committee

Health Information Technology Advisory Committee (HITAC) Virtual Meeting

Transcript | September 12, 2024, 10 AM – 3 PM ET

Attendance

Members

Medell Briggs-Malonson, UCLA Health, co-chair
Sarah DeSilvey, Gravity Project, co-chair
Shila Blend, North Dakota Health Information Network
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
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Citizen
Katrina Miller Parrish, Patient.com
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Mark Sendak, Duke Institute for Health Innovation
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, Neantix Inc

Members Not in Attendance

Hans Buitendijk, Oracle Health
Steven Hester, Norton Healthcare
Aaron Neinstein, Notable

Federal Representatives

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

ASTP Staff

Micky Tripathi, Assistant Secretary for Technology Policy and National Coordinator for Health IT
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Designated Federal Officer

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

Seth Pazinski
Good morning, everyone and welcome to the September HITAC meeting. I am Seth Pazinski with United States Department of Health and Human Services (HHS), Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP). And I will be serving as your Designated Federal Officer for today. As a reminder to everyone, this meeting is open to the public and we encourage public feedback throughout. You can share your feedback through the chat feature throughout the meeting. We also have time dedicated towards the end of our agenda for verbal public comments. I am going to get started with roll call. And I will first welcome our ONC executive leadership to the meeting. We have Micky Tripathi, the Assistant Secretary for Technology Policy and National Coordinator for Health IT. And we have Elise Sweeney Anthony, Executive Director for the Office of Policy. I am going to go to our HITAC roll call. And I will start with our co-chairs. When I call your name, if you can please indicate that you are present. Medell Briggs-Malonson.

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Sarah DeSilvey.

Sarah DeSilvey
Good morning and welcome.

Seth Pazinski
Shila Blend. Hans Buitendijk. Michael Chiang.

Michael Chiang
Present.

Seth Pazinski
Derek De Young.

Derek De Young
Good morning.

Seth Pazinski
Steven Eichner.

Steven Eichner
Good morning.

Seth Pazinski
Lee Fleisher.

Lee Fleisher
Good morning.

Seth Pazinski
Hannah Galvin.

Hannah Galvin
Good morning.

Seth Pazinski
Raj Godavarthi.

Rajesh Godavarthi
Present.

Seth Pazinski
Steven Hester. Bryant Thomas Karras.

Bryant Thomas Karras
I am here.

Seth Pazinski
Hung Luu.

Hung Luu
Good morning.

Seth Pazinski
Trudi Matthews.

Trudi Matthews
Good morning, everyone.

Seth Pazinski
Anna McCollister. Deven McGraw.

Deven McGraw
Good morning.

Seth Pazinski
Katrina Miller Parrish.

Katrina Miller Parrish
Good morning.

Seth Pazinski
Aaron Neinstein. Eliel Oliveira.

Eliel Oliveira
I am here.

Seth Pazinski
Kikelomo Oshunkentan.

Kikelomo Oshunkentan
Good morning. I am present.

Seth Pazinski
Randa Perkins.

Randa Perkins
Good morning.

Seth Pazinski
Rochelle Prosser. Dan Riskin.

Dan Riskin
Good morning.

Seth Pazinski
Mark Sendak.

Mark Sendak
Good morning.

Seth Pazinski
Fillipe Southerland. Zeynep Sumer-King.

Zeynep Sumer-King
Good morning.

Seth Pazinski
Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Seth Pazinski
I will call on the federal representatives of HITAC. I did get a message that Keith Campbell from the United States Food and Drug Administration (FDA) will not be able to join us today. Jim Jirjis.

Jim Jirjis
Present.

Seth Pazinski
Meg Marshall.

Meg Marshall
Good morning.

Seth Pazinski
I got a message that Alex Mugge will be joining us late today. Ram Sriram.

Ram Sriram
Good morning.

Seth Pazinski
Thank you. Is there anyone I missed or who just joined us that would like to announce their presence? I will turn it to Micky Tripathi for opening remarks.

Welcome Remarks (00:03:53)

Micky Tripathi
Thanks, Seth and good morning, everyone. Thank you for being here and I will be relatively brief. I know we have a great agenda today and I want to make sure that you get an update from us. But I will quickly turn it over to Sarah and Medell after that. A few areas that I just wanted to cover, one is the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. The draft is now out for comment. We put forward proposals to advance interoperability, improve information sharing among patients, providers, payers, and public health authorities and a variety of other things contained in that rule. We very much appreciation the responses we have gotten to date. And we know there will be more to come. Please send your comments. I know this task force has been hard at work with 22 Proposed Rule task force meetings over the past eight weeks, which is a tremendous amount of work. And I am grateful to all of you on the HITAC for your commitment to helping us make sure that rule is helping to forward our common agenda of improving interoperability to benefit patient care.

We look forward to receiving all of the recommendations of the HITAC on the HTI-2 proposals and we will be concluding the HITAC's work on HTI-2 with comments. And I am reminding the public that the 60-day public comment period ends on October 4, 2024. You still have time to get in your comments. The comment period ends on October 4, 2024. We look forward to receiving your comments and working with you on the finalization of the rule. The next thing I wanted to briefly announce was at the August HITAC meeting, we presented an overview of the HHS health IT alignment policy. As you may recall, a key piece of that effort is a recently Proposed Rule from our partners, the HHS Assistant Secretary for Financial Resources that's called the HHS Acquisition Regulation. It is a draft rule. I will not go through the full name of that. But that has gotten some comments from certain public comments and in the media. We are very eager to host a webinar that we will be doing on September 19 from 3:00 to 4:00 p.m. where we along with Assistant Secretary for Financial Resources (ASFR) will be hosting that public information session to provide more information on the rule.

Just as a side editorial comment, I think we have seen comments I think expressed a little bit of a misreading, and perhaps overinterpretation, over reading of the rule in certain ways. So, we look forward to provide more information to help people interpret that rule. As I said, September 19 from 3:00 to 4:00 p.m. I hope to see you there. And we will put the link in the chat, maybe it is already in the chat now, on how to register. Two other topics I wanted to cover. One is related to Trusted Exchange Framework and Common Agreement (TEFCA) and our work proceeds a pace in TEFCA. The TEFCA community, the TEFCA governance process is very actively at work on developing further standard operating procedures. I think in the last meeting, we did talk about the release of standard operating procedures related to better definitions of required response for treatment exchange, which is a really important feature and foundational principle for operationalizing trust and nationwide interoperability networks. We approved the standard operating procedures for healthcare operations, which is a significant breakthrough from nationwide interoperability perspective.

The approval of that standard operating procedure enables the ability for exchange among providers for care coordination, for quality measured data, for key reporting data, as well as for population health management. We are very excited to have that now as an approved use case with a timeline for when it turns from an optional use case to a required response use case. As I said, I think it is a very significant breakthrough for the industry and we are excited and grateful for our partners in the TEFCA community for working really hard to get that to a really good place. The other thing we are very hard at work on and about to finalize is the policies related to the ability for authorized delegates to be able to participate directly in TEFCA exchange with the authorization of the covered entities on whose behalf they are requesting information as business associates, for example, in a Health Insurance Portability and Accountability Act (HIPAA) pathway.

That is a very important step to be able to have the operationalization of trust that we need to have in nationwide networks but with the ability to have the broader ecosystem participate to enable more efficient and effective exchange of data through authorized pathways. A lot of great progress there. In terms of TEFCA rollout and adoption, we have had very important announcements that you may have seen from Carequality about the alignment with TEFCA and the transition to TEFCA based exchange. A number of partners like Epic have made announcements about their intent to have their customer base live on TEFCA before the end of the calendar year and their intent to transition to TEFCA based exchange by the end of 2025, which is a significant development, obviously, and we are very grateful to the Epic community for their engagement there. Also, there are also announcements from the CommonWell Health Alliance about the availability of the TEFCA platform for their participants in TEFCA, which is also a very significant development.

And we are grateful for all of the work that the CommonWell Health Alliance and their community has been doing to make that available. And that establishes the pathway for CommonWell Health Alliance participants to be able to directly participate in TEFCA and adopt TEFCA as a Qualified Health Information Network (QHIN) by participating. A lot of great movement as well as the availability of Fast Healthcare Interoperability Resources (FHIR) application programming interface (API) in TEFCA for patient facing FHIR APIs that you may have seen that Epic announced as well, which is the enablement of FHIR-based exchange in TEFCA and great pathway for direct patient access and direct patient participation in TEFCA enabled exchange, which is an important, incremental step to get the kind of access to information and availability of information for patients in a safe, secure manner that we have been hoping for, for a long time. We are very excited about the prospects that that opens up as we think about the adoption over the coming months and years.

A lot of great stuff happening with TEFCA. Just to step back and to speak about the reorganization and the standing up of the Assistant Secretary for Technology Policy Office. Maybe you have seen that we have an active search for a Chief Technology Officer, Chief AI Officer, Chief Data Officer. We have gotten tremendous response, which we are grateful for. We are going through that right now and hope to be able to make announcements soon on the selection of individuals to serve in those very important roles that will help us as a department move forward with a very proactive strategy as it relates to technology policy across the department in technology broadly and innovation broadly and AI and data strategy. More to come there but we are excited about the progress we have been able to make there and the market response we have gotten to the leadership positions.

The last thing I will mention with respect to ASTP, we are working hard on the AI front working very hard with the AI task force on the development of an AI strategic plan that is scheduled for a release in January and working hard on that across the agency, as well as with the White House as part of the Executive Order. We are also putting together the Department AI use cases across the department, which is a public release on an annual basis. These have been released over the last couple of years. So, the 2023 use case inventory is on the HHS website for those who have not seen it, which has 160-plus AI use cases that were documented a year ago or a year and a half ago. We are hard at work collecting that data across the agencies and that will be released on a timeframe that United States Office of Management and Budget (OMB) has laid out before the end of the calendar year.

That will be the next version of the AI use cases and you will not be surprised to know that there are many more use cases than last year, as we as a department start to fully embrace the opportunities of being able to use AI to better the healthcare delivery system and healthcare and life sciences and human services and public health at large. We are very excited about the work ahead there and much more to come. Last thing before I turn it over to Medell and Sarah, I want to take a moment to highlight that we will be having the ASTP 2024 annual meeting in Washington on December 4 and 5. So, we look forward to you joining us for two days of learning, networking conversation. For those who are unable to attend, the main stage sessions will be live streamed and we will put a link in the chat now on how to register. As always, there is no cost to attend.

Thank you, again, for lending your time and expertise to the HITAC. We are enormously grateful for it. We cannot say enough about how grateful we are. And let me now turn it over to Medell and Sarah, our terrific HITAC co-chairs for their opening remarks and to begin the meeting today.

Opening Remarks and Review of the Agenda (00:14:34)

Medell Briggs-Malonson
Well, we are grateful for you and on behalf of HITAC, let us say congratulations on your new role as Assistant Secretary for Technology Policy. We are proud of you, as well as the entire ASTP team. Thank you for sharing the exciting updates of what is going on. We are so grateful to take part in providing some of those different recommendations from HITAC. Today is going to be a very packed agenda, so I will not take up too much time and I will turn it over to my fabulous co-chair, Sarah.

Sarah DeSilvey
Echoing Medell, as always in our gratefulness and our respect for Micky and the work of ASTP. We have an incredibly packed agenda, so I am going to get to the agenda and its review next because we have a lot to cover today. I said this last time, but noting the elevation of ASTP indicates that we all know the importance of the work we do in this space. We have gone through the roll call and welcoming remarks. We are currently reviewing the agenda and then, we have our jam-packed agenda, which is significant and I hope you had a chance to review the materials sent along prior. We did indicate this is a critical component in our last meeting. We had the honor of hearing our colleagues present on their HTI-2 Proposed Rule from the task force. Thank you for all the amazing work you did there. That is going to be an extensive amount of time because it is a critical element and there are a lot of recommendations to review.

We will go into a brief break and another critical topic on the agenda is the updates from the Annual Report Workgroup that Medell Briggs-Malonson and Eliel Oliveira will give. Then, we go into another topic, which is ever so important intersecting, which is Beth Myers from the ASTP presenting on United States Core Data for Interoperability (USCDI)+ and quality. And then, a brief break just to catch our breath and then, closing with public comments and final comments at 3:00 EST. There is a lot to cover. We are grateful for all of your engagement and I hope to quickly segue into the work with introducing our colleges for the HTI-2 Proposed Rule task force recommendations and the ensuing HITAC vote. Next slide, welcoming Bryant, Mark, and Rochelle to present on the HTI-2 Proposed Rule task force 2024 recommendations enabling the HITAC vote on this concept.

HTI-2 Proposed Rule Task Force Recommendations – HITAC Vote (00:17:12)

Mark Sendak
I think I am opening up the slides and will be handing off to individual colleagues who are co-chairs on the task force. I want to recognize all of the task force members who contributed their time. It has been a very busy eight weeks and we are thrilled to be where we are today. Let us go to the next slide and review how we are going to

work through the task force recommendations. First thing is we will show the roster, everyone who joined the task force, talk about the charge, how we split up into three subgroups, and the vast majority of the time will be reviewing the individual topics and recommendations. There will be time for discussion and we will wrap up with a HITAC vote. Next slide, please. So, the vast majority of HITAC members participated in the task force and there were a number of external experts who were invited. I think all but eight HITAC members really appreciate everyone's time adding on to their busy schedules with this. Next slide, please.

So, the overarching charge of the task force was to evaluate and provide draft recommendations to HITAC on HTI-2. Our specific charge was to review and provide recommendations on three different topic areas, public health, which was led by Bryant, standards and certification, which was led by myself, and information blocking and TEFCA, which was led by Rochelle. And recommendations, we worked over the last eight weeks to get to where we are today, where we met individually, we met as a full group task force. And what you are seeing today is after all of that process narrowing down to the set of things we can agree on to bring forward to HITAC. Next slide, please. So, the way that we did this large amount of work is we split up into three groups. As I mentioned, there were three co-chairs, each co-chair led a subgroup of the task force that met to review the topics independently and then, we met over the last few weeks as a big group together to reconcile any differences.

We did invite external subject matter exerts to complement expertise from HITAC. And I know some of our subgroups had large numbers of external experts, so we appreciate everyone who joined from outside. And the last two bullets I already covered. We met independently and together to reconcile any changes. Next slide, please. So, the topics, I think these are my last few slides. We will go to the next slide. This kind of gives it a big overview of Group 1, public health. We are going to drill down into these different areas. The next slide. Group 2 was the group I led. We are going to drill down into these areas of the recommendations we are bringing forth and then the next slide is information blocking and TEFCA, which was led by Rochelle. And she is going to lead us through the recommendations put forth by this group. Next slide. I think I am handing it off to Bryant now.

Bryant Thomas Karras
I think you have a few you before mine but go ahead. Next slide.

Mark Sendak
Okay, so am I doing these ones, too?

Bryant Thomas Karras
I think.

Mark Sendak
I know Medell and maybe Seth, I know we are limiting time for this. Do you know how long we have for per recommendation item?

Bryant Thomas Karras
We are not reading them in totality that is for sure.

Medell Briggs-Malonson
Correct. I was looking for Seth to give us the exact timeframe. We have for the presentation and the vote, we have approximately two and a half hours. We anticipate some discussion, so we are not going to read them entirely because all of these recommendations have been provided to the full HITAC committee. So, just summarize all of the different recommendations. So, we will give about an hour and a half to go through this to allow for discussion and for the review and the vote.

Mark Sendak
Got you.

Seth Pazinski
Echoing Medell's point, we can go over at a high level. Some of the slides have multiple recommendations and some have one. Just a quick overview of the recommendations.

Bryant Thomas Karras
And looking at the slide deck, the recommendations from each of the subgroups are not together as a block. They are put together chronologically as they appear in the notice of Proposed Rule, is that correct? There are a few that you have up, Mark, first.

Mark Sendak
Got it.

Bryant Thomas Karras
And then, it jumps to me, back to you and then, Rochelle.

Mark Sendak
Perfect. I will not read these entirely. This first recommendation, so we support moving to USCDI v4. The other thing that we wanted to highlight is there are still some gaps. What you see here in parenthesis, a list of examples of data elements prioritized by different members of the task force to be considered in future versions. Are there any comments that folks want to add to this? Otherwise, we will go to the next one.

Medell Briggs-Malonson
Mark, one of the things for all of the different co-chairs. We are going to go through all of the recommendations and at the very end, we will have discussion, so feel free to go through the entire presentation.

Mark Sendak
Okay. Let us go to the next slide. Here, we have two. First is we need to specify references to the SMART health cards and FHIR resources. There was some confusion around the terminology and Recommendation 3 is also about reconciling the implementation of SMART concepts. Next slide, please. So, this was a longer recommendation. There was confusion about the health cards versus the health links, so this is the fourth recommendation as it relates to vaccine and testing implementation guides. These testing and implementation guides have not yet been published, so there was concern about getting ahead of ourselves but we would continue to track their status. Overall, also reasserting the importance of patients accessing immunization records. Next slide, please.

So, we also want to recommend that ASTP work with the implementation guide developers to complete the development and publication of these implementation guides and that this is a public health function. Oh, shoot. I just saw your message, Medell. Next slide, please. Recommendation 6 is about the trust communities, and that it is already part of the Unfair, Deceptive, or Abusive Acts or Practices (UDAP) requirement published as part of the end point. Next slide, please. So, Recommendation 7 is that we address security concerns as it relates to imaging links and Recommendation 8 is that API access be mandatory in enabling patients to access their information. Next slide, please. Recommendation 9 is about trying to encourage that there be testing of the Health IT module capabilities. This is related to the imaging links and imaging. And then, Recommendation 10 is to clarify that it is not just about transmission of the links but persistence of the links. Next slide.

So, here we have four recommendations that automated reconciliation not be required. We need to develop best practices for implementation guidance to conduct automated reconciliation. We should go to six USCDI data elements for certification and that ASTP align recommendations on dynamic client registration with protocols. Recommendation 15, there was some concern about the language when we talk about providers and payors and to be consistent to take a single certification criteria and then, make it two to address each of the stakeholders. Next slide.

Bryant Thomas Karras
I think this is where I jump in. Wait, no.

Mark Sendak
I think I go to 31.

Bryant Thomas Karras
Sorry. Go ahead.

Mark Sendak
No worries.

Bryant Thomas Karras
I have the slide numbers off because of introductory slides. Go ahead. Keep going.

Mark Sendak
Three recommendations here. No. 16, we need to align the target dates for both payer and provider criteria. No. 17, similar to previously mentioned, be consistent across both stakeholder groups, so take a single certification and split it so it is clearly defined. No. 18 is that we recommend that Centers for Medicare & Medicaid Services (CMS) Medicare Part D require real-time prescription benefit tools. Next slide, please. No. 19 recommended a change to terminology replacing "health IT storage" with "server-side." Next slide. We made no changes. We put forth no changes to the encryption of authentication credentials. Next slide. So, Recommendation 20 is around the naming conventions focused on the actor.

Bryant Thomas Karras
So, I think this is where I start.

Mark Sendak
Cool.

Bryant Thomas Karras
Okay. Thanks so much, Mark, for getting us through those. Recommendation 20 is an overarching comment that we would like to see consistent naming conventions and some use of the term bidirectional rather than talking about who are the parties involved. So, replacing things like provider or laboratory rather than just describing things as bidirectional, and using terms to more accurately specify who the recipient is, in some cases, a program area like immunization within a public health agency. Next slide, please. So, I think, I want to thank either it is just dumb luck or thank the staff at ASTP. The F1 criteria start rate on Recommendation 21, and you will see there is a pattern that F1 and F21 are both related to immunization. So, there are several on immunization. It is one of the bread and butter activities of public health. Again, reiterating some of the nomenclature that needs to be put into place to more accurately describe the actors and perhaps renaming the criteria itself to not be bidirectional but, in fact, be representative of the fact there is an immunization reporting activity and there is a separate bidirectional activity for query and response of a forecast of what vaccines are needed. Next slide, please.

More on immunization, diving into the use of FHIR potentially in the future, and that we think, in some instances, there is a section we want to remove that may no longer be necessary if we pull back from our readiness for FHIR. Next section. Still in the immunization specification. The immunization specific queries is not a term used in any of the Individual Access Services (IAS) implementation guides. We would like to stay consistent with what is used in practice. And clarification on there seems to be an inconsistency in different sections of the notice of Proposed Rule, sometimes referring to January of 2028 and sometimes referring to 2027. Next slide. I think this is the last one for immunization. This harkens back to what Mark presented on SMART health cards and SMART health links, which is more than just a public health functionality but we would like to see that truly highlighted for public health and their support to get these Health Level 7 (HL7) implementation guides finalized. Next slide.

I think there is a continuation. Yes. Continuing on that topic with more detail. Next slide. I think one more. And then, some recommendations of modification of the wording and some terminology consistency query or request for data be used consistently. Next slide. All right. Now, we are on to the next activity for public health, syndromic surveillance. This is the F2 criteria that we are very familiar with. It is one that, particularly during COVID, was incredibly important for situational awareness of what was happening in our health system partners. So, there is some modifications to update to newer implementation guide standards. Next slide. And recommendation that ASTP work with the organizations and associations in addition to the Centers for Disease Control and Prevention (CDC) to ensure we are working in the right direction to enable this important transmission standard to evolve as standards for the rest of healthcare evolve from traditional HL7-2.X standards into FHIR. Next slide, please.

On to the F3 criteria, this is another bread and butter for public health, laboratory reporting, notifiable conditions. It is hugely important. We are very supportive of continuing and, again, we recommend that ASTP work closely with partners. Next slide, please. So, additional on F3, lab reporting, there is some new technologies around LOR/ Laboratory Results Interface (LRI) and we will have more on that when we cover subsequent slides, but I will mention it here. Next slide, please. And then, additional tie-in to e-case reporting, which is in F5 that the labs can be part of e-case reporting that the providers may be sending but the laboratory still needs to send the laboratory component. This is particularly important in that sometimes, information that is in the order or the clinical information does not get transmitted to the laboratory, and it can be critical that public health find that out. Next slide. We are on to the last one on lab. Next slide.

So, now we are on to cancer case reporting. Again, another important activity for monitoring of cancer throughout our country. Updating the standards that are currently in use. We wanted to see clarification on there is a recommendation to update to FHIR for pathology reporting. We want to make sure the Clinical Document Architecture (CDA) report is still state-of-the-art and part of the certification process. Next slide, please. Again, more on perhaps phasing in FHIR utilization for the case reporting itself. Next slide, please. All right. Moving on to e-case reporting that I touched on earlier during lab. The two go hand-in-hand, so updates to the implementation guides to make sure they have evolved to what is now available. Some information about the reportability response, what goes back to the provider to give them feedback on what they have reported to public health. Next slide, please. This is really diving into the quality and the content of those messages.

We have seen inconsistent implementation of e-case reporting across the country, so we want to make sure that Logical Observation Identifiers Names and Codes (LOINC®) and Systematized Nomenclature of Medicine–Clinical Terminology (SNOMED CT) codes and additional data that might have been collected in the required ask at order entry be included in the case report, so they can be matched up with the labs that we talked about earlier. Next slide. And again, the quality metrics that we need to see improved. Next slide. We also recommend that there be some consistent implementation across organizations that ASTP and HHS does not necessarily have oversight to, Department of Justice, DOD, and United States Department of Veterans Affairs (VA), as well as Homeland Security needs to be aligning in the use of this technology. Next slide. Some detail on which version of the e-case

reporting should be, the latest published version is 3.1 rather than 2.1.1. Next slide, please. And now, we are on to antimicrobial use and resistance reporting, AUR. This is a transmission that goes from providers directly to CDC. So, we have some recommendations here around updating those implementations as they become available. Next slide, please.

And on to healthcare surveys, which also goes directly to CDC, and there is an almost or soon-to-be published release that we want mentioned if possible. Next slide. This one is a little controversial. Birth reporting, we recommend get pulled and not be included in certification criteria. It felt like we did not see any real-world use of this or piloting use of this yet. We would like to see that tested before certification criteria could be developed on both the provider side and the public health side. Next slide. And prescription drug monitoring program, a couple of slides on this. This is one that has been elsewhere in certification. This is movement of the prescription drug monitoring program into the public health data exchange criteria. And we are supportive of that and see there are some alignments and coordination that ASTP can do beyond HHS to make sure this is consistently recognized as a public health crisis. Next slide.

I will cover this here on the continued. One of the things we see is we think because of the competing standards and transport protocols that are in practice across the country, not consistently used that this may need to be a functional criteria rather than a technical criteria until which time the standards are completely aligned. Next slide. All right. Now, as I shift, let me take a deep breath. We are on the public side, as Micky likes to say, the catcher's mitt side of the exchange. New certification criteria that did not exist before to standardized and look to improve consistency and functionality across the public health community. So, F21 is the parallel to F1, the standardization is needed for the immunization information systems. How am I doing on time? There are a ton of these on immunization, so I am going to click through them pretty quickly. Next slide. So, some tie-ins between immunization and some of the generic API work that Mark described. Next slide. Some comments we had on the bulk capability that is currently in testing. And some nomenclature consistency work. Next slide.

A lot more detail on our harkening back to the SMART health card and SMART health links framework, which was used successfully for COVID vaccine sharing in half the states across the country. Next slide. And some administrative improvements and technical transport improvements. Next slide. And this is a comment. I am going to pause on this. You will see this echoed in just about all of the F20 criteria that we wanted to see more specificity or explanation on the definitions of receive, validate, parse, filter, and exchange. These have slightly different functionalities in each of the different domains of public health. And they may need some nuance to make sure that the certification of each of these respectively goes well. Next slide. Last one on this. Cost estimate. Our immunization information system, our colleagues did a great job of digging into the cost estimates of what it is going to take. We think there is an underestimate in the documentation.

And we suggest that get examined to not just include IT costs but implementation costs that would be necessitated by public health. Next slide, please. All right. We are on to F22. We will pick up the pace and go faster now. This is one that we think actually has an impact back on F2 but it is really on the public health side. Many public health agencies have evolved beyond secure File Transfer Protocol (FTP) and use modernized Integrating the Healthcare Enterprise (IHE) based protocols for receiving syndromic surveillance data. We do not want folks to have to go backwards in terms of modernization, so we would like to see some improvements there that allow for the advancements towards more sustainable infrastructure that utilizes information exchanges and QHINs. Next slide, please. We are still in syndromic surveillance. This is recommendation that there are implementation guides in evolution and that we suggest that the ASTP work with the community of practice for syndromic surveillance, which is housed within the Council of State and Territory Epidemiologists to make sure things are moving as well as they can and again, as I said earlier, there is clear understanding and definitions of receive, validate, parse and filter. Next slide.

All right, on to F23. The Electronic Laboratory Reporting (ELR) functionality needs to have an improvement and quality initiative similar to what AIRA has done to evaluate and lift immunization across the country. We caution against over filtering or validating in the validation phase for fear that the critical information that needs to be reported to public health would be blocked from being notified to public health. Next slide. Again, this is an update to the implementation guide. We want to sure the most recently published one that came out prior to the publication of the Notice of Proposed Rule Making but maybe was not available at the time that the rule was drafted. It is now available and has been in the field for some time and has important corrections that will make implementation easier across the country. Next slide. Oh, and again, as in others, clear definition of receive, validate, parse, and filter. Next slide.

Now, we are still on lab. Okay. We do not think this should be a one size fits all approach. Many health departments have implemented this with a combination of different systems, not a single application like electronic medical records systems has. Next slide, please. And again, we are worried on both the public health side and the clinical side that real-world applications and implementations need to be tested and certified because synthetic data often works perfectly because it was synthetic data. We need to make sure these things are working in the wild. Again, working with the rest of the federal agencies to ensure these enhanced standards take effect in the entire ecosystem. Next slide, please. So, the expiration dates, we think 2027 is ambitious. There needs to be some grace for public health to get to the finish line. It took our clinical colleagues ten years to do their modernization for promoting interoperability. Next slide, please.

Now, we are on to cancer reporting and certification on that side. Most public health agencies use a system supplied by the CDC for the cancer reporting registry management, so we need to make sure that is advanced in conjunction with the National Association of Cancer Registries. And again, consistency around the terminology. Next slide, please. F25, this is our e-case reporting. There are several slides on this reflecting the updated standards that I mentioned earlier. Next slide. Working with other federal agencies beyond just HHS, and again, the expiration date may not have adequate time for public health to evolve to real-world situations for this complex implementation. Next slide, please. We recommend further distinction. This is a little bit more than just a two-party transmission. There is a critical intermediary in the Association of Public Health Laboratories working on behalf of states as an intermediary, and there is tremendous input from Council of State and Territory Epidemiologists for maintaining those rules. Next slide, please.

Jumping ahead to F28. This is the birth reporting one that I talked about earlier. Again, we recommend that it not be moved forward. We would like to see some funded pilots within states to make sure this implementation guide or the implementation guide has been published. We have not seen any real use of that standard for trial use. If, however, it is moved forward, we have some recommendations that CDC and ASTP work with National Association for Public Health Statistics and Information Systems (NAPHSIS) others to ensure that that moves ahead in an understandable way. Next slide. Additional clarity on how that can work if it were to move ahead and an overarching recommendation that perhaps, since this works with our registries of both birth and death, our vital statistics programs across the country, all 50 states and territories and districts that perhaps the standards for birth and death be advanced at the same time. And then again, clarity on receive, validate, parse, and filter.

The last F criteria, the prescription drug monitoring program. Again, some standardization on the public health side. We think this needs to be a functional criteria, not a technical criteria. But I would like to point out there is a new opportunity that did not exist before in that pharmacies are now actors within elsewhere in the rule and pharmacies are critical in reporting into opioid registries or prescription drug monitoring program systems, so making sure and looking for the opportunities to standardize how that work is done. And then again, receive, validate, parse, and filter may be slightly different in these situations. Next slide, please. All right. G20 is the public health exchange parallel to G10 that Mark talked about earlier. We think there is perhaps some too soon adoption

of bulk queries. And we think advancements along the use of these APIs may need to be utilizing more dynamic capabilities to advance standards such as Standards Version Advancement Process (SVAP). Next slide.

Helios is the public health activity and this crosses into you, Mark, but recommending additional testing of the bulk data access implementation prior to certification would be critical. Next slide. And please tell me I can give my voice a break.

Mark Sendak
You get a break. I will take a few slides and I will give it back to you.

Bryant Thomas Karras
I have my tea ready.

Mark Sendak
So, these two relate to actually ensuring that the IT vendor tests the connection in trying to relieve the burden from smaller providers is the top one. The bottom recommendation, 90, is the creation of a registry, so organizations can report issues if the certified health IT products are not able to connect to a data exchange. Next slide. Recommendation 91 is that we support a modular approach and it should be considered in G10 and G20. Next slide. Here, this is about the dynamic registration standard. We recommend that dynamic registration under TEFCA and aligned with the Creating Access to Real-time Information Now (CARIN) initiatives and we support dynamic registration in the trust communities and require absent business-to-business solutions use dynamic registrations and clarify that data holders that the B2B solutions, it is either not relevant or not available to certain apps in business-to-business (B2B) solutions. Next slide, please. So, three recommendations here for 93.

We want to clarify that revocation should be managed by IT operations supporting clinicians and not clinician end users of health IT. Recommendation 94 is we want to define a specific set of scopes that are useful for patients and that if we fail to do that, it is too broad and would add too much burden to patients. And then, Recommendation 95 is we want to clarify that B2B is referring to clinician accesses user scenarios, and we want to further specify the definition of B2B. Next slide. So, No. 96 is we recommend that this item is optional within G20 partly because not all electronic health records (EHR) have access to immunization data. And then No. 97, we recommend that health IT certified to G10 and G20 support two to three subscriptions across both and not two to three per certification criteria, and also, point to the fact some of this is covered in G34 and G35. Next slide.

Recommendation 98 is about the multifactor authentication and we recommend clarifying that when the user brings their own identification (ID) and password. It may not be available with the certified software. Next slide. I am handing it back to Bryant.

Bryant Thomas Karras
And of course, the mute button is stuck. The final stretch for public health. As you can tell, public health had a lot of things in the Notice of Proposed Rule and a lot of activity back. But these last five recommendations I mentioned earlier, so I should be able to get through them relatively quickly in the electronic laboratory reporting. This is looking to take advantage of new capabilities at the order entry point and the result reporting LOI and LRI to make sure that any relevant public health components are able to make their way to public health. One of the recommendations we had here, 100, looks into the fact that public health state laboratories are oftentimes unique and different from laboratories within the clinical system or a third party or national or commercial lab outside of the organization. So, clarity around the different roles and how that certification might occur for this criterion is important. Perhaps splitting it up into multiple criteria, so it can be differentially applied.

Of course, as I mentioned earlier, R5, the most current should be adopted rather than the ones listed in the notice of Proposed Rule. Next slide. Context of which lab orders are placed. In some cases, additional information may need to be collected and a lot of the laboratory information management systems, Laboratory Information Management Systems (LIMS), that previously have not been regulated by ONC, now ASTP, may not have the capability of storing some of this information, so there is going to be some lift that needs to occur to make sure and ensure that information can flow on to public health when needed. So, an examination that some of that information may not exist within the LIMS system and may be in a billing system or may be lost if it is not stored elsewhere. Next slide. I think this is one of my last. This one, I think I touched on it a little bit, commercial laboratories are different from public health laboratories.

And the electronic test and order results requirements need to stay aligned. There are great examples in the implementation guide, specifically on how public health labs that do newborn screening testing consistently across the country can take advantage of these technologies, so we can get results back to providers and ultimately to new moms in a timely fashion. From public health to jump to the 2.5.1 to new message types may be problematic. We have seen some implementation stumbles across the country but this needs to be invested in advance. Next slide. Continuation of that one. We think orders between two laboratories, when a lab goes on to a reference lab, limited capabilities should not be included. I think that is it.

Mark Sendak
Last one, Bryant.

Bryant Thomas Karras
Jumping back to the G10 and G20, again, this is another clever naming convention on ASTPs that there is a nice parallel. We are excited about the potential for these API capabilities, and we think there should be exploration for how follow up queries by public health to the laboratory could be used to find some of the missing data that may have inadvertently not been reported to public health. But this is going to be a future potential utilization. Next slide. All right, back to you, Mark.

Mark Sendak
Thank you. Next slide, please. So, the next few pages are very similar where we recommend across a number of criteria to align with CMS rule and we propose changes to specific language. For Recommendation 102, we would like to refer to the provider as provider access API, distinguished from Recommendation 107 where we would reference the payer as the provider access API payer server versus the provider plan. Next slide. These also, the top three recommend alignment with the CMS rule proposal for 109. It is looking at prior authorization. For 110, also, prior authorization. For Recommendation 111, we recommend that the language be clarified with the patient facing use to reference the API as provider director API patient facing health plan coverage. Next slide. Now, we are in the section for conditions and maintenance of certification requirements. I have a few here. Next slide. So, for 112, we recommend stratifying. I had to look this up again. Immunization Information Systems (IIS) is immunization information system because of the variability and what is available across jurisdictions.

And Recommendation 113, we recommend removing one of the measures from an optional list, and also, specify that one of the measures seems redundant with a different measure, and that is the justification for why it should be removed. Next slide. So, Recommendation 114, we recommend that patients who opt out should be excluded from the measure. And then, for 115, we recommend that ASTP focus insight measures on technical performance and not programmatic performance. Next slide, please. This is my last one. We did not have any changes to the attestation conditions and I am handing off to Rochelle.

Rochelle Prosser
Hello, everyone. For some reason, my video is technically challenged. Can the host turn on my video, please?

All right, can you see me?

Mark Sendak
We see you now.

Rochelle Prosser
Perfect. Thank you. My portion, which is Group 3, we will begin with the administrative updates. Next slide, please. Under the administrative update, there is language to either add into the definition or change a specific word. It was just more a cleanup process. Next slide. And now, we will begin the information blocking enhancements. Next slide. So, in this portion here, we wanted to look at providing the healthcare provider definition term to align with the rest of the administration and this is the recommended language. Next slide. And continuing on in the terms of definition, we wanted to explain the shorter form of health IT is the same as health information technology. Next slide. Again, we wanted to clarify and come to a consensus that next business day would be upgraded to business day, not any day of the week. Next slide. Where we agree with inference and interference, we had no recommendations here. Next slide.

And under policy exception, we added additional language and clarification that it should be modified that the requester or responder must be **[inaudible] [01:14:11]**. Next slide. Now, going through the infeasibility exceptions. I am not going to read all of these, but based on some of them, we were looking at what is the definition or who is the nonpublic entity and asking for clarification under the HIPAA policy in Recommendation 123. In 124, we asked to provide actual examples of a non-provider entity. In 125, we chose as a group to adopt a 10 business day turnaround for notification of infeasibility. Next slide. Under protecting care access exception, our recommendation was to amend the language below to enhance and ensure we are covering the most broadest definition of what a patient could be. Under 127, we wanted to add language that any actor acting in good faith would be not subject to any information and would be subject to care access exception, as long as you are doing so in good faith. Next slide.

Request for preferences exception and to just briefly go through the three recommendations, we wanted to consolidate the meaning and manner for exception and then, ask for clear guidance to prevent healthcare provider or IT developers from steering requesters in a way they did not prefer. And finally in 130, recommendations for clarifications of manner, the difference between manner exception. Next slide. And here, we fully supported the exceptions that involve practices related to participation in TEFCA. Next slide. Great. Moving on to the TEFCA agreement and in here, we will talk more specifically to the updates and language towards that. Next slide, please. So, under the trusted exchange framework and common agreement, in Recommendation 132, we proposed to have a five percent threshold with a maximum of twenty-five percent in terms of individual or collusion with multiple individuals as a group. Next, under 133, the task force is looking to add a board because TEFCA does not acknowledge having an advisory board. And we propose to put one in place to ensure that we are adopting as to how the rest of the different entities propose. Next slide.

Under 134, we are looking to make a recommendation that we are supporting high quality data. And 135 is looking to advance interoperability between USCDI and other health IT. And in 136, we are fostering QHIN support for all exchange purposes for health IT, including **[inaudible] [01:18:15]**. Next slide. Here, it is more of a clarification about the stability and what would happen should a QHIN disappear. In 138, we wanted guidance on the potential of QHINs lack of adopting FHIR. In 139, we recognize there is no general investigator or Office of Inspector General and we propose to put one of those entities in place. Next slide. Additional recommendations for future consideration. And I am not sure if that is me or if that is you, Bryant.

Mark Sendak
That is me.

Rochelle Prosser
Oh, all right, Mark, back to you.

Mark Sendak
I will close us out. So, these are three recommendations that are kind of high level, general feedback. And they are kind of similar. The first recommendation, 140, is that there is a need for some type of registry and mechanism to report challenges that organizations have with certified health IT products and we do kind of provide an analogy here to FDA's registry for drug and device reporting. Recommendation 141 is that we recommend that ASTP increase audit capacity to be able to test certified health IT products and report audit findings publicly. And the last piece here is better mechanisms to incorporate feedback from health IT vendor customers. And that is related to our last recommendation on the next slide, which is also about ASTP. We recommend more effort to incorporate feedback from health IT vendor customers and that there is not sufficient mechanisms today to provide feedback and verify that the required data elements and functionality are performing adequately. And similarly, this ties back to we need some type of registry or reporting mechanism to publicly report this information on functionality. And that is the last recommendation. Next slide.

Medell Briggs-Malonson
Excellent. First, I want to thank all of this amazing work that was conducted by our co-chairs, Bryant, Mark, and Rochelle, as well as the rest of the HTI-2 task force. This is immense amount of work, 146 recommendations. At least my time on HITAC, this has the largest number of recommendations that has gone towards a Proposed Rule while I have served on the committee. Thank you so much for all of this amazing work. Now, what we want to do is start to go into our discussion. Before we start discussion, I want to make sure we are very clear. The purpose of today is now that we have reviewed all of the various different recommendations that are put forth by the task force, we as the whole committee of HITAC need to approve these different recommendations. So, we will take a formal vote to approve these recommendations today. Now, there have been some discussions, so we are going to go into the discussion period.

If anyone has a recommendation or revision to any of the recommendations that have been presented by the task force, what we are asking for is for you to write down your recommendation, put that directly in the chat. Our ASTP teams on the back end are collecting this and we, as a committee, have to, A). vote to include that recommendation, and then B). we then have to vote to improve all of the recommendations. So, I just want to walk everyone through that process, so we are all very clear. By the time we finish this session, we hope to have the discussion, think about any additional friendly amendments that the HITAC committee members have, and also, take a vote. And so, there are several items that have already been mentioned in the chat. And if you do want to speak verbally, please, of course, raise your emoji hand. I am going to go through the various different recommendations right now with the content we have received so far and ask if any of the HITAC members want to elaborate on the comment they put in the chat.

The very first one was on Recommendation 1, Katrina. We know you had thoughts about this and we had thoughts from the general public that had thoughts about this as well. Katrina, any additions that you wanted to add to the comment you placed in the chat?

Katrina Miller Parrish
I just wanted to call out that sounded weird. It did not sound like a recommendation. It sounded like a note. I think Bryant suggested it might be "and," so maybe it can be edited.

Bryant Thomas Karras

Yes. I think it was intended to be part of the sentence before and I think it could be a movement of the comma and then, it needs to be "are in USCDI 5" since it is part of the string of things that are in USCDI 5.

Medell Briggs-Malonson
Excellent. Great. We can clarify all of those items. Yes. What we are going to also try to do is, our Accel team in the back, when we do call upon the recommendations, yes, Accel team, if you can place that recommendation up for everyone to see as we discuss it. The next recommendation in which there was a comment was from Ike on Recommendation 36. Ike, we will welcome you to discuss your recommendation or thoughts on that recommendation with the co-chairs.

Steven Eichner
Sorry, I had to find the un-mute button.

Medell Briggs-Malonson
No problem.

Steven Eichner
I think we need to clarify what happens when we look at dates around January 1 and closing out of new standards, so we are not closing out a standard in the middle of a reporting period or looking at an impact on healthcare providers participating in and promoting interoperability or something like that and looking for clarify about what happens when we are changing certification on January 1.

Medell Briggs-Malonson
Great, thank you, Ike. Is there a recommendation that you would like to propose or is this is a general comment for us to take into consideration?

Steven Eichner
I think the ask is for ONC to clarify what dates we are looking at, in terms of looking at it and consider and what are the impacts for these particular standards. For example, which is briefly report that CDC produces all infectious disease. If we are looking at a timetable that shifts January 1, it is in the middle of the reporting week.

Medell Briggs-Malonson
Great, thank you. Any other comment about what Ike is bringing up and Ike's recommendation? Okay. We have that also on record, Ike, and for ASTP to think through that and help us with that piece. Thank you so much for that. The next piece was also, Ike, and were these all connected for recommendations 25, 27, 36, and 46?

Steven Eichner
Yes. electronic case reporting (eCR), syndromic surveillance, cancer reporting, immunization reporting.

Medell Briggs-Malonson
Absolutely, great, thank you. Seth, I saw you come off of mute.

Seth Pazinski
Yeah. This is a point of clarity. It says is the proposal here for a new recommendation to be added or for additional text from Ike in the chat to be added to each of the four recommendations for 25, 27, 36, and 46?

Medell Briggs-Malonson
Ike.

Steven Eichner
I think it would be a self-contained recommendation that says across the F criterion, make sure we are implementing adoption dates that align with other programs or program requirements.

Medell Briggs-Malonson
Okay. So, if there is that recommendation, then what we would need, since it will be a new recommendation, Ike, we would need you to place that recommendation in the chat. The full written recommendation, and then we as a HITAC committee will have to vote on incorporating it into the task force Recommendation 1. And if that vote does pass then, we will move on collectively to approve the recommendation. So, Ike, if that is your new recommendation, we would need you to write that language and put it into the chat before we end the discussion.

Steven Eichner
Thank you. Typing now.

Medell Briggs-Malonson
Okay, great, thank you. The next piece we have is Deven in terms of recommendations 126 and 133. I see there is a lot of movement in the chat but we welcome you to discuss this.

Deven McGraw
Yes. I just noted that the framing of 124 made it confusing to me. I think it was framed in terms of not penalizing individuals and caregivers as information blockers but they couldn't be because they are not subject to the information blocking rule. It sounded more, per Rochelle's comment, wanting to make sure that patient and caregiver preferences be honored and not have that be an information blocking violation. I do not disagree. I think that is already the case under the rules but it never hurts to reinforce because interpretation sometimes differ around these things. So, I do not at all disagree with the intent. It just protects from accusations of information blocking, as though the individuals and caregivers would be accused of information blocking. They cannot information block. They are not responsible.

So, it is the actors who might be accused of information blocking if they are honoring a patient preference, which should not happen. Did I get that right? I thought that was the intent but it needs some tweaking.

Medell Briggs-Malonson
Would any of the co-chairs like to respond to Deven?

Rochelle Prosser
This is Rochelle. That is the correct assumption. I was responding back to your point. We are trying to ensure anyone acting in good faith to honor a patient's preferences is not considered to be information blocking.

Deven McGraw
Right. It has always been my impression. Mike Lipinski responded not to everybody but I hope it is okay, Mike. Consistent with current law but it never hurts to reinforce where that is being interpreted.

Medell Briggs-Malonson
Therefore, is there a recommendation to tweak the language or rewrite one of these recommendations, so it is very clear?

Deven McGraw
I would tweak it so that it makes clear that it makes the intent more clear. I am happy to take a stab if that is helpful.

Medell Briggs-Malonson
That would be incredibly helpful. If you are able to take that stab, especially in the areas where there was lack of clarity that will be helpful and place that directly into the chat, so we can have that on record. We will circle back to that. Thank you, Deven.

Deven McGraw
And my other question got resolved by the chat back and forth around a recommendation for advisory boards that are multi-stakeholder for TEFCA. For whatever reason, I read that initially that we are trying to have advisory boards be expressly recognized as entities that could query but that set off alarm bells in my head like we are going to have to define what that means because it feels like a loophole for entities that might not otherwise be eligible to get data to get them by declaring themselves to be an advisory board. That was not what you all meant. I think that was just my misread. I do not know that I have anything that needs to be add. Thank you for the clarification to the group. Great work by the way.

Medell Briggs-Malonson
Deven, thank you. Thank you also, Rochelle, for responding to that. And Deven, that you for refining that recommendation or those two recommendations.

Deven McGraw
I am going to take care of it right now.

Medell Briggs-Malonson
Thank you. Now, we have gone through all of the various different conversations that were in the chat. I want to open it up for a few moments, especially while Ike and Deven propose some of the additional language and thank you so much, Bryant, for putting in the revised Recommendation 1, which was a small, little tweak in terms of comments. Any other discussion about the HTI-2 recommendations? Or any points that are needed for clarification?

Bryant Thomas Karras
Just a friendly amendment to make sure there is consistency across the F20 criteria for public health. F75 mentions receive, validate, parse, and filter, but it does not, as it is recommended in the other criteria, ask for additional clarity on how those are defined on this particular use case. I added that as a friendly amendment to a final sentence to Rec 75.

Medell Briggs-Malonson
Thank you so much. I see Michael's hand that is raised.

Michael Chiang
First, I just want to congratulate the group. I think this was an awesome job. My head got bigger reading it. I only have a quick comment about Recommendations 140 to 142 about the sort of feedback, basically, from customers. I think that is a great idea and extremely useful. My comment is that my experience is clinicians often have what I think is kind of a learned helplessness about using EHRs. My view is they often have far more concerns than they articulate. And I just would suggest disseminating some educational or background materials to clinicians or professional societies. It would be useful in implementing things like this, so people know what they can do or they could have a voice.

Medell Briggs-Malonson

Thank you, Michael. Your points are very well taken. I will turn it over to the co-chairs. I believe, Mark, this was your section to respond, and then we will discuss the next steps will be.

Mark Sendak
I completely agree. We may want to add language that, if, in addition to creation of a registry and some mechanism to provide feedback would be to create educational content for how to report feedback and what types of things to report. Does that kind of address your concern, Michael?

Michael Chiang
Yes. Mark, definitely, yes. I think this is much more complicated than what we are able to discuss here. I am sure you know the details far better than I do. But I think what you suggested would go a long way toward this. Thanks, Mark.

Mark Sendak
Thank you.

Medell Briggs-Malonson
Michael, just for clarification, are you recommending right now that we change some of the language in the Recommendation 140 or are you recommending that this is a topic that we should discuss in a later point? Because if we do revise the language right now, we would need that recommended language so we can vote on it as an amendment and then, also incorporate it if the vote does pass directly into the full task force recommendations.

Michael Chiang
Yes. Thanks, Medell, for asking that. My original thought would be this would be considered for future implementation going forward. What Mark said went beyond what I thought originally. And if you think, Mark, there is a way to incorporate that wording or that it would be worth thinking about it right now, I do not have a way to write that that I thought about. So, Medell, any of those, I would leave that to your judgment.

Medell Briggs-Malonson
Great. Thank you, Michael. Mark, any thoughts about that?

Mark Sendak
I am happy to put a sentence in the chat to add to maybe it is best under 141. No, no, no. That is the capacity for audit. Can we go to the next slide? So, 140 and 142 are pretty similar. I can add a sentence to put here. And then, Medell, I did notice in the Annual Report Workgroup, there is a topic for future discussion around an AI registry, which I think this could relate to that, too. This could be something that we bookmark for that discussion around reporting and how to educate folks for using a registry.

Medell Briggs-Malonson
Sounds wonderful. Thank you, Mark. Therefore, Mark, if you do think it is appropriate to add to 142, what I would do is ask you to take the entire recommendation and put in the sentence where you think it works best and then, we will bring that forward when we go through all of the different, one, two, three, four amendments right now.

Mark Sendak
Perfect. I will do that.

Medell Briggs-Malonson

Thank you. Any other thoughts or comments? Okay, if there are no other thoughts or comments, I am going to wait. I am going to look once and I will look twice. Again, wonderful work by the HTI-2 task force. We know how often you are meeting. We know all of the efforts that you put into this. We are incredibly, incredibly thankful for all of this amazing work and I know ASTP is as well. Excellent, excellent work. What we are going to do now is we are going to go through each of the various different amendments in order to vote them into the final recommendations. And so, what I am going to do is they are in the chat and I just want to double check. Accel or ASTP team, have we grabbed these amendments to place on a Power Point or would you prefer me to read them directly from the chat in terms of the revisions?

Bryant Thomas Karras
Just checking, has Steve had sufficient time, Ike, to finish his friendly amendment?

Medell Briggs-Malonson
We are still waiting for Ike as well as Mark. We still have time. We have to go through various votes as well. We will make sure we capture both Ike's, as well as Mark's amendment. It is just starting the voting process.

Bryant Thomas Karras
I just want to make sure we accommodate.

Medell Briggs-Malonson
Oh, 100%. Even if we have to come back to it after our break, we will do that as well because we know Ike is working on that. All right. So, let us go ahead with the individual amendment votes, so we can get that process started. I am scrolling up to the first one. Again, all amendments will be considered.

Seth Pazinski
Medell, Maybe I will suggest, it sounds like we are ready to move to a vote on the individual amendments and the overall recommendations. So, I might suggest do we want to take a break now and we can assemble a slide with the amendments? I think that will be the easiest way to go through them.

Medell Briggs-Malonson
That sounds fantastic and that will give Ike more time as well. Why do not we do that? I like that suggestion a lot. Thank you so much, Seth.

Seth Pazinski
So, I just wanted to make sure on, Deven, on your comment, is that on Recommendation 126?

Deven McGraw
Correct. I am trying to type into the chat. I should have done it outside first and copied in it. So, use the one after the word oops.

Seth Pazinski
Got it.

Bryant Thomas Karras
Do not put oops into the federal registry.

Deven McGraw
Thank you.

Seth Pazinski
I think I have got it outside of Ike's that we are waiting on and we will start assembling slides that recap the proposed amendments. At this time, we will move to break. And I will ask Accel if you can pause the recording at this time.

Medell Briggs-Malonson
Thank you so much. I will say it, again, thank you so much for all the recommendations from HTI-2. We do have several different amendments that we would like to take a vote on in order to incorporate into the larger recommendations. Now, this is the first series of votes I believe we have had with the new HITAC committee. So, we will proceed according via Robert's Rules of Order. The first recommendation, I will read it and all of the different changes are highlighted in red. This was for Recommendation 1. And the recommendation just in a summary was that the task force is supportive of the adoption of the United States Core Data for Interoperability Version 4.

However, the task force recommends that for future versions of USCDI-1, the task force will continue to advocate for addition of data elements recommended in previous ASTP common cycles. And that includes several different fields including mother's maiden name, multiple birth indicator, and birth order for minors, medication administration information, laboratory results, date and time stamps, laboratory test performed date, specimen collection date and time, and lot number is in USCDI Version 5. I would like to entertain a motion to approve this amendment.

Sarah DeSilvey
Motion, Sarah DeSilvey.

Medell Briggs-Malonson
There is a motion. Is there a second?

Hung Luu
Second.

Medell Briggs-Malonson
Hung Luu has seconded this motion. The motion has been appropriately second. I will call for any additional discussion on this motion. Not seeing or hearing any, I will call for the vote. All in favor please raise your emoji hand. Excellent. All opposed, and you can please lower all of your hands. All opposed, raise your hand. The motion carries unanimously. Thank you so much. We will go to the next recommendation. The next recommendation revolved around Recommendation 75. And the amendment, I will read the entire recommendation with the red letters that are part of the amendment. The Recommendation 75 amendment recommend that ASTP update to reflect receive, validate, parse, and filter content from the electronic initial case report and reportability response received via HL7, FHIR, eCR, IG or HL7, CDA, electronic initial case report (eICR), IG, and HL7, CDA, Reportability Response (RR) IG into destination systems for use.

Recommend additional clarity on what is meant by receive, validate, parse, and filter. At this point in time, I would like to see if there is a motion to approve this amendment to Recommendation 75. Feel to raise your emoji hand. There are several people. I have received an initial motion by Bryant. Is there a second? And I see Rochelle has seconded this motion. So, this amendment has been appropriately moved and seconded. Is there any discussion? Not seeing or hearing any, I will call for the vote. All in favor of approving the amendment to Recommendation 75 as stated, please raise your emoji hand. And just one moment. I did receive a special note. While you are raising your emoji hand, we are going to have a voice vote as well for the record. All in favor, also say aye. Thank you.

You can put down your emoji hands. And all opposed, say nay. The motion carries. All right. Let us move on to the next recommended amendment.

There is one amendment that is being put forth for Recommendation 126. I will read the amended language. The task force is supported of the recommended language. The protection care access rule attempts to protect actors from accusations of information blocking when they decline in clinical situations to share information where they are protecting patients and/or caregiver's privacy and their preference for privacy are honored by the care the care provider team. While ASTP cannot create rules that supersede applicable laws, the task force believes this rule goes to extent that can it assure protection from my charges of information blocking provided the parties are engaged in an ethical and standard clinical practice relationship. That is the read of the amended language. Is there a motion, I am going to call for a vocal motion as well, is there a motion to approve the amendments to the recommendation?

Deven McGraw
I move.

Medell Briggs-Malonson
Thank you, Deven. Deven has appropriately moved for the revisions to this recommendation. Is there a second?

Rochelle Prosser
Second.

Medell Briggs-Malonson
I will take Rochelle. Sorry, Hung, I did see your hand but I am trying to take it verbally simultaneously. It was seconded by Rochelle. Is there any discussion on this motion? Not seeing or hearing any discussion, I will call for the vote. All in favor of approving the amended recommendation say aye.

Group
Aye.

Medell Briggs-Malonson
Thank you so much. You can take down your emoji hands. All opposed, please raise your hand and say nay. The motion carries unanimously. Thank you. We will go to the next recommendation. And this next recommendation is regarding Recommendation 142. I will read the entire recommendation as well as the amended language. Recommend that ASTP incorporate feedback from health IT vendor customers and other users such as patients on the adequacy of the functionality of health IT venders as part of the certification criteria. There is currently no mechanism to incorporate feedback from health IT vendors, customers, and patients to verify that required data elements and functionality required as part of the certification process are supported and function adequately for the purposes they are intended. This feedback process could mirror medical device reporting by the FDA that provides a mechanism for users to report issues with approved devices as a post-market surveillance tool.

We also recommend creation of education and marketing content to support health IT vendor customers and users to provide feedback and report challenges with health IT functionality. I will now ask to see if there is a motion to approve the recommended language as written. And please raise your hand and say verbally, so I can see and hear you.

Sarah DeSilvey
Sarah DeSilvey with a motion.

Medell Briggs-Malonson
Thank you so much. This has been moved by Sarah DeSilvey. Is there a second?

Rochelle Prosser
Second.

Medell Briggs-Malonson
It has been moved and appropriately seconded by Rochelle. I will see if there is any discussion. Katrina, I do see your hand up. Do you have a question or point that you would like to make?

Katrina Miller Parrish
Yes, please. In the earlier part of the text, we said health IT vendor customers and patients. In the revised text, we have health IT customers and users. I recommend that we change users to patients, so there is no confusion that users is somehow different from patients in the prevalence part of the text.

Medell Briggs-Malonson
Thank you so much. There is now an additional recommendation to amend users to patients so that it is consistent with the rest of the text. And so, once again, going back to Robert's Rules of Order, we will have a vote on changing users to patients. Actually, we are still in discussion. Hung, I recognize your hand. Hung, did you have a comment here?

Hung Luu
No, I did not.

Medell Briggs-Malonson
Okay, great. Rochelle, I recognize your hand. Katrina, I recognize your hand.

Katrina Miller Parrish
I am now seeing it says "other users such as patients" so, I suppose users is clear enough.

Medell Briggs-Malonson
Excellent, thank you so much for that. Therefore, Katrina, do you want to withdraw your recommendation?

Katrina Miller Parrish
I think so. I think it is okay.

Medell Briggs-Malonson
Thank you, Katrina. Excellent. Are there any other points of discussion? If there are no other point of discussion, I will call for the vote. All in favor of approving the amendments to Recommendation 142 as written and as read, please raise your emoji hand and state aye.

Group
Aye.

Medell Briggs-Malonson
Thank you so much. You can place your emoji hands down. All opposed to accepting the amendment to Recommendation 142, raise your emoji hand and say nay. The motion carries. Great. And I believe, let us keep on going forward, Accel. I think those were the various different amendments.

Bryant Thomas Karras
Sorry, I will text Ike. But was there one he was drafting?

Medell Briggs-Malonson
We were drafting. We were waiting for Ike and Ike, I know the team was following up with your amendment. Did you still want to submit your amendment?

Steven Eichner
Yes, I did. I thought I submitted it. I will see what happened.

Medell Briggs-Malonson
Okay, thank you, Ike. Yes, the team, we were following up. We did not see that. Do you still have that written?

Steven Eichner
Yes.

Medell Briggs-Malonson
If you can place that in the chat.

Steven Eichner
Absolutely.

Medell Briggs-Malonson
Thank you so much, Ike.

Bryant Thomas Karras
It might have gone to one person instead of everyone.

Medell Briggs-Malonson
We are going to double check that. I know we were in the background double checking. It may have disappeared in the ethers, but we have been in the background double checking for that amendment. And Trudi, I recognize that your hand is up. Is that remaining from the vote?

Trudi Matthews
My apologies.

Medell Briggs-Malonson
Not a problem. We will wait for a few moments. Thank you, Ike.

Steven Eichner
Sending it now.

Medell Briggs-Malonson
No problem.

Steven Eichner
It just went to hosts and panelists.

Medell Briggs-Malonson

Yes. I am going to post it as well to everyone right now, Ike.

Steven Eichner
Thank you.

Medell Briggs-Malonson
I cannot either. Just give me a moment. We are working on something in the background. Thank you so much, Accel. All right. We are going to read this directly from the chat. I want to make sure we have the exact number on the recommendation.

Seth Pazinski
Medell, I believe this would be a new recommendation that Ike is proposing, so this will be Recommendation 143.

Medell Briggs-Malonson
Thank you so much. This is a new proposed Recommendation 143. And the language states, ASTP should consider the dates of certification expiration and align these dates with other program requirements such as CDC reporting and promoting opportunity program reporting. And so, I would like to see if there is a motion to approve this new amendment as read and as written.

Steven Eichner
It should be the interoperability program.

Medell Briggs-Malonson
Can you say that one more time?

Steven Eichner
You misread it. CDC promoting interoperability.

Medell Briggs-Malonson
Got it. Great. That was a typo that was here, so let us just change that typo and put that back in the chat. Thank you so much, Seth. Once again, I will read the appropriate wording here. We are reading directly from the chat. This is a new amendment. ASTP should consider the dates of certification expiration and align these dates with other program requirements such as CDC reporting and promoting interoperability program reporting. Is there a motion to approve this new recommendation?

Bryant Thomas Karras
I so move.

Medell Briggs-Malonson
Excellent. There is a motion put on the table by Bryant to approve the recommendation as read as well as written. Is there a second?

Rochelle Prosser
Second.

Medell Briggs-Malonson
Thank you so much. It has been appropriately moved and seconded by Rochelle. I will see if there is any discussion. Not seeing or hearing any discussion, I will call for the vote. All in favor of approving the new Recommendation 144, I believe, as read and written, please raise your emoji hand and state aye.

Group
Aye.

Medell Briggs-Malonson
Great. Excellent. You can go ahead and put down your hands. All opposed, please raise your emoji hand and state nay. The motion carries. Now, we have five additional either amended recommendations plus one additional new recommendation to the HTI-2 task force recommendations. Now, I would like to move forward to calling for vote for the entire body of recommendations for HTI-2. So, is there a motion to approve the HTI-2 recommendations as discussed?

Katrina Miller Parrish
Move.

Medell Briggs-Malonson
Thank you, Katrina. Katrina moved to approve the HTI-2 recommendations. Is there a second?

Hung Luu
Seconded.

Medell Briggs-Malonson
The motion has now been appropriately seconded by Hung. Is there any discussion? Not seeing or hearing any discussion, I will now call for the vote for the approval of the HTI-2 recommendations, which also include the five new revisions and the one new amendment or recommendation. All in favor of the approval of all of the HTI recommendations, please raise your hand and state aye.

Group
Aye.

Medell Briggs-Malonson
Thank you. Please lower your hands. All opposed, please raise your hand and state nay. Not hearing any nays, the motion carries. Congratulations to, not only the HTI task force but congratulations to HITAC for approving this vast body of recommendations for the Proposed Rule of HTI-2. Great work, everyone. We can proceed on and, Sarah, I am going to turn everything on over to you.

Sarah DeSilvey
I am going to receive the baton and pass it back to you. Excellent work, everybody, on that massive and significant set of recommendations. It is my honor to introduce as per the agenda, our colleagues, Medell and Eliel, to go through the Annual Report Workgroup updates and set the crosswalk through the next period of time. Medell, Eliel.

Annual Report Workgroup Discussion (02:01:04)

Medell Briggs-Malonson
Thank you, Sarah. Eliel, I am going to turn it to you and I am going to take a break.

Eliel Oliveira
Thank you, everyone. It is a pleasure to be with you today. We are going to go over the Annual Report Workgroup discussion details from the last meeting. And we look forward to hearing your thoughts on it. I think, Seth, you usually take the next slides but I am happy to continue.

Seth Pazinski
Go ahead, Eliel.

Eliel Oliveira
Okay, here is our agenda for today. We are going to go over the workgroup membership that you are familiar with. We are going to go over the meeting schedule that we have going forward, and we are going discuss the crosswalk of topics, again, that you have seen about. We missed one last time related to patient access, and we are going to talk about next steps. Next slide, please. Here is our team. And I think you know them all, so next. And our meeting schedules and next steps. Please, next slide. Here we are. We have just met this week to continue to work on the crosswalk and topics and strategic stories that are going to go into the Annual Report, which I think many of you have enjoyed seeing last year, so we are keeping those. We are going to meet in September again to develop the draft on your Annual Report and prepare for that review in the October meeting with a draft Annual Report for the HITAC meeting that is coming in October in person. At the end of October, we will have the Annual Report ready for approval that finally at the end of the year, we will have it ready for submittal or transmittal. Next slide, please.

Again, today, we are going to go over the report development status and show you where we are. In October, we are going to review that report in person, and then we are going to vote on November 7, the Annual Report that then will be prepared for submittal. Next. With that said, just in summary here, we are continuing to develop the crosswalk of topics and the draft report at group meetings, that is where we are. Another thing we are doing at the workgroup meetings is developing illustrative stories. We have gone through them this week, all of them, and I am providing them electronically for the team to provide some comments back. And we are going to cover that again in the next meeting coming up this month. And then, we are going to focus on prioritizing the topics, either immediate or long term, and immediate being between 2025 and 2026 calendar years and long term between 2027 and 2030 and beyond.

Everything seems to be immediate, as you guys would imagine. So, we are going to be trying to work maybe defining what is it that we can put to a long-term view. So, with that said, that is where we are and where we are headed. Next slide, please. So, now back to you, Medell to talk a little bit about the crosswalk as we are today and go over where we left off last time we met.

Medell Briggs-Malonson
Excellent. Thank you so much, Eliel. As you can see, the Annual Report Workgroup has been working very diligently to make it through all of the crosswalk and move on to the prioritization, which you will receive a preview of all of those items during our next meeting, our next meeting in person, in fact. We wanted to have a discussion of the draft crosswalk topics of the one target area we were unable to get to last meeting, which is patient access to information. Next slide, Accel. This is one of our primary areas that we focus on in our annual report and these are the five target areas defined in the Cares Act. During our last meeting, we went through one through for and we ended on privacy and security and some of those key topics that we thought would be important to highlight in this year's annual report. For this time that we have together today, we are going to go over patient access to information. Next slide.

So, this is a breakdown of the standard columns. We will first start off with the first topic in the patient access target area, which is patient-generated health data. This has always been a topic area that we as HITAC hold near and dear to our hearts and have been in several annual reports in the past. The gaps we identified for this year is accessing patient generated health data (PGHD) requires special efforts for providers and patients, including challenges in uploading to EHRs and controlling directly one’s personal data. In addition, PGHD devices for consumer and medical, as well as software developers, are not subject to the same levels of health IT certification

but they play a critical role in our overall care processes. There remains inequities in the availability and accessibility of PGHD devices, especially among populations with low bandwidth, internet access, or those who have low digital literacy. Some of the recommended HITAC activities that are being proposed to address these gaps are 1.) to explore opportunities to use PGHD to improve quality measures, recognizing that there continues to be barriers to be adoption of use of PGHD by patients and the need to not add data collection burden for patients.

Even when it comes to improved quality measures, in a very thoughtful, strategic way, not just automatically incorporating this forcing patients to provide this information. The second recommended activity is to evaluate opportunities to further standardize PGHD across the ecosystem. 3.) Evaluate funding opportunities to make PGHD devices more accessible and education available to more communities with even lower access due to being under resourced or lower digital literacy. Next slide. The next topic is reducing patient burden, which is also a key priority. The gaps that have been identified include patients continue to face issues in obtaining, consolidating, and using their health information to manage their healthcare. And there is a lack of interoperability between health care providers, which increases the patient's workload.

Some of the activities that we are recommending for HITAC is to convene a diverse set of patient advocates and others who are interested parties to identify use cases and health IT solutions that can advance efforts and easy the burdens for patients in managing their health data while also, 2.) requesting ASTP to consider patient perspectives and impact on reducing patient burden as part of HITAC charges and overall hearings throughout. 3.) Explore ASTP opportunities to leverage the individual access services capabilities of the TEFCA to support patients' access to the consolidated health information by requiring certified health IT developers to participate in the TEFCA and support individual access services. Next slide. And the next topic, the impact on patients by the use of AI in health and healthcare. And just for clarification, since we do not have the overall master crosswalk in front of you, there is a different topic of the impact on the use of AI on providers and other clinicians in health and healthcare.

This is the one targeted to patients. And the gap that has been identified is AI data models used for algorithms and predictive analytics may not be representative of diverse populations, nor of high quality data raising the risk of harm to patients. And the recommended HITAC activities that are being proposed are 1.) coordinate and strategize with ASTP on framework for AI use in healthcare and other purposes that addresses patients' concerns and integrates patients' perspectives. 2.) Explore steps ASTP could take to increase transparency into the datasets used to train AI models and how this could be flagged in health IT systems for providers, patients, and payers to identify when the model or its outputs are appropriate or inappropriate to use. 3.) Consider developing a registry of AI models and tools used in patient care. Next slide. Great, so Eliel, I will turn it back over to you.

Eliel Oliveira
Thanks, Medell. And folks, I think this is, again, a little summary of next steps, which is to present a draft report for discussion in the next meeting on October 17 and address any comments, edits that you recommend at that point by the November 7 meeting. And eventually get that approval for us to transmit for approval. With that said, those are the next steps we have. Next slide, please. So, we are open for discussion if anyone has thoughts or questions. Thank you.

Sarah DeSilvey
Any questions from our HITAC members on the Annual Report? Deven.

Deven McGraw
Thank you, Sarah. This is great. These are fantastic recommendations. I think they also take on issues that have languished. the access to patient generated data has been not one that has sufficient emphasis. So, I applaud the

group for elevating that and the AI issues as well, which have great concerns for patients. I think the only thing I will say, and I am not suggesting an additional recommendation, but letting the workgroup know of other activity going on. The ability for patients to access their data through FHIR APIs also via TEFCA, but that is still fairly nascent and developing, but through FHIR APIs where we should have expected a little more maturity and robustness, there is a number of issues that plague that and make it harder than it should be. This is something that some external groups are working with ONC to try to fix. I am just raising it to let the workgroup know that even though we have not prioritized it necessarily in the work plan going forward, I want to make sure people understand, it is not a solved set of issues.

There are still obstacles that patients face in being able to connect through APIs. I think most of that pain gets felt by the tools and applications they hire who sometimes face a number of obstacles in facilitating the connections or the tokens do not persist, so a connection the patient makes one time, the next time the patient has to reconnect again and again and again. At any rate, if there is a desire on the part of the committee to understand most of this work is being done out of the CARIN Alliance and some other groups affiliated with the CARIN Alliance. If there is interest, we would be happy to brief more on what is going on. The purpose of my comment is not to suggest more be added because they are really good priorities that are attuned to patient concerns and some things that have not had sufficient attention and I do not want to disrupt that. But we have issues on the other piece, too. Thank you.

Medell Briggs-Malonson
Thank you so much, Deven, for that. I think that brings up so many important pieces because that goes more into reducing the patients' burden. And we need to figure out how to streamline access. Thank you. That is definitely something we would want to hear more about that, so appreciate that offering.

Sarah DeSilvey
Thank you, Deven and thank you, Medell. Mark.

Mark Sendak
Thank you for all of the work on this. I am going to give feedback on the last slide around the AI recommendations. So, just a few things to call out. One is when we talk about transparency to patients and public registry, one thing at least in my head, this seems like it should be easier than doing something new is just to expand the scope of Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. So, HTI-1 specified the source attributes to make it available to clinicians that if that same set of material can be made available publicly and to patients that would go a long way. So, I want to put that out there because that could potentially be an intermediate win on the way to doing something more robust. And if we go into trying to increase transparency and reporting for AI, another challenge we have seen in the field is there is not a good framework to identify and stratify risk of AI. So, one of the most common challenges I hear when talking with folks about AI transparency is do I need to report to patients spell check in tell me EHR?

It is going to become so burdensome if every AI tool I have to document. So, I think there is a clear need to stratify low risk versus high-risk use cases. That would be helpful to folks and I agree with Ram that we can start with National Institute of Standards & Technology (NIST) but at least formalizing health systems around reporting requirements.

Medell Briggs-Malonson
I have a couple of quick comments. I fully agree, and in fact, just to let you know, Mark, and please forgive me for not knowing every line of HTI-1 but was HITAC did make that recommendation about the transparency also to patients. And I cannot remember 100% if it made it into the final rule. I did not think so because I know all of the slides. That was a recommendation that we did make as part of our initial recommendations because of exactly

what you mentioned. So, that is something that while HTI-1 is already in its final states, we are in a new era of this work. I think we all agree that transparency to patients is very important because all of these various different tools are used as part of their care and they themselves are using various different tools. We want to make sure our patients are informed and supported as possible. In terms of the framework, yes, I agree with all of that, too. It goes back, once again, to making sure that we are in partners with our patients in more ways than one.

Mark Sendak
Thank you.

Sarah DeSilvey
Thank you, Mark and Medell. Michael.

Michael Chiang
Thank you. I am sorry my camera is not turning on. I hope you can hear me. My comment is also about the last AI slide. I really like that. My comment is similar to some comments that were raised in the discussion last time about the framework for providers. I think there is a ton of possible applications of AI and different scenarios and use cases. For example, AI could be used in primary care clinics or Consumer Value Store (CVS) for disease screening, or it could be used in specialty clinics for giving advice to clinicians at the point of care. The way those different AI systems would need to be developed and validated would be extremely different, and the thresholds for acceptable performance would be very different. I think it makes it extremely confusing. My hope, and that is true for both patient-facing and provider-facing technologies, my hope is that ASTP can take a leadership role HHS wide in coordinating across agency activities in this area in terms of presenting this framework.

For example, the framework might be a grid that shows: these are the different common scenarios and use cases, and your work would fit in this box of all of the different probabilities. Because I think at NIH, what we do is sponsor research to make effective systems and the researchers need to know what box does it go into and what is good enough for real-world application. FDA may want to do post-market surveillance of technologies in the different boxes. So, that is just a plug. I hope ASTP, especially the new ASTP, can help coordinate this among different agencies and I would love to be a conduit for NIH if that ever comes up.

Sarah DeSilvey
Thank you, Michael.

Eliel Oliveira
Such a great point. I kept thinking that there is so much here that needs to be done for this to become feasible. The opportunities are great, but at the same time, in some of the work we do, for instance, we still do not have a way to do clinical decision support in a scalable fashion. I am not even talking about AI. So, the decision support interventions that we put in HTI-1 is an improvement but as you can see, just like in decision support interventions, if we do not have a base data that we can trust and it is replicable across the nation, you cannot really be using this decision support system. The same is going to apply for AI. Where that knowledge comes from and, as you know, data quality is going to affect a bit how AI and data precision is going to provide guidance. It is very interesting how everybody wants to move so quick and it is great. At the same time, it is not going to be that simple.

The thoughts that are coming to my mind, just like you are saying about surveillance technology like this, I think that is exactly what we need to get to. And the point I was trying to make recently was that that is not necessarily going to slow down progress. Meaning, when we look at pharmaceutical regulations, the U.S. and Western Europe are probably the tightest ones and where most innovation come from as well. From the U.S. and Western Europe. Those regulations enable innovation and growth and then, surveillance. I feel like process for AI development

should follow a similar setup. But in order for that to happen, we need to have at least the bases covered with high quality and then, we can have systems that can scale. There is a lot of work there and a lot of opportunity, as well. And I think the work we are doing is going to pay off in the long run.

Medell Briggs-Malonson
If I can just say something very quickly. Michael, I agree with your points about the new ASTP and being the leader. And the reason why is because I am even right now reflecting on the final role that has now Section 1557 the Affordable Care Act. And in Section 1557 now with the Affordable Care Act, which was sponsored by the Office of Civil Rights, it clearly states that all of our various different forms of health technology right now that are especially involved with clinical decision support or any of these other areas, we have to ensure it is not producing discriminatory outcomes. Because of that, we have to have a systemic approach how we are going, not only in terms of AI, but this extends beyond AI. This is all of our health technologies because now there are significant, not only implications on our patients and patients' outcomes, but also on all of our health system providers, our insurance companies across the board.

So, I do think it would be wonderful to start organizing this and making sure we are clear about how we are going to engage in this work because as all of the different agencies and the different legislation is coming down with new requirements, we want to make sure and need to make sure everything is aligned as possible. Just another plug for we all have full confidence that ASTP should be the leader and can be the leader in this space for numerous reasons. I just wanted to amplify that point.

Sarah DeSilvey
Thank you, Medell. Rochelle, do you have a comment?

Rochelle Prosser
Yes, I do. I wanted to respond to Deven's comment about patient security and just add to that. She was mentioning about the tokens expiring and how it is more difficult for the patient to have free access. And I wanted to mention the difficulties of the developers where we are trying to put protections of data and ensuring we have cyber security. And I wanted to propose to this group, if there is feedback on that side to do it better because, to her point, we make these tokens and then the patient is supposed to log in or log out according to their use case. And should they take a month or wait for a certain test and not use it for a series of time that will expire according to do the proper cyber security protections for certain high-trust certifications, etc., as we look at health technology. Then, that becomes onerous on the patient or the end user if they have to use multifactor authentication and reconnecting with systems and then, it is multiple systems, etc.

So, I bring this back to the HITAC community and our board to see if there are other challenges that others are experiencing using multifactored authentication and tokens in accessibility, portability, interoperability, etc., and there are other ideas of doing it better that can ease the patient or end user burden.

Sarah DeSilvey
Just so I can understand, are you suggesting an additional topic of conversation within the Annual Report Workgroup?

Rochelle Prosser
Or something for the future. It is really for the future.

Sarah DeSilvey
Thank you. Medell and Eliel.

Eliel Oliveira
Yes. Those are excellent points. We did work related to this where underserved populations have a harder time accessing information technology. And that to me is widening the digital gap between individuals that have different socioeconomic status. So, we need to level the playing field here in some way to make accessible the technologies and eliminate some of the challenges that Rochelle and Deven are talking about. Those are not easy. We need a digital person identity being created that allows someone to easily access their resources because it is a very different challenge. I think you all know how hard it is to log into systems and keep tab of multifactor authentication and so forth. That is harder for individuals, especially those that struggle the most, so those are great points to follow-up.

Sarah DeSilvey
That sounds like a topic that might be great to put it back into the Annual Report Workgroup to see if it is applicable for this cycle or future cycles of the annual report. Is that correct? Okay. Then we have Anna.

Anna McCollister
Hi, there. Thanks, Sarah and Medell and Eliel, for summarizing it so well. I am a member of the Annual Report Workgroup, so I will not belabor my points too much. For context and additional input, I wanted to point out a couple of things. When it comes to patient generated health data, this is something I have been leading efforts to get patients to give comments to ONC to include PGHD since **[inaudible] [02:27:58]** was the head of ONC. It never goes anywhere and I understand it is complicated. There are a few things, reuse the data from all of the certified health IT and all of the things we are doing as the primary source of development of outcome measures and quality measures. And the idea that the data that is collected through clinical labs and is readily accessible through EHRs at this point is in any way representative of life with chronic disease is a bit of a joke. We limit our ability to truly understand and measure quality and care without the ability to assess and collect and include in measures things like continuous glucose monitoring data or blood glucose meter data or blood pressure data.

These are very basic things that are collected in the home multiple times a day by individuals that would give us a better sense of whether or not a particular drug or treatment or provider are working appropriately. The fact we have not done it yet to me is a little bit astonishing, especially given the amount of time and effort that we have put into this over the years. One of the things that makes this is challenging is that we do not yet have the ability in certified health IT for patients or caregivers to be able to write data into the EHR, whether that is directly in terms of correcting mistakes, and I understand there are an array of legal and other issues related to correction of the mistakes. But until we are able to enable the direct writing of structured data from blood glucose meters, continuous glucose monitors, and blood pressure monitors just as an easy baseline directly from the patient into the EHR, we have to find a way to do that.

And that has not been prioritized in any of the rule-making, and we need to address that. Yes, there are complicated things related to what kind of continuous blood glucose monitor data that we want to incorporate. Is it each data point? That would overwhelm an EHR system, but there are aggregate views of that kind of data that can be incorporated. That stuff are things that could be and are being figured out, but we have to solve the basic problem of being able to enable individuals and their devices to write directly into the EHR. And I realize that is a super easy thing to say, but it is absolutely critical if we are serious about having an electronic health record system and an equality measure system that is representative of life outside of the clinic. Secondly, when it comes to the burden of patient access to information, this continues to be significant. I saw a provider yesterday that has a portal.

I still cannot get access to my data through a portal. It is really critical data that includes imaging that could be helpful for me to be able to share, for me to be able to see and fully understand. I cannot get access to it. This provider has certified health IT. They are probably getting paid by Medicare at a particular rate. I am not going to

name names, but this is a significant burden, even for somebody like me who sits on HITAC and is on the board groups like Sequoia Project. We have to solve this issue. It is fine to convene a diverse set of patient advocates and other interested parties. That is always great. We have done that with some of the work I am leading with the Sequoia Project. We have done a lot of documentation of that. And there are plenty of other people who have done that over the years.

I think it is time to get to solutions. And again, there is nothing wrong with convening another set of patient advocates and stakeholders. For each of these convenings, we are requesting time, expertise, effort from individuals who have illnesses. So, we need to be respectful of the time and expertise that these individuals have already given rather than continuing to ask them to say the same things over and over again. It is time for action. Anyway, it is not as if we do not know what the issues are. The part about advancing efforts and coming up with specific solutions, I think there is some work that has been done on that. We certainly know that we need more solutions, but it is just doing it and having the will and the sense of urgency to do it and to understand and accept the consequences that result and have resulted from this not being prioritized. So, anyway, finally with AI, some of these comments that I and others made during the discussions around HTI-2, I do not necessarily think it was incorporated into the final rule-making.

But we really need to have a significant understanding of this training data, and we need to be transparent about what training data is being used. And there are some efforts out there that would provide some degree of certification or validation on that training data is appropriate. I am a little bit concerned about some of those because I fear that having an external group saying, yes, this is a tool that has been trained on appropriate dataset provides a false sense of security, particularly for diseases like rare disease, especially if you get into some of the ultra-rare diseases and how you that might interplay with other disease areas that if you have a rare disease but you also happen to have diabetes, what happens with AI focused on diabetes but does not consider the needs and specific characteristics of rare disease could have significant implications. So, we need to be transparent and thoughtful about what we are doing and what we are requiring, as well as these external bodies that are setting up these validation methods and recognize those may be a good step in the right direction. But they, too, have limitations.

Oftentimes, we forget those limitations exist after we decide they are an appropriate way of validating particular things. You can see that in different types of clinical trials and randomized trials all of the time. And there are very real implications of that. And we certainly do not need to extend that degree of dysfunction into the use of AI. So, that is all.

Sarah DeSilvey
Thank you so much for your comments. I am so glad you are part of the workgroup and lending your expertise in this very critical document from HITAC. Are there any other comments from our co-chairs? I saw Medell's thoughtful reply and comments.

Medell Briggs-Malonson
Thank you, Anna.

Sarah DeSilvey
Yes, I am so glad. Jim.

Jim Jirjis
I just had one comment to Anna's comment. I am a recovering primary care internist, and I used to be head of Oral and Maxillofacial Surgery (OMS) at Vandy. The notion of patient data that they are collecting by automated device or direct entry is an interesting one. Two quick comments on that. One is we start to get into device immigration

standards. We have not had a focus on of who governs and can require standards. There was a center for medical interoperability that was stood up. Unfortunately, its business model did not work. But they were trying to use a procurement pressure to have all of these device manufacturers, some of which are in the home to adhere to a set of interoperability standards. One question is what is the mechanism for that? The second is a lot of practices either have medical records regulations that do not allow information to enter their medical record without a clinician interfacing with it.

And that has been often a challenge because outside of accountable care organizations, the notion of providers spending additional time getting the stream of data from one of their outpatients has not been a model that has been sustainable. Interesting that you bring that up. I am with you as a tech person and a former primary care doc. We had a model that worked. It required case managers who were nurses between visits collecting blood pressures and adjusting things. I guess a question maybe we could pose to our ONC friends, what is the status of device interoperability standards. And for the data, when it goes into the electronic medical record (EMR), what is the landscape of allowability from a local governance standpoint and from a workflow standpoint? I think understanding those things and seeing a path, Anna, helped them conduct pilots, etc., that give the confidence that a scalable solution can end up in regulations. I would love others' thoughts on that. It is challenging for the reasons I mentioned.

Eliel Oliveira

Jim, I have a few thoughts. One is that the idea that all pieces of data needs to be in EHR is one that is very complex. I think some of the pieces of data that you described from sensors like what Anna was talking about, I do not feel the systems are flexible enough to do that. We need to figure out ways where EHRs can tap into data that is being collected and stored in other systems but are also validated and certified in some way. Again, there is environmental data, device data, and genomic data. It is not feasible to believe that all of that is going to flow into one place. I want to mention that and that we need that ability to connect the dots. I do want to go back to Anna's comments because they were excellent. And I can see how hard it is to still be here and where we are and what advancements we need to make to allow patient access and that integration. And I have so many thoughts on that. One of them is, not too far back, we were using paper,15 years back.

We were dreaming early on in the HIT pathway that things were going to be in a completely different state by 2024. We would be on different planets and doing all sorts of amazing things. And then, we realized things are really hard. And I think that might be a little bit of where we are. But the advancements that we have been making, I think, are paving the way to that. I mean, when we talk about FHIR, something like that that needed to be created first and then, TEFCA, something that needed to be in place to allow the API points to deliver data at the right time in regulations that enforce certain things to take place, all of that needed to come together. I do not think we realized early on how hard this was going to be. But I think more important than that is enforcement. The fact that ONC is elevated now to a technology policy, it is going to help quite a bit in my opinion because there is still a lot to do to be enforceable to get to the next level.

I am excited about what is coming forward. I think we are putting the pieces and parts together. Putting data back into EHR is a going to be a tough one. I can see that now because of the complexities, the quality and what the data means and validations and whatnot. But I am hopeful that we are getting somewhere critically to be able to allow patients better access to their data and improve their own care. So, there is a long way to go and I think one of that is we keep hoping that market forces may address some of this. And I do not believe that is realistic, especially for underserved populations. The government needs to come in and enforce certain requirements to allow for patients to have better access to their data. Anyways, I will stop there but I loved your comments and I wanted to reply to that.

Sarah DeSilvey

For the sake of time, we are at the duration for this comment period. If there is ability to move to the granularity back to the Annual Report Workgroup that would be appreciated. But I did want to make sure we honor the hands we have raised. But we are at time for the discussion period on this topic. So, if you have comments, if you can put them in the chat, so they can be logged. That would be lovely. Lee, do you have a comment to add in consideration of the Annual Report Workgroup presentation?

Lee Fleisher
I did put the comment about leaning in with Anna and for some reason, it will not allow me to turn on my camera. I was at the medical device innovators conference yesterday and they talked about the ability of these devices to get into the EHR in service of patients. I think you are right, market forces, I think the market forces are there. They talk about hospice at home, which I was deeply happy about given my role at CMS in that area. I want to echo the goal that it needs to not just say this is high priority. There needs to be a timeline.

Sarah DeSilvey
I want to thank you for that. Of course, rural family practice is my daily beat. If we are using these measurements on a daily basis to align with clinical guidelines, such as American College of Cardiology (ACC), American Heart Association (AHA) guidelines on home blood pressure management, yeah, it is silly in some sense that I am not able to have the information flow directly from the machine and it has to be expressed in words and transcribed by a person. Yeah, I see you.

Lee Fleisher
This is a huge equity issue.

Sarah DeSilvey
It is a thing and it is a provider time issue. So, thank you so much, Anna. Thank you to our co-chairs for this amazing presentation. The work of the Annual Report Workgroup continues on. If there are no final comments, we are going to be going into our next presentation. Oh, we are having a break, I think. No, we are not going to move to the break?

Medell Briggs-Malonson
I think we are going directly into the presentation.

Sarah DeSilvey
Yes, because of the time, correct. We are moving into our next presentation welcoming Beth Myers from ASTP on USCDI+ and quality.

USCDI+ Quality (02:45:01)

Beth Myers
Thank you. Hopefully, you can all hear me and see me with my fancy, new ASTP background. I want to thank you for making some time on this packed agenda. You all have done amazing work very quickly on both of the significant and substantial agenda items for the day. What we have for you before you all get to escape is an update on the USCDI quality domain and the draft Version 1 of the whole domain data set that was published for public comment. I am going to do a little bit of walking through the current state, how we got to this version of things and what has gone into it. Some of you, you will know way too much about it having been directly involved in some of the discussion. For others, some of this may be new. We have included the questions in the presentation and what we will be going through today, the questions that we have presented to the public. Recognizing that you have not had time to do any homework, you may not have feedback on those.

We did save time for discussion, so if there are gut reaction feedback or thoughtful feedback about something you have been thinking about in this space that you want us to consider, take a look at, we are open to that. We wanted to give you extra time for this particular piece because it has been such a big USCDI+ project piece moving forward. And it has so many interplays in so many part of the industry, including, obviously, our partners at CMS. We did want to leave time for discussion. We will see how much time we have and how quickly you are jumping off of the phone. Let us start with going through the content of our slides. If we can go to the next slide, I want to level set for you all that this is out for public comment. There is plenty of time if you have not gotten to look at it yet. It is open for this round of public comment until October 15, and it is on the USCDI platform this time. So, the USCDI+ platform was not quite ready the first time we did the quality dataset back in 2023.

We did it on the Electronic Clinical Quality Improvement (eCQI) Resource Center that those who are familiar know is the place where the vast majority of HHS and CMS electronic clinical quality measurement discussions happen. It is sort of an online base and there is a lot of information that goes up on discussion forums, resources and technical tools on that site. We moved from using that site, although it does cross reference to the platform, and put it on the new USCDI+ platform. So, it is in the same space as the other domains that have been published this time around. You can find it there and we will distribute this in your slide deck and attached to the agenda. The comments are due by October 15. I do want to make very clear that there is a reason for that. For this particular version of the data set, we are aiming to get to a reference version of the dataset that we can start working through things like implementation specification that we want to be looking at for FHIR-based implementation of quality reporting on a broader sweeping scale.

You are probably familiar with the work we have been doing with CMS to do quality modernization in a similar way to how we have been doing public health data modernization. So, that is the core goal. That is the reason why there is a close to this public comment in October. Obviously, this will be a continuing process and we will continue to reiterate and review and take in new ideas for the overarching domain but we are trying to get to a reference set. We will talk a little bit more about that in just a minute. We can go to the next slide, please. So, there are a couple of key goals that are really important for us to revisit and keep putting at the forefront. We do expect these types of goals are going to change over time for patience quality data. It is funny that someone just said that in the chat as I was about to say this. For patient reported outcomes, physician experience data, the types of things that are now sort of coming into play and evolving more in the quality space where there is a lot of exploration happening.

We do think some of the primary or overarching goals will continue to evolve over time. But as foundational principles, this is where we are coming from. I think some of these bullets you will note will not change over time and one in particular is capturing the data needs for quality reporting that fall outside of the scope of the current version of USCDI, whatever version that is. And I like this visual because it shows you how these things are expanding over time and quality is part of that that flows into USCDI. But making sure that we are always looking at what is in the scope of USCDI and what is needed for quality on an evolving basis. The second bullet, which I think is a really important point and part of what we are trying to make sure we got right in this particular posting, you will see questions about that when we get to that part of the presentation, is harmonizing quality data elements.

And this includes harmonizing within different use cases in the quality domain itself that we got input on in the last draft or that we went out and sought out inputs for. In some cases, we hit the road and asked people for things because we did not think we had enough meat to sum up the input that we got to from the last round of public comment, and trying to think about how it works across domains. Harmonizing within the domain, harmonizing within USCDI and harmonizing across the domains. There are a couple of examples, in particular in harmonizing to the USCDI. You will see in this most recent version that should be interesting and hopefully helpful for people to start understanding how this will play out across all of USCDI and USCDI+ as we continue going forward. There

are a couple of core foundational principles that are reiterating here that are probably less a big deal now than when we first started it, but hopefully are still exciting to people.

Everybody is now aware that CMS is moving full steam ahead on digital quality measurements and FHIR strategies, which is hugely exciting, although it probably gets fewer fireworks than it did when we first worked with them and announced it together a year or so ago. It is still incredibly exciting. There is lots of good work going on there. This is also aligned with the Health Resources and Services Administration (HRSA) Uniform Data System (UDS) project, which you have heard a lot about and had presentations on. And it is also looking at other areas that we did in partnership with CMS and in partnership with the whole quality community trying to identify where has CMS or us or HRSA or Substance Abuse and Mental Health Services Administration (SAMHSA) been trying to look at places for quality and where has the industry been looking at gaps in quality that we can start to incorporate here and fill in and flesh out. There is a baseline foundational principle of this working with CMS and the CMS program based on the very accredited modernization work to move to FHIR, but then, taking into account these other principles as well with the most important point being capturing new needed data for quality and harmonizing that data. Next slide.

You have probably gotten sick of this slide by now. You have seen it four times by now. This is our mini roadmap of the types of data we have been pulling in. We keep moving along and we are in the blue box area. Previously, we were in the yellow box area in the last draft we put forward. This particular area is now that we have updates on the initial draft that have been incorporated. We have taken in updates from source IGs like Personal Functioning and Engagement Implementation Guide (PACIO) IG, the Quality Improvement Core (QI-Core) IG, and similar resources like the CARIN IG that were pulled in to expand and incorporate additional sets. We looked at the other USCDI+ domains, which have advanced since the last time we have done a draft USCDI+ quality. So, that includes behavior health, cancer, and broad sweeping looks across the other domains, including public health. That is where we are coming from now. I will reiterate one more time, this dataset includes all of the data elements specified for the CMS Electronic Clinical Quality Measures (ECQM) to Digital Quality Measures (dQM) process. So, the specifications for FHIR for quality reporting for CMS Medicare programs. That is NIST and hospital Interquartile Range (IQR).

That is a core and foundational point that this includes, but it also has incorporated additional data to really start to advance a standard that can work for FHIR-based quality data exchange in addition to the reporting requirements for CMS. So, we are continuing to expand this as we go. We will get comments this time around to expand it further. But we are going to continue the collaborative coalition that we have created in partnership with all of the partners, especially with CMS to identify other places where we can continue build this out to cover the concept of quality as a whole and quality data exchange as a whole. Next slide. This is just for your reference purposes because I know you are broadly representative of our various types of industries. So, we did want to mention some of the folks that have been involved in specific deep dives. We are continuing to grow so this is a snapshot in time. But it does include a fairly broad spectrum of folks. And we are continuing to expand that and asking more and more to get involved.

And obviously, this is looking at it from a slice within the scope of the particular quality responses, but you have to keep in mind that we also looked at other domains and datasets for things that flow through, including recommendations from partners on things we should consider looking at it flow through. That is how we are thinking about this now and it will continue to grow and evolve as we continue forward. Next slide. So, we had a few priorities that you will see represented within the current draft dataset. I want to highlight those because within the dataset, you can see references for source IG or information of where it is flowing from. That is an important and nice feature that we have from the new platform, the USCDI+ platform that allows you to have more information about how things fit together, where is it coming from, what was the source of the information, where is it used in reality.

Again, we did start from our 2023 version and the comment period and submissions received during that period and submissions received interim to that while we were in draft phases. We did a deep level analysis of the CMS ECQM, the upcoming formats, the data elements, the CMS data element library for Long-Term and Post-Acute Care (LTPAC), and across other domains. There are just a couple of examples of specific actionable steps that we are trying to make sure we are taking for datasets that are in development to make sure they are taking a look at where the data elements are being used in the field in addition to conceptual needs that we may need that in order for us to expand and continue the standards and development work. Next slide. The other thing that is important when you are looking at this, we will get to data elements in question very shortly, I promise. So much contextual information in such a big space.

The other thing to keep in mind when you are looking at this data element list is that there are layers to how quality works from a USCDI+ quality domain point of view, from a dataset point of view, and from what we understand from industry. What we have heard from industry, and by industry, I mean health IT developers, standards developers, healthcare providers across a very wide spectrum, including different specialty societies, including **[inaudible] [02:57:32]** and several other non-meaningful user areas that we have taken a look at and talked with, but also among sort of quality reporting registries and organizations and we have had conversations with public health agencies and public health at the state level about how they use quality measurement because it is all cross cutting for them.

In trying to get a handle on that whole picture, we heard pretty loud and clear that apart from everybody knows we have to have some sort of CMS reporting requirement that is met foundationally and ensured to be met by certified technology, which is, obviously, a priority according to statutes. There is a need to be able to have a dataset that does not further silo quality data, that does not create artificial distinctions in use case because part of the challenge for quality data is you need to be able to interchangeably aggregate data from many different sources in order to actually do robust, actionable quality measurement that can be nuanced and meaningful to improve clinical care. Because of that, we sort of layered the quality domain in a couple of different ways. There is an overarching domain that you will see represented in the USCDI+ platform that includes a wide range of things. Potentially, almost anything that people have suggested is included in there and is there for review, for public comment, for analysis.

It is there because we have been told it is important and it matters and needs to be represented. Some of the things in the great, big bucket that are under the whole domain do not have enough specificity or clarity to be what we would consider if we looked at USCDI to be a Level 1 or Level 2. Some of them are what we would call an equivalent to comment level. Because of that, we understand they are probably not read to be what we would consider a reference version that might have implementation specification built in relationship to it. We do not want them to get lost and we think it is really, really important to highlight the need to continue to focus attention on those areas where there are standards that need to be developed or more clarity for the clinical concept that is represented so that it can be identified if it does already align with the USCDI or data alignment that is specified or if it does not and needs additional specification.

That is the big, overarching bucket. I realize it is a very simplified visual but it is capturing this concept. Within that, what we created and released for public comment about a month ago, and open until October 15, so please take a look, the draft USCDI+ quality Version 1 is a standard reference version or a draft reference version that we believe is a subset of the broader sweeping, overarching quality that reflects policy alignment around the existing programs, but also reflects policy alignment around core priorities and goals identified by the healthcare industry. So, things like long-term care are incorporated into there as are things like health equity. Those data elements also have some form of readiness for implementation, meaning they basically meet a level equivalency for the USCDI

of a Level 2. They can be included, they can be referenced, they have standards to represent them, and we have enough clarity and specification that we can consider this to be a draft of a reference version.

We also had to ensure in this draft version, we actually included data elements from USCDI and USCDI+ for other domains that we think are relevant and then, the harmonization so that what is incorporated in the dataset is representative of those data elements as a whole scope. So, you can see the USCDI data elements in there as well. So, there is a clear representation of what it would look like if we are talking about a big, quality bucket, including the USCDI data elements. We also included a clear reference that this does include all of the data needed to calculate a CMS ECQM for reporting to programs, recognizing that there is a core dependency for a certified technology health IT module that can report to CMS programs to be a bit of a guarantee that providers can have access to that health IT functionality. Next slide. So, I am going to go into a little bit of detail but not a lot of detail about the data and data elements themselves.

I hope that you will have an opportunity to take some time to dig in a little bit. I do see chat comments and questions coming together, so it looks like we could have good discussion about this more broadly, which is what I was hoping for. So, I am glad about that. I will save a little bit of time just for context so that when you do homework and take a look at it and give us comments on it, you will have more awareness of what we have done and why. There are 32 data classes and 10 new data classes. So, those 32 data classes are across the board. Ten of them are currently not included in the USCDI Version 5, meaning we added data classes, not just data elements to what you might see in the USCDI Version 5. There are also data elements that we think correlate to existing data classes in USCDI Version 5. So, we have identified that correlation and used those data classes where appropriate.

Some of the big ones that you will see and probably notice right off of the bat, advanced directives, adverse events, which is a broad and sweeping scope with multiple data points that are necessary for adverse events for reporting for patient safety and patient quality, including safety measures that are looked at by Agency for Healthcare Research and Quality (AHRQ). And there are some pieces that you will notice are somewhat new. We do have standards associated with them, so we are excited to put them forward, including things like characters and outcomes. Obviously, there are pieces from cancer care and pregnancy information that relate to the crosswalks, USCDI+ maternal health, USCDI+ cancer, newborn delivery information in that bucket as well.

So, the care experience and outcomes and communications and referrals is sort of **[inaudible] [03:04:06]** care planning and care experience that includes provider and patient observations of experience. So, those pieces are connected to this care planning concept as well. So, you will see that these very much are expanding into some of the areas that quality measurement is trying to go towards, but they do look at things that may flow through and align for future reference for things that may be more expansive and more complete. We are going to talk a little bit more about the questions that we have asked. But I do want to highlight one interesting example that you will see if you dig in on the nutrition and diet area and the substances data class. As you are familiar with USCDI, you know there are data elements within the USCDI that talks about substances that are causing an allergic reaction or intolerance.

One of the things that has been demonstrative that this actually works the way we thought it should work is that the USCDI+ quality data review process allowed us to identify that we had a gap between the inclusion in the USCDI of substances for allergies and intolerances and the need in the USCDI+ quality for substances like nonmedication substances that had nothing to do with an allergy intolerance, for example, breast milk. Again, the maternal health issues that are coming up in the maternal health USCDI+ and flowing through. So, what we see is that particular example is identifying a flow through between multiple USCDI+ but it is also helping us to inform where we might want to think about changes to USCDI in the future to be more clear for substances that are non-medications and cause an allergy or intolerance and areas that we need to take a look and say this thing that we have here, is this

the full scope of what we want to be seeing? Do we want to take it one step further based on the information that we see from the quality space?

It is really exciting. I know that is a geeky detail. Hopefully, you are geeking out with me about how that little bit of process on the harmonization of this particular data element between the multiple USCDI+ domains, USCDI+ quality and flow through with the harmonization with the USCDI has been able to inform how we think about data element classification, data element definitions and being as clear as we possibly can to make these things as clear and implementable as we possibly can for really capturing clinical concepts that are necessary and being able to make them computable and interoperable across systems. I realize that is a geeky moment but we will move on. The next few slides I am going to flag for you. These are the questions that we are specifically asking. I am raising them, so you can have them rolling around in your head. And when we get off the call, if I let you out early, maybe you can spend time poking around and looking at the dataset.

They are what we are asking the public specifically about. So, there are broad, sweeping questions like are there additional data elements that need to be added for alignment across all quality programs, including beyond the scope of the CMS QI programs. There are so many other quality programs out there. We looked at a bunch of them. We looked across CMS programs and we also looked at HRSA and HMRQ and SAMHSA and some others as well, including CDC. Beyond that, are there other as well, including all payers, state programs, county programs and health center programs that are specific but then, they may be working with different types of specialty registries or an alternative payment style. Looking at that as a big picture across quality programs is a question for everyone. Are there things that are happening now that we missed? In other words, things that are being exchanged now that we missed that we can incorporate that would be helpful. Again, federal and nonfederal quality measurement initiatives that should be reflected.

Those two pictures relate together. Big picture, did we miss anything, tell us what we missed and how to fix it. Then there are things we asked specifically about the interplay between the state overarching quality datasets and what we have identified as at a level of clarity, specification, and readiness for use to be part of the reference set that we are calling the v1. Is it big, sweeping discussion space, is it the equivalent of a USCDI Level 2 that we could incorporate into a reference version? We would be interested to hear if we did miss something there or if there is something we included that is not as ready as it seems. We would welcome that feedback as well. We would also welcome additional context. For example, usage notes, implementation guides, all of these things are important data points for not only us in understanding what is the readiness, is it in use in IG, is it in use in a program or measure, but also, where else is it potentially in use?

That is where we can start to identify those weird, little disconnects and variances that cause a lack of interoperability that are more challenging to address because everyone thinks that they are doing the same things in the same way. But when the rubber hits the road, they are looking at different concepts or they are capturing the data slightly differently or representing it slightly differently. So, harmonizing efforts are necessary to advance that. Anything we can do to help us inform that process of identifying points where additional harmonization could be effective would be helpful. So, usage notes, implementation guides, value sets that might fit within this bucket or that seems to not fit quite right. It would be interesting for us to look at. We do remind you when we look at USCDI or USCDI+, you know this but I am going to say it out loud, we are not looking at a level of the value set, we are looking at a level above that at the data element, which would include any number of value sets that fall within the scope of that category or the specific data element that can be represented by the standard.

That is why when we go back to talking about these definitions, it is important to have those right and understand if there are gaps in the definition or clarification of a data element that mean that values cannot be grouped in a way that is going to be actionable and computable. Those are really important pieces for us to understand. Next slide. So, the other thing that we are specifically calling attention to in the following as part of our review is the data

elements included in another USCDI cluster that should be considered for USCDI+ quality. We have done our homework. We have looked across all of the domains multiple times, and we have done harmonization and we have asked tough questions about what does this mean. All of this is saying quality is somewhat nebulous. We can put everything in quality. We are trying to draw parameters and lines around making a draft version that can be a reference version that can be a real tool for starting implementation that is not itself another ocean that needs to be boiled.

That is part of what we are treeing to do, but if there are things that we missed in other USCDI+ domains that you think are particularly relevant that we should take another look at, that is a specific area that we want to explore. And then, there is a goal that we have for exploring patient reported outcome measures. That is one of the top questions that we are asking people about. We did try to incorporate what we could find clearly specified and useful for incorporating things that were relate to patient outcomes. But that is a clear gap, in our opinion. That is a particular gap we would appreciate input and support on and we specifically ask about. And I wanted to specifically ask about it here so we can start chipping away at the data that is missing from being able to do real robust patient reported outcome measures, including thinking about if there are things in other domains that maybe are not represented in current patient reported outcomes.

There is a fairly limited set of clear computable specification for PRI but that might be able to inform or that you are aware of initiatives they are taking a look at the concepts in a way that is trying to expand or advance patient reported outcomes related to that topic. For those types of things, we are asking specifically. We really want more on that. We would like to make sure we are getting as much of that as possible. And even if there is not enough representation or not enough clarity for it to go into a draft version, we want it in the domain, so we can start focusing on it and working on it because we think one of the biggest barriers to really moving patient reported outcome measures forward is that there is not a lot of clarity on what the data elements that relate to concepts that weigh want to be measuring are that is really robust and in use in a wide scale. It is an important piece that, hopefully, we are going to get useful feedback about but I wanted to highlight for you all. I think there is a granularity question that is sort of our second specifically targeted specific attention question. And this is the point that I was just making. We have this with USCDI. And we have it even more with USCDI+, especially when you think about quality and all of the nuances to quality measurement and inclusion criteria and exceptions.

We cannot be doing metadata and value level, but we need to make sure that the data elements are at a level that is going to be effective to allow for those things to roll up and have representation using the standard. In particular, when one of the things that we noticed that we struggled whether to include or not include, we erred on the side of including for now but are asking a specific question about is there a multiple date and time nuanced references within quality measures that have unique specifications for X and such date, X and such time? It is a creation of multiple data elements that all capture that concept that way. As we are looking at that, we sort of think this may be better met, especially as we move toward a FHIR enabled universe by including date and time concepts that already exist and are robustly used, along with the specific instance of if it is an adverse event, the actual information and data element about the adverse event and taking time separately.

So, that is a specific question where there are some challenges within this. If you have immediate thoughts, I welcome them now. But otherwise, please take a look at that and use that in your comment responses. I believe my last side is my shameless plug and we can go to if there are discussion questions or discussion points or suggestions. I did see the chat blowing up while I was talking. I apologize. I cannot multitask well enough to read. I got some of them but I could not read all of them, and I welcome thoughts.

Medell Briggs-Malonson
Thank you so much, Beth, for this informative presentation. I think I can confidently state that you are amongst good company. We are all data geeks in every single way, and this is something we all love. So, we appreciate

you. There are additional questions that are in the chat and I ask for the HITAC members because there is a large number of chat, if you are willing to raise your hand and ask your question via voice that would be quite helpful. If not, I can go through the chat. Great. Trudi, I see your hand.

Trudi Matthews
Thank you so much. Very helpful to have your presentation. The question I put in the chat is where in development or is it represented in one of these domains and I just do not see it are health related social needs? Obviously, that is a newer measure for CMS hospital inpatient quality reporting, but it is also growing in a number of other CMS quality programs. I realize it is new and it may not be represented here, but I wondered if you have talked about it as the ability to share that data as it is such a new measure, it might enhance it to some degree. I wanted to see if you could address that.

Beth Myers
Sure. An excellent question. I am very glad you asked it. The specific measure, I believe it is **[inaudible] [03:17:26]** patient process for its individual specification. So, CMS is going through their measures and specifying them as quickly as they can and taking that and filling it in. Some of the data elements that we already know, the low hanging fruit data elements that we already know are already incorporated. Any of the social determinants of health (SDOH) data elements that are incorporated in USCDI like food insecurity, transportation needs, all of the ones in USCDI we specifically identified already in the v1. We included them as names, not just **[inaudible] [03:17:55]**. We named them because of exactly that purpose. We are trying to put emphasis and highlight there. So, where we could, we incorporated data elements ahead of some of the specification work that is going on. Where it was clear that that was feasible, we did so.

I believe that the measures are still in development and we are working with sort of the broader sweep, like electronic Long-Term Services and Supports (eLTSS), the whole scope of some of the social determinants of health measures that we have been looking at together and that Gravity has been looking at and that PACIO project has been looking at for long term post-acute care. There are five different workflows all coming in to try and get some of those social needs measured data elements ready. I do not think we have the whole specification for the particular measure that is in IQR right now yet. I think it is in the works, but we have pulled some of the data elements that we knew we could into this version.

Trudi Matthews
Great, thank you.

Medell Briggs-Malonson
Thank you, both. Bryant.

Bryant Thomas Karras
Thanks so much for this amazing update. I quickly put in the chat, you shared a slide that I am thankful for of ASTP, ONC working across HHS to pull in comments from our partners, CMS, NIH, National Cancer Institute (NCI), FDA, Indian Health. I did not see SAMHSA on there.

Beth Myers
It should be been. I know. I was thinking the same thing as I was saying it. They are included.

Bryant Thomas Karras
And of course, CDC.

Beth Myers

Yeah, I need to update that slide.

Bryant Thomas Karras
We on the public health side have additional interfaces to other federal agencies outside of HHS. So, when time permits for you to expand your scope to coordinate across agencies like our partners at United States Department of Justice (DOJ), DOD, VA and Department of Homeland Security and United States Environmental Protection Agency (EPA), we think those agencies have a tremendous impact on our public health ecosystem. And the interoperability with them is also critical. I had the a-ha moment at Healthcare Information and Management Systems Society HIMSS last year talking to a general at the DOD about USCDI and TEFCA. And they looked at me with a blank stare and what is USCDI and I have never heard of TEFCA. So, I think there is some outreach to do.

Beth Myers
That is an excellent comment. I noticed on the slides that there are a few things missing. I will say we started conversations with VA. It is not a problem with VA. The challenge with the VA is they are huge. We need to find all of the people, but we do have good conversations going with them. We have also started conversations at least starting with our BJA friends, Bureau of Justice Administration, who work on things like opioid prescribing and Cloud Data Management Framework (CDMC) in partnership with the CDC. So, we have connected with them and are working towards the CDC guidelines and what data elements can we incorporate for those. I could go on and on. There is exciting stuff happening in additional conversations. Yes. The one that you mentioned that I am in the background cheering for and I guarantee Elise Anthony is in the background cheering for is the EPA. It is an interesting point and area when we talk about social needs and we need to be talking about social needs and environmental needs.

These are all related, interconnected, unable to be detangled influences on our health. We are interested in seeing where we can explore that as well. And if you have specific suggestions, we are open to them.

Bryant Thomas Karras
We are happy to help out and lend our thoughts. Washington State was the guinea pig for both the DOD and the VA roll out of their modernized electronic medical record system. We have lots of thoughts.

Medell Briggs-Malonson
Thank you, Bryant, for those comments and it is very exciting about truly thinking about the incorporation of all of our environmental drivers of health because that is important and key and an area that we need to highlight more of. Michael, I see your hand.

Michael Chiang
Thank you for presenting. I have four quick comments/questions. Do not worry, I will make them quick. The public comment slide mentioned asking about additional data elements. I was wondering if there is a data element list in the request for information (RFI). The current things that were in the slide were broad things like clinical notes and problems that you cannot calculate clinical quality measures based on. That is No. 1. The second comment is there are other organizations, groups like OHDSI, groups working on common data models that I feel like are doing of what seems like similar work in parallel. And I think it would be awesome to harmonize with them to work towards the same goal, so just a suggestion to consider that. No. 3 is every time I look at clinical quality measures and how they are computed, I find there is enormous variability, even the way they are defined at the granular level. When two different people calculate them, they end up sometimes with very different numbers. I just wanted to call that out. I think that is a huge problem in my experience.

And my last comment is on one of the slides, you had mentioned NIH. And it sounded like from some of the other comments that NIH meant National Cancer Institute or some other specific institutes. I am just wondering if you are looking for broader input or if you would rather start by a relatively small set of inputs to go with. I will stop there but thank you. I think this is really neat work.

Beth Myers
Sure. I am going to go as fast as possible. For Question 1, there is a full dataset that you can look at in a granular level, including standards, estimated leveling, references where we know they are in use in IGs but we welcome additional points for that. All of that is on the USCDI+ platform. That link is in the deck but I will send that to you separately, Michael. Yes on accelerators. I would love any connections for Odyssey or whoever else you are thinking about. We would love those connections. We want to talk to everybody. We talked to the fourth question about NIH. We did have connections with others beyond NCI. NCI, obviously, flowed straight through from the USCDI to put cancer into the program, but we did talk to folks looking at LIM broadly and asked them to help us think about how to encapsulate some of the things needed. There was a sense of NIH as a fire hose and we were trying to figure out the best way for NIH to be able to easily contribute for you all as well because it is a challenge of you have so much that you are looking at. Where do you want to start? I think that is a great conversation for us to continue and I know our teams would love to have the next step on that conversation.

And then, very last, calculating measures. One of the great things that we hope will come out of moving to a FHIR-based system where data can be aggregated in a lot of different ways, so we are talking about quality data exchange, not just quality individual measure, current measure state reporting, we know that last thing is very important. We know there are statutory mandates and program requirements and that is where we are today and need to keep being for a while. The idea of getting to quality data exchange should help us get to what we think we even mean by quality measure. So many quality measures are clinician, process measures as opposed to patient outcome measure. And the latter is where we want to move. To do that, you have to be able to think about across providers, across settings, across care types. And that is going to be, hopefully, what we can start to enable by doing this process together.

Medell Briggs-Malonson
Thank you so much, Beth. Thank you Michael, for those questions. Rochelle.

Rochelle Prosser
Thank you so much. These were wonderful thoughts. Can you hear me?

Medell Briggs-Malonson
Yes, we can hear you. Yes, we can hear you.

Rochelle Prosser
So, my thoughts were on the quality aspect of interoperability and looking at patient reported outcomes. My focus is really on the **[inaudible] [03:27:21]** in the oncology spectrum where we are still crafting what the patient reported outcomes there are, whether in treatment, on treatment, out of treatment, etc., and looking to find what the standardizations are. My thought is have you included some recommendations from NIH or other cancer NCI entities or guidelines on that patient reported outcomes? And what is the ultimate goal for the quality aspect? **[inaudible] [03:28:07]** patient reported outcomes where clinicians or facilities have to adhere to certain standards of basic promised health within epidemiology or public health version for the patient? Or are we looking from the clinician when this is the minimum standard of what is compliance?

Beth Myers

I think I am going to restate what I think the question is and, hopefully, this will help. Rochelle, please follow-up with me. I know we are running out of time. Please follow-up with me and I will respond directly if I miss the boat here. What we are looking for USCDI+ quality if the reference version right now, it is largely for the public good. There is not a regulatory requirement associated with it. We are trying to advance standards and trying to advance the need to really zero in and focus on standards that are feasible and implementable for quality. The reason we are asking about patient reported outcome measures and asking what else can we get, what else can people give us for that is to your point. There is a lot of development going on with those measures. What we do not want to see is new fragmentation happening when our ability to give starting datasets that could meet those needs could help to prevent fragmentation.

That is part of the driver behind getting a draft referenced version out as quickly as possible and being able to say, as you are looking at new measures, as you are looking at development, start with these data elements and see if they meet your needs. If they do not, identify the gap, identify the concept ,and tell us about it, so we can make sure it does meet your needs with the goal of having data that could be used across setting. To be really clear, we are still talking about the tech capabilities, not the providers being required to document such and such thing. They should have the capability to capture whatever the information they need to document is in structured data, as structured data, and to share it as structured data in interoperable format. Our goal is very much in the tech capabilities as minimum capability of the technology for to provider to be able to use.

Medell Briggs-Malonson
Thank you, Beth. Katrina, we see your hand.

Katrina Miller Parrish
Thank you for a great presentation. I am so sorry to ask such a remedial question but I am going to do it. That is the overlap between USCDI Version 5 and USCDI+ quality and the reason is your Slide 8 where I am just trying to understand if what you had done is taken certain classes and elements out of USCDI Version 5 but really all of USCDI and tagged them as a quality element and created new data classes and elements because it was not yet in USCDI. Does that sound right?

Beth Myers
Partially. What you are seeing in real time is the USCDI Version 5 was not fully baked when the Quality Version 1 was fully baked. What we consider for USCDI+ quality, all of USCDI is in it. USCDI is the core data for interoperability. It does not matter if you put quality in front of it, whatever you put in front of it, from our perspective, USCDI is always the core. It is always the center and then, additional things, you are right. We look at what is not in there needed for quality and we added more to it. The reason you will see specifically called out Version 5 things is because when quality was being baked and put into the platform, 5 was being baked, too. We were not quite sure what the final results were going to be. It ended up that they went out almost at the same time, so that is what you see. We would now, if we were redoing it tomorrow, and what you will see whenever we get through public comment and put the next out, all of v5 will be in.

Katrina Miller Parrish
And just a comment on making sure that the new data classes that are added into quality are considered or on deck for USCDI in future versions?

Beth Myers
The answer is yes. It is part of what we consider. The public provides input on to what should go into any version of USCDI but so do we. When we are looking at things, we are seeing things that may rise to, wow, this in five different domains. This is hugely what we used. This is ready to go. And we might move something forward. We might make adjustments. So, there are a lot of different ways we would think about that. There is never going to be

a perfect correlation that we add things in USCDI+ and can immediately flow through them in USCDI because USCDI information has to be scoped and buildable each year. But from our point of view, it is a direct swim lane that we are taking all of the things that we look at from USCDI+ and we look at them side by side for any submission we get from the public for USCDI.

Katrina Miller Parrish
Okay, thank you.

Medell Briggs-Malonson
Any other questions or comments? Beth, you have been amazing. This was a very informative presentation and gave us so much to think of. And I am sure we will be sending various different thoughts and recommendations to you. Thank you for coming and presenting the USCDI quality plan for us. Thank you.

Beth Myers
Thank you very much.

Medell Briggs-Malonson
Thank you. Have a great day. So, at this point in time, I think we have come to the end of our agenda. So, Seth, I will turn it to you because we may be able to proceed into public comment a bit earlier.

Public Comment (03:34:46)

Seth Pazinski
Thank you, Medell. So, we will open up the meeting now for public comment. If you are participating by Zoom today and would like to make a comment, you can use the hand raise function, which is located in your Zoom toolbar at the bottom of your screen. If you are participating by phone, you can press star nine to raise your hand and once called upon, you can press star six to mute and unmute your lines. While we wait for folks to raise their hands, a couple of reminders. One is that our next HITAC meeting is scheduled for October 17 from 9:30 a.m. to 3:00 p.m. Eastern Time and that will be both an in-person meeting, as well the virtual option to participate. The second reminder is that all of our HITAC materials from today and our HITAC meetings can be found healthit.gov. If you are looking for materials, please visit healthit.gov to find those. I see we have no comments on the phone at this point and checking the Zoom. We have no hands raised on the Zoom at this point either. I will turn it back, Medell and Sarah, to you for your closing remarks and to adjourn the meeting.

Final Remarks and Adjourn (03:36:02)

Medell Briggs-Malonson
Thank you, everyone, so much. As we mentioned, this was going to be a filled agenda and you executed it with expertise. I want to thank the three co-chairs of the HTI-2 task force, as well as the entire HTI-2 task force for all of your amazing work. Also, for everyone that provided, not only revisions to the amendments but also our brand new recommendation, that is amazing. I just want to say thank you. Thank you all for all of the great work. As Seth mentioned, next month, we will be in Washington, D.C. together. And just as a reminder, there is going to be a dinner beforehand, so you will be receiving that email. Please try to reserve some time to join us for dinner. We are finalizing some of the restaurants right now. An email will be coming your way soon. Have a wonderful September. I cannot wait to see all of you in October. Sarah, I will turn it to you.

Sarah DeSilvey
Nothing more to say. Medell, thank you so much. I was going to echo and say the work that was put into this meeting is evident. The extensive work from the ASTP team and all of the workgroup members, we are just

incredibly grateful and I look forward to seeing you in person in October. Thank you for your time. It is valued and your expertise is valued as well and have a lovely rest of your day and I hope you enjoy your bonus hour.

Medell Briggs-Malonson
Have a good one.

Questions and Comments Received Via Zoom Webinar Chat

Jim Jirjis: Good morning

Jim Jirjis: Bryant is your favorite! :)

Eliel Oliveira: I will turn my camera on that one!

Jim Jirjis: I asked God for an eighth day of the week. He denied the request, stating that I would just fill it up as well

Rochelle Prosser: I am here

Maggie Zeng: Federal Register: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability: https://www.federalregister.gov/d/2024-14975

Maggie Zeng: HTI-2 Proposed Rule Task Force 2024: https://www.healthit.gov/hitac/committees/hti-2-proposed-rule-task-force-2024

Maggie Zeng: HHS Acquisition Regulation: Acquisition of Information Technology; Standards for Health Information Technology: https://www.federalregister.gov/d/2024-17096

Maggie Zeng: HHS Acquisition Regulation Proposed Rule Information Session: https://www.healthit.gov/news/events/hhs-acquisition-regulation-proposed-rule-information-session

Shila Blend: Shila Blend, present

Deven McGraw: Approval of an operations use case for TEFCA is very big news.

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

Micky Tripathi: Argh, I forgot to mention the amazing work of our CDC and STLT partners in getting public health live in TEFCA. There are now 9 jurisdictions participating in electronic case reporting on TEFCA and a number are also enabling electronic case investigation. Sorry for the oversight and thank you to our public health colleagues!

Jim Jirjis: MIcky there are about 50 jurisdictions now receiving eCR data through TEFCA pipes!

Jim Jirjis: APHL just updated us

Katrina Miller Parrish: Did we need that last sentence in there?

Mark Savage: Re additional data elements to add, the Interoperability Standards Workgroup recommended data elements for USCDI v5 in April which were not included, such as Shared Care Plan data element. HITAC unanimously approved those. These are worth considering to add as well!!

Seth Pazinski: Suggest including the recommendation # if you are putting a comment in the chat. So the HITAC can know what recommendation your comment in on when we go to discussion.

Katrina Miller Parrish: Not a big deal but with Rec 1 at the end we have "Lot Number is in USCDI v5." seems more a note than recommendation.

Katrina Miller Parrish: All the best to CA folks!

Mark Savage: Per Seth's guidance and my earlier comment on IS WG recommendations such as Care Plan, that was HTI-2-PR-TF-2024_ Recommendation – 01

Steven Eichner: Good morning! A typographic error was noted in the draft recommendations:, On page 11 (HTI-2-PR-TF-2024_Recommendation 36), there is typo in the word “demographics” where it references “critical demograthaphics. Can this be corrected prior to submission/transmission?

Tina Lai: Would these slides be provided to us?

Seth Pazinski: All HITAC materials, including these slides, for today's meeting are available on healthit.gov. Here is the link... https://www.healthit.gov/hitac/events/health-it-advisory-committee-72

Anna McCollister: Anna McCollister is here. My apologies for running late.

Steven Eichner: The adoption date for utilization of updated standards should align with data reports generation dates so that interoperability standards do not change in the middle of a reporting period. Similarly, there should be alignment between certification criteria expiration dates and requirements for using currently certified technologies, such as requirements within CMS' Promoting Interoperability program. For example, additional information regarding the impact of standards expiring on January 1st on a provider's Promoting Interoperability Reporting Period beginning on January 1st would be useful.

Steven Eichner: @Seth Recommendation 25, 27, and 46, among others refer to January 1 across different reportable information.

Deven McGraw: Rec 126 - individuals and caregivers aren’t subject to the info blocking rule. Are we instead asking for entities covered by the info blocking rules to not be held responsible when they are honoring privacy requests from patients and caregivers?

Deven McGraw: Can you say more about what you mean by “advisory boards” (133)

Bryant Thomas Karras: @katrina MP, i think that it shout have been: " , and Lot Numbers is in USCDI v5."

Rochelle Prosser: 126 @Deven, no we are not. We are saying we are honoring patient preference

Katrina Miller Parrish: KUDOS LEADS!!!

Steven Eichner: Deven- advisory boards are recognized in general in the TEFCA agreement, Would there be advantages in recognizing and advisory/oversight board in regulation with representation including patients, public health, providers, payers, and others.

Rochelle Prosser: Under Advisory Boards, TEFCA is summarized of multiple private and public entities. Therefore an advisory board should be adopted to ensure patient privacy concerns and interoperability is considered instead of self regulation.

Melissa Soliz: I missed recommendations #134-136. Would an administrator be able to drop those into this chat?

Deven McGraw: Ah - you are asking for them to create advisory boards vs. recognizing advisory boards as entities that can participate in exchange of information under a TEFCA purpose?

Bryant Thomas Karras: rec 1 :

The Task Force is supportive of the adoption of the United States Core Data for Interoperability Version 4 (USCDI v4). However, the Task Force recommends that for future versions of USCDI, the Task Force would continue to advocate for the addition of data elements recommended in previous ASTP comment cycles (e.g., for immunization-related fields, Vaccine Administration Date, Vaccination Event Record Type, MRN (and other IDs), Mother’s Maiden Name, multiple birth indicator and birth order (for minors), medication administration information, Laboratory results: date and timestamps, Laboratory Test Performed Date, Specimen collection date/time), and Lot Number are in USCDI v5.

Deven McGraw: HTI-2-PR-TF-2024_ Recommendation – 134

The Task Force has found data quality to be the missing gap that is fundamental to health IT sharing and TEFCA. Therefore, the Task Force recommends ASTP refer to, prioritize as a goal, recognize, or focus on high-quality data within data sharing as its goal to create an atmosphere of trust.

Deven McGraw: HTI-2-PR-TF-2024_ Recommendation – 135

Recommend that ASTP continue efforts to create more equal information exchange to advance interoperability between USCDI and across health IT.

Deven McGraw: HTI-2-PR-TF-2024_ Recommendation – 136

Recommend that ASTP foster QHINs' support for all Exchange Purposes for health IT, including the one they prefer to address.

(For Mel Soliz 🙄 and anyone else who missed them)

Melissa Soliz: Thx you Devin!

Katrina Miller Parrish: Thanks Deven!

Bryant Thomas Karras: rec 75:

Recommend that ASTP update (f)(25) to reflect: receive, validate, parse, and filter content from the electronic initial case report and reportability response received via HL7 FHIR eCR IG or HL7 CDA eICR IG and HL7 CDA RR IG into destination system(s) for use. Recommend additional clarity on what is meant by receive, validate, parse and filter.

Deven McGraw: Oops - typo. Protection care access rule attempts to PROTECT actors from accusations of information blocking when they decline in clinical situations to share information where they are protecting patients and/or caregivers by honoring a patient's privacy and their preferences for privacy. {Rest of the recommendation that begins with "While ASTP…." Remains as is.

Deven McGraw: (Emphasis added)

Sarah DeSilvey: Well done, colleagues. Excellent and exhaustive work. We appreciate you

Deven McGraw: Incredible body of work

Mark Sendak: Recommendation 142: Recommend that ASTP incorporate feedback from health IT vendor customers and other users such as patients on the adequacy of the functionality of health IT vendors as part of the certification criteria. There is currently no mechanism to incorporate feedback from health IT vendor customers and patients to verify that required data elements and functionality required as part of the certification process are supported and function adequately for the purposes that they are intended. This feedback process could mirror Medical Device Reporting (MDR) by the FDA that provides a mechanism for users to report issues with approved devices as a post market surveillance tool. We also recommend creation of education and marketing content to support health IT vendor customers and users to provide feedback and report challenges with health IT functionality.

Rochelle Prosser: Thank you everyone

Mark Sendak: Added the sentence to the end ^

Deven McGraw: I had a typo in my first iteration - fixed in in the second one ;)

Sarah DeSilvey: thank you!

Noam Arzt: Just note that that last long sentence is not really in English...

Deven McGraw: Seems clear enough to get the point across, though 🙄

Noam Arzt: Yes... :)

Noam Arzt: But the top says "others uses such as customers." Does not seem like the last change is actually consistent.

Noam Arzt: Sorry, such as patients... right

Accel Solutions: From Ike: Recommendation: ASTP should consider the dates of certification expiration and align these dates with other program requirements such as CDC reporting and Promoting Opportunity program reporting.

Noam Arzt: I think that's Promoting Interoperability...

Seth Pazinski: Recommendation: ASTP should consider the dates of certification expiration and align these dates with other program requirements such as CDC reporting and Promoting Interoperability program reporting.

Bryant Thomas Karras: woohoo!

Sarah DeSilvey: well done!

Katrina Miller Parrish: Again KUDOS Leads!!

Mark Sendak: Thank you all!

Mark Sendak: Big fan of #3, happy that was included

Ram Sriram: There is NIST's AI Risk Management Framework that could be applied to health care

Ram Sriram: Agree with Mark. The NIST's Framework needs to be extended/expanded for health care. It could be a good starting point

Ram Sriram: Won't be able to attend the afternoon session, as I have to attend another meeting.

Deven McGraw: Important feedback, Rochelle - am going to bring that back to the group(s) considering these issues in which I participate. And would welcome a bigger conversation about this if deemed appropriate by the co-chairs & ASTP.

Sarah DeSilvey: Thank you, Deven!

Melissa Soliz: Question from Public participant (for the public participation portion, if there is one): Does the HITAC view the Section 1557 regulations as already requiring regulated entities as meeting WCAG standards, and does there need to be better alignment between 45 CFR Part 170 and the Section 1557 regulations? (And if I shouldn't be using the chat function please let me know. I'm not sure on protocol for public comments. I have to hop off in about 15 minutes, so wanted to ask.)

Seth Pazinski: @Melissa Soliz Thank you for sharing your public comment. Yes, public comment is encouraged throughout the HITAC meetings using the chat. There is also time at the end of each meeting for verbal public comment.

Susan Clark: FYI DirectTrust is actively working on Identity. Including comments being developed to the 2nd public draft of NIST 800-63-4. We already have regular meetings with ASTP/ONC. Let us know if you would like to have us provide any more information.

Lee Fleisher: I want to second Anna’s comments about the need to prioritize these perspectives and important information for the individual. This is critically improtatnt

Medell K. Briggs-Malonson: @Melissa, I cannot speak on behalf of HITAC, but there are overlaps between regulations. The purpose of the final rule of Section 1557 is an expansion of non-discrimination protections as charged by the Office of Civil Rights that includes Heath IT. The agencies work well together, but our point is that supporting a highly-coordinated approach to advance safe, ethical, and just heath IT among all agencies with a lead agency would be helpful for all.

Jim Jirjis: even blood pressures etc can be a huge set of data points that need to be processed

Rochelle Prosser: Understanding RPM devices must have a HCP to act on critical reporting or findings. There for there won't be a removal of the human touch for verification of those findings.

Melissa Soliz: Thx @Medell! One of the challenges on the implementation side is understanding what level of industry standards should be used (or must be used) to meet the Section 1557 requirements. It would be useful for the certified health IT regulations to specify this to help advance those standards (at least for the certified health IT). Thx you for this work and allowing public participation!

Anna McCollister: My blood glucose data and blood pressure data both write structured data to health kit. Why can't data that can be written into health kit be also written into the EHR? Or why can't it be pulled into the EHR from health kit.

Susan Clark: Device security is also a barrier to interoperability. I just heard my friends in biomedical engineering talking about this at an event in August.

Derek De Young: For patient entered data - It is possible to do this today with different EHRs. With Epic (which I can speak to confidently), patient entered device data can be brought in directly through MyChart, monitored and viewed by clinicians. We can integrate with Apple and Google health kit through MyChart. If there is a workgroup talking about this and wants to bring in experts to talk through some of the challenges, I would be happy to bring in some Exports on our side.

Jim Jirjis: +1 Derek

Medell K. Briggs-Malonson: +1 Derek. We are able to do the same. However, I do think the process to connect the device(s) is still a bit too complicated from a patient perspective. Simplifying and scaling this technology is key.

Bryant Thomas Karras: would like to see non-HHS Fed agencies added as well

Jim Jirjis: +1 Medell that is why standards for device interoperability seems to be key...to avoid the complexity of interfacing all of these proprietary interfaces. It just was not clear how to address the incentives to adhere to them

Bryant Thomas Karras: DOJ; DoD; VHA; DHS; EPA

Medell K. Briggs-Malonson: + 1 Jim, I agree. With all of the devices that are on the market, I have seen patients struggle to interface with our MyChart system to upload their data. This has placed a burden on patients (and clinician) and has led to patients opting out of great clinical programs that would be of benefit. And there has been a larger opt out by our more vulnerable populations.

Derek De Young: +1 Medell - Agree - we would be happy to come discuss what we see working and where we see challenges when it comes to devices. We see the most success using the Health Kit products today.

Medell K. Briggs-Malonson: That sounds great, Derek!

Eliel Oliveira: +1 Medell. Without saying that there are a large number of electronic systems many that are not required to be certified and many that are used by community health center, FQHCs, LTPAC, etc. So, having one system that can do some of these integrations is very limiting.

Sarah DeSilvey: +1 Eliel from a very rural FQHC family practice provider

Medell K. Briggs-Malonson: +2 Eliel! That is an entirely more challenging and highly important discussion given the Health IT infrastructures in these settings.

Trudi Matthews: For Elisabeth Myers: Where in development are the data elements needed for reporting the health-related social needs for CMS hospital inpatient quality reporting and other CMS quality programs? Are they represented in any of these domains? Or are there plans to include them in future?

Anna McCollister: My continuous glucose monitor, blood glucose meter, blood pressure cuff, digital scale all write directly to apps on my smart phone that stores the data directly in health kit. Health kit pulls data directly from EHR

portals (when the trust tokens aren't expired). I use. iPhone but all of these devices work with android systems, as well. If the smart phone call pull data from the EHR, why can't it write data to the EHR? That would not create additional burden for patients. It can be enabled to happen automatically without adding to the workload. The data is already normalized, validated, etc. The digital divide for smart phones is increasingly small, even for very under resourced. Individuals and settings. This feels very doable. We just need for it to be a priority.

Sarah DeSilvey: The good thing is that every present and incoming HRSN eCQM aligns with Gravity and thus our USCDIv2 elements

Sarah DeSilvey: Thank you, Beth!

Katrina Miller Parrish: https://uscdiplus.healthit.gov/uscdi?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=7ddf78228745b95098e5edb90cbb3525&view=sp

Eliel Oliveira: 🎉

Deven McGraw: Thanks to the co-chairs and ASTP staff, and of course all who contributed to the work we considered today.

Questions and Comments Received Via Email

No comments were received via email.

Resources

HITAC Webpage
HITAC - September 12, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 10/10/24.