National Committee on Vital and Health Statistics

Transcript
April 12, 2024 8:00 a.m. – 3:00 p.m. ET
Hybrid Meeting

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sarah Lessem	**DHHS**	**Executive Staff Director (Acting)**
Rebecca Hines	**NCHS**	**Executive Secretary**
Angela Alton	City of Hope	Member
Catherine Molchan Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	Network for Public Health Law	Member
Tammy Feenstra Banks	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Healthcare Consultant	Member
Valerie Watzlaf	University of Pittsburgh	Member
R. Lenel James	Blue Cross Blue Shield Association	Member
Steven Wagner	University of Pittsburgh	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Shirley Castillo	NCHS	Staff
Gwen Mustaf	NCHS	Staff
Naomi Michaelis	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
JaWanna Henry	Office of the National Coordinator for Health Information Technology (ONC)	Interoperability Systems Branch Chief
Mariann Yeager	The Sequoia Project	CEO
Chantal Worzala	Alazro Consulting, LLC	Principal
Steve Gravely	Gravely Group	Founder
Jennifer Goldsack	Digital Medicine Society	Chief Executive Officer
Jonathan Jungck	Palantir Technologies	HIPAA Security Officer

Von Nguyen	Google	Clinical Lead
Garrett Adams	Epic Systems	Lead, EpicCare Ambulatory Research and Development
Timothy Noonan	Office of Civil Rights	Deputy Director for Health Information Privacy, Data and Cybersecurity

Call to Order/Roll Call

Rebecca Hines: Good morning. Welcome to day two of the National Committee on Vital and Health Statistics, NCVHS, meeting. Our spring convening in-person. Delighted to be here together again. My name is Rebecca Hines. I am the executive secretary and designated federal officer for the committee. I will put in the chat information about the agenda and the bios for all of our wonderful panelists here this morning. We have two panels today. Let us just get started by taking care of roll call, starting with our chair, Jacki.

Jacki Monson: Good morning, everyone. Jacki Monson, Sutter Health, chair, NCVHS, no conflicts.

Rebecca Hines: Cathy.

Catherine Donald. Hi. Good morning. Cathy Donald, Alabama Department of Public Health, member of the Full Committee, member of the ICD-11 Workgroup. If there are any discussions regarding reproductive health, I will recuse myself.

Rebecca Hines: Thank you, Cathy.

Deb Strickland.

Debra Strickland: Deb Strickland, member of the Full Committee and member of the Standards Subcommittee. I have no conflicts.

Rebecca Hines: Michael.

Michael Hodgkins: Michael Hodgkins, member of the Full Committee, member of the Subcommittee on Standards, ICD-11. I am the immediate past chair of the Sequoia Project and Sequoia is the Recognized Coordinating Entity. But I do not think that creates a conflict for this panel today.

Rebecca Hines: It creates necessary expertise that we so desperately need.

Val.

Valerie Watzlaf. Good morning, everybody. I am Val Watzlaf. I am with the University of Pittsburgh. I am on the Full Committee. I am chairing the Privacy, Confidentiality, and Security Subcommittee and I am on the Workgroup for ICD-11. I have no conflicts.

Rebecca Hines: Lenel.

R. Lenel James. Lenel James, Blue Cross Blue Shield Association, member of the Standards Committee and the Full Committee, have no conflicts.

Rebecca Hines: Jamie.

Jamie Ferguson: Jamie Ferguson, member of the Full Committee, chair of ICD-11, member of the Subcommittee for Standards and PCS. I have no conflicts, but I am a member of the Board of Directors of Sequoia and co-chair of their Governance Committee.

Rebecca Hines: Thank you, Jamie.

Tammy.

Tammy Banks: Tammy Banks, member of the Full Committee, Executive Committee, co-chair of the Standards Subcommittee, no conflicts, principal for ImpactQue.

Rebecca Hines: Steve.

Steven Wagner: Steve Wagner, member of the Full Committee, the Executive Committee, and the Standards Subcommittee, and I have no conflict.

Rebecca Hines: Thank you. And we hope to see Denise Chrysler here shortly.

Let us move over to online. Good morning, Wu Xu.

Wu Xu: Good morning. My name is Wu Xu with University of Utah. I am a member of the Full Committee and ICD-11 Workgroup. I have no conflicts.

Rebecca Hines: Thank you, Wu.

Angela Alton.

Angela Alton: Good morning. I am Angela Alton with City of Hope. I serve on the Full Committee. I am a member of the Subcommittee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: We have a quorum so we can meet. Let us move over to staff starting with ASPE.

Sarah Lessem: Sarah Lessem at ASPE.

Rebecca Hines: Lorraine, are you on?

Lorraine Doo: Lorraine Doo with the Centers for Medicare and Medicaid Services, the Health Informatics and Interoperability Group, and lead staff to the Standards Subcommittee.

Rebecca Hines: Beautiful and we have in the room Shirley Castillo and there are two other staff from the National Center for Health Statistics with us here today, Naomi Michaelis and John Halter, who you all will have an opportunity to meet.

We had public comment yesterday, but again if anyone is so inclined to send a message or a comment to the committee, you can always email it at any time to NCVHSmail@CDC.gov and that information also is on the committee website. I will pop the agenda in the chat and turn it over to our chair.

Welcome Remarks/Agenda Review

Jacki Monson: Great. Let us go through the agenda. We just covered roll call. First up today is going to be TEFCA. WE have panelists led by Michael Hodgkins. We then have a break. Then we will have an update from the Office for Civil Rights, Tim Noonan. And then we will move into the NCVHS Workplan Development led by me and then take a break for lunch early today. And then we will move into a panel on the exploration of privacy and security with AI in technology and health care, led by Val and me. And then we will move back into NCVHS Workplan Development and then we will do next steps and wrap up by 3 o'clock today.

Let us go ahead and get started. Michael, I am turning it over to you.

TEFCA (Trusted Exchange Framework and Common Agreement) Update

Michael Hodgkins: Good morning. I wanted to welcome our panel. You should know that you are the only panel to my knowledge where we actually assemble the full page of questions and scenarios to provide you in advance and to provide the committee members in advance, which I think is a testimony to the heightened interest in all things TEFCA before the panel.

The committee has the bios of all the individuals. I am just going to do my best to try to keep us to 10 to 12 minutes each for your opening comments because this committee has a lot of questions that they are going to want to throw at you and I am sure that it will be an interesting discussion.

With that, I think we are going to start with JaWanna Henry. JaWanna, can we tee up your slides?

JaWanna Henry: Great. Thank you all for having me as the first person on this panel. I am the Interoperability Systems Branch Chief within the Office of Policy. I have the pleasure of really starting out the conversation about TEFCA and talking about where we have been, where we are, and where we are expecting to go. And then I will pass it over to the RCE to really get into some of the details about TEFCA, some of the changes that have been made and then Chantal will have the pleasure of talking about where we are from a public health perspective. I am not introducing the panel. I am just indicating what we are going to talk about here.

First, just to get us started. Again, where did we come from? TEFCA started with 21st Century Cures Act in 2016. And ONC was charged with developing or supporting a trusted exchange framework for trust policies and practices and for that common agreement to support exchange between health information.

With that, we have three goals for TEFCA and that first one really was establishing a universal floor from a policy and technical perspective to support nationwide interoperability. And when setting that floor, the second goal was actually making sure that connectivity was simple. We wanted to make it simple but also make sure that it was secure for the purposes of improving patient care, enhancing the welfare of populations, and generating health care value. Once we established that floor, simplify connectivity, our third goal, which we cannot forget, is really enabling individuals to gather their health care information.

You will see on this timeline, we have done a lot of work from 2016 to 2024 since 21st Century Cures came out that really established TEFCA. We spent a couple of years really coming up with that first draft of TEFCA. And then in 2019, we selected the Sequoia Project as a grantee or an awardee to serve as our Recognized Coordinating Entity. Once we got our relationship with RCE, we really started our stakeholder engagement that you can see from 2020 to 2021. Throughout the years, the work that we have been doing aside from getting the first draft of the common agreement, we have worked with RCE in drafting our first QHIN Technical Framework and addressing or updating some of the Elements of the Common Agreement.

In 2022 of January, we were able to release the first Common Agreement, that first version, that first QTF and some additional materials such as our Standard Operating Procedures.

And then excitedly in February 2023, we were able to get our first applications for TEFCA and start going through that process and becoming qualified or designated qualified health information network.

And then we were excited in December. You see the two stars here because in December 2023, all that work starting from 2016 to 2023 led us to that point of becoming operational. With that, we released the Common Agreement Version 1.1 and the QTF 1.1.

Where we are now is we are in that first quarter of 2024. We are working with the RCE so that we can get that draft version of the Common Agreement or that final version of the Common Agreement 2.0 that really focuses on facilitating FHIR. We are looking forward to releasing some additional materials within this first quarter as well.

I mentioned that I was going to give you that overview of where we started, where we are going, where we are and where we are going. I just recently released a Report to Congress, which actually highlights where we started and where we are with TEFCA and in that report. It really focuses on the progress that has been made with our health information networks and our health information exchanges nationwide. They have been making significant progress. But we do understand that there are still some limitations in that information exchange. This is where TEFCA comes in to hopefully address some of those limitations.

As part of that Report to Congress, we obviously highlight that we had our initial group of designated QHINs in 2023. And exciting news, I think we had about five in December and then leading into February, we reached QHINs that were designated. Our hope for the future is that we will have much more to come. We have been working really to develop that pathway that through TEFCA can advance some of those common standards that we have been working on such as USCDI and HL7 and continuing to update our document so that we can continue establishing those expected business practices for sharing electronic information.

Within that report, you will find some statistics where you will see the progress that HINs and HIEs have been making. You see 85 percent of hospitals reported being able to query information or find information. About half of physicians reported being able to search or query for patient health information in EHRs.

But the thing I really want to highlight is that when you look at the data and this data all comes from the American Hospital Association Survey that was conducted I believe between 2021 and 2022 is that 64 percent of US hospitals reported using national networks that enable exchange across different health IT systems in 2021. And that most common method of exchanging information is through health information networks.

But with that success, there are also some barriers that are reported in this report as well. You can see that there are some challenges with exchanging electronic patient health information and across other settings. You had about 72 percent of hospitals per this survey that reported challenges in exchanging data across different EHR vendors. Then you had about 54 percent who had challenges with different interfaces across vendors. And then about 75 percent who reported challenges with matching and identifying. Then you had about three-quarters of US hospitals that actually reported experiencing at least one challenge to electronic public health reporting in 2022.

I give you again just the successes but also looking at some of these barriers that we still have seen in 2021 and 2022 to say that again there are these challenges that we need to address and our hope is that we can do that through TEFCA.

The exciting news, as I said before, is TEFCA is operational. These are our the seven QHINs that as of today are able to immediately begin supporting the exchange, who started exchanging. And these QHINs collectively cover most of our US hospitals and tens of thousands of health care providers across the US.

We would like to talk about really the benefits of TEFCA. When we talk about these seven QHINs and who they support across the US, we are looking at technology developers who can take what we have done with TEFCA and really scale it from a policy and technical perspective for individuals as I mentioned as our goal three. It really is trying to give them access to their information that they may have across multiple providers from state governments and public health authorities. The goal is really to make connections easier for them so that they can have timely data.

For health care providers and health systems, we are really working through this so that we can improve care coordination and population health so that they actually can receive the data that they need to have a more informed picture of their patients.

And then for health care plans, really using TEFCA so that they can access and share their data to be able to manage care.

Generally, those are some of the benefits across the different groups. But the benefits for TEFCA that we want to highlight is that we are really working towards is increasing secure access to electronic health information, really working to ensure that throughout this exchange of information that there is a core set of data that is available per the Common Agreement for different exchange purposes. And with all of this, we want to make sure that we at least decrease costs and really improve efficiency and not having folks to have to join multiple HINs or sign multiple agreements or create one-off interfaces just to have access to information.

And then the thing to highlight that I believe you all are here to hear more about is really the common set of privacy and security requirements to protect patient health information.

Again, just an overview. TEFCA really does establish the policy and technical requirements for sharing information. We have the Common Agreement, which is really the contract for TEFCA. It sets the clear policy but also highlights some of the technical requirements through referencing our QTF.

The things you will find that are applicable to our QHINs, to our participants, to the sub-participants, is that shared governance, a structured onboarding process. Common protocols for authenticating and authorizing users. The shared directory services that are being built out of this and then really guidance on how QHINs should respond to requests for data that are required under the Common Agreement.

These are just again a couple of things just to highlight such as again our guidance on compliance and relevant privacy and security rules and security incident notifications.

This slide really just highlights how TEFCA is really providing the strong privacy and security protections. It is described more in our Common Agreement. But most of our organizations who are HIPAA-covered entities are business associates of covered entities and obviously have to comply with the HIPAA Privacy

and Security Rules. But those who are also non-covered HIPAA entities – they must protect the individually identifiable information as well as we believe that to be TEFCA information in pretty much the same way as our HIPAA-covered entities.

Again, we would like to highlight this as an important feature as we think about QHINs and our participants and sub-participants, really facilitating exchange of information for individuals.

I would just like to highlight our exchange purposes that we are supporting through TEFCA. We have about six right now. There are three that are actually required: our individual access services and our treatment and our health care operations. I know we oftentimes say these are the six exchange purposes. But to make it very plain, these exchange purposes are there to support our individuals, our health care providers, the health plans, our public health authorities.

For example, some of the examples are patients again who may have multiple health care providers, being able to have access to that data through a consumer-facing app so that they can actually have all of their data in one place. A primary care physician who is seeing the patient, who wants to have a full picture of that patient prior to the visit, being able to have access to that data on that patient. And then for our public health authorities, just the example of being able to perform case investigations and having access to that data.

The way that we are doing TEFCA aside from the Common Agreement, really highlighting the technical part of this, is we are working through some of the things that we have already had in place or that we have been working through the past couple of years is our common standards and looking at modern health IT capabilities. These are the things that you are familiar with: USCDI, things that within our HTI-1 Final Rule, which really is focused on promoting equity, reducing health disparities, and obviously supporting public health data, and interoperability.

The things that you will find at HTI-1 if you have not read it yet are really the advancement of FHIR and the use of API. You can see here again from the American Hospital Association that there are about four in five non-federal acute hospitals that are actually using APIs to enable health care provider APIs that can write data and read data and that is specific to certified health information.

The thing to really highlight for this slide is again these four things at the bottom. The standards that we are using, health IT capabilities that we are expecting to see through TEFCA is the use of USCDI, the use of APIs, electronic health information that can be exported for a single patient, just thinking about FHIR, the use of FHIR, both FHIR and looking and multi-factor authentication and encryption.

The exciting news as I talk about these things and common standards and where we are going is that we are expecting TEFCA to support FHIR and we are working very hard to get to that point to be able to share the information with you. Once we became operational, we got our first set of QHINs in place. We also were excited to release our FHIR Roadmap for TEFCA, the second version, which really highlights from a technical perspective where we are and where we are going and really that we are keeping that momentum so that we can get to the point of the future FHIR with TEFCA.

We are also looking forward to releasing our most recent version of the Common Agreement, which once you see the final version of that, you will see the updates that require support for HL7 FHIR-based transactions.

At this point, we feel like again from 2016 up to 2024, we are in the beginning of the TEFCA era. In 2023, we became operational. We went live. The thing that we are expecting as we see TEFCA continue to grow is that we want to see it grow. We want to see more QHINs added to the network. We are working with the RCE to continue onboarding more applicants, more applicant QHIN organizations. This is happening on a rolling basis so that we can expand TEFCA.

We are working on our education efforts so folks will have a better understanding of what TEFCA is, how they can join TEFCA. And then we are also engaging our federal partners as well so that we can get a better understanding of the role that our federal partners can play in TEFCA.

What is next in this new era of TEFCA and this network-to-network interoperability? I am just looking at the role of TEFCA to decrease administrative burden. Again, we are working with our federal partners, increasing the use of FHIR, the adoption of FHIR for exchange and for our public health agencies working with the CDC to be able to provide that data and reduce the burden of data collection and also working with our state and local HIEs again to really enhance these networks that we have through TEFCA.

With that, I will pass it over to Mariann to again talk about more of the details of TEFCA and where we are on.

Michael Hodgkins: Thank you, JaWanna. Mariann, please.

Mariann Yeager: Alright. Thank you. It is a pleasure to be here. I am Mariann Yeager, CEO of the Sequoia Project, also serve as the RCE team lead.

I am going to provide a little bit more context about TEFCA in action, sort of what it means, how it works, and then Chantal is going to talk a bit about public health.

JaWanna talked about the goals of TEFCA and this came about from the 21st Century Cures Act. But what was also taking place in 2016 was a very nascent private sector framework that was in development called care equality and that a lot of the language and concepts that TEFCA really embodies were built upon this fledgling effort at that time in the private sector.

I think one of the things I want to impart is that TEFCA was intended to build on what exists. ONC was directed to develop or support a TEFCA. That, again, was building upon existing foundations.

The one thing I want to mention on this slide and JaWanna covered the benefits but think of TEFCA as being a multi-purpose network to support multiple stakeholders that have a need for information and to support multiple use cases. Instead of having a national network or a network of networks to support health care treatment and then a separate one for more payment in health care operations and then a separate one to support individual's access and then a separate one for public health, we are building one network for all. If you imagine years from now when we have another pandemic, we will not be scrambling trying to get data to public health agencies. They can tap into this critical infrastructure. And that is what TEFCA really is about.

TEFCA is live. These organizations that were designated in December and February had to meet a very rigorous set of expectations that are laid out in an onboarding and designation process.

The intent here is that these are supposed to be high performing, high resilient, high secure nodes. Together, they represent a backbone for information exchange that they themselves interconnect other

organizations. When I mention critical infrastructure, it is legit. This will serve as part of the critical infrastructure in the US. That is the level of I would say important due diligence that each has to do.

How is TEFCA designed to work? ONC is setting policy. They retain certain inherent government functions in terms of governance. They have selected the Sequoia Project to work with them as a private sector organization. We are a 501c3. We have more than 12 years of experience of developing and supporting trust frameworks. We have a very experienced team working on this.

Our role is really working with ONC to develop the foundation policy and technical requirements in support for ONC for TEFCA. We are the only body that can actually designate these networks that want to be TEFCA-designated qualified health information networks. They have to demonstrate to us both through documentation and attestation and testing that they meet the rigorous requirements. And each of those networks in and of themselves represents a connected set of participants or sub-participants. The idea is that they are going to be diversity in QHINs and diversity in the communities and organizations that they connect.

When we think about what Sequoia does specifically as the RCE, it really falls into these five buckets. The first is that we are coordinating with ONC again working on developing the baseline policy and technical requirements. We evaluate and designate QHINs. We also monitor and oversee ongoing compliance, so things do change and we have to make sure that they continue to meet the same bar and rigor.

One thing folks may not realize is that we also maintain a FHIR R4 based health care endpoint directory. That is sort of like the yellow pages of endpoints and that also indicates what each organization is able to support in terms of use cases and what not. That is a very important way for folks to know with whom they can exchange information.

We are in the process of establishing a governance and engaging and getting feedback from stakeholders, which I have to say is probably one of the most important – the last two bullets are two of the most important things that we are doing to make TEFCA successful. One, good governance is the absolute foundation for trust. And two is that we have to make sure that those who want to participate in TEFCA have a voice in the process. This is different.

Here are the components of TEFCA, not that you have to understand the underpinnings of all of them but there is a contractual agreement that folks have to sign. These are legally enforceable via contract, the requirements.

There are a lot of details that may change. Instead of putting them in a legal agreement – the legal agreement are the terms that endure without change over time. There are a lot of other supplemental documents that are pointed to such as the standard operating procedures that delineate how the terms of the agreement will be implemented.

The QHIN technical framework is just a way of saying it is an implementation guide. It points to existing standards. It is not reinventing the wheel there. And then there are processes around onboarding, metrics for assessing for how we are performing and then governance.

There are slides that talk about each of these in more detail. I probably will not go into those into too much detail. But to give you a sense of how this plays out in practice, the common agreement is one agreement. It is identical that the RCE we sign and that the QHIN signs. Everybody is subject to identical

terms. If there is even one change in a character, it has to go through a whole change management process. The value here is once you sign onto TEFCA, everybody is abiding by the same rules and you have a strong degree of assurance that that is happening.

Each QHIN is obligated to have their organizations that connect to them to sign terms of participation. Again, think about health care organizations in completely different parts of the country and have to know and rely on that if anyone who is requesting or with whom they are sharing information is subject to the same standards without having to assess were they complying with HIPAA or are they going to appropriately use and disclose the information. This is the level setting across the board. And of course, that flows down now.

There are some organizations that are evolved more as enablers. They provide connectivity services or gateways or technology solutions to them. And then the TEFCA-connected entity is of course either connected directly to a QHIN or maybe they connect to an HIE that connects to QHIN. That is kind of how that works.

There are more details and definitions of each of these artifacts. I have a feeling you probably do not care too much about that. But it is here if you are interested. These are the many different documents that we do support and develop and maintain over time. They are – Chantal, when we put these out first. Stakeholder feedback – was it 19 of them? It was 19. It was a common agreement that was revised. The common agreement that the QHINs are signed and it is used for production. We revamped that significantly, put it out for stakeholder feedback. This is not rule making. This is all private sector facilitated with ONC government-endorsed framework. But those stakeholders had an opportunity to review the revised common agreement, the revised terms of participation, a whole companion of documents that accompany it as well.

I will spare you of the QHIN technical framework. The RCE directory tells you a little bit more what that is about. Again, it is more a technical service that the QHINs access so they know who they can share data with and that is updated periodically.

Probably the most important thing to drill down on is governance. Right now, we have stood up a transitional governing council. Their goal is to fulfill the governance obligations on an interim basis until we can establish caucuses that are representative of the QHINs and representative of the entities that connect to QHINs. They have certain rules in voting and agreeing to changes and that leads into an overall governance approach.

We are in the process of chartering our very first advisory group. That group is interesting because they are the ones dealing with the many nuances and intricacies of understanding the policy and technical requirements of TEFCA and importantly establish security council. That group has been stood up as well. We are I would say in the informative stages of establishing the governance structures and processes. We have a lot more work to do to mature those and to make sure they support the longer-term charter governing council going forward.

Again, we have a lot we are going to be supporting going forward. Of course, supporting FHIR-based exchange. Importantly, supporting use cases beyond treatment such as health care operations and public health and individual access services, which is the ability for a person to access their own information.

We did move from leaving the QHINs to determine how they flow down provisions to have standalone terms of participation that are static so that everybody knows. Everybody is subject to the exact same obligations downstream. And then the ability for participants to connect to multiple QHINs because they often have different data sources.

I think that is all we are going to have time to cover today. I think this is when I am turning it over to Chantal.

Michael Hodgkins: Thank you, Mariann. Chantal, please.

Chantal Worzala: Great. Thank you. Good morning. I know we want to get to the conversation so I will be brief. We are in the middle of finalizing a new set of documents. It gets a little complicated because we say TEFCA is live, and it is. The QHINs are today sharing data. They are doing so under Common Agreement version 1.1 so kind of the middle panel here as where we are today.

Very imminently, we will release Common Agreement version 2 that provides more flexibility, really focuses on FHIR and is creating the ability for a little more nimbleness in how TEFCA operates. We are also working very carefully on a transition plan. People have been asking how do we get from 1.1 to 2. And that is being managed in a way that will allow for transition times. For example, the QHINs themselves, those who are already designated do not actually have to re-sign version 2, but we are giving them a transition period to ramp up to the requirements in version 2 just as one example.

We are coming to you at a time where we are in a little bit of policy evolution that will lead to take off in participation in TEFCA once we have the Common Agreement v.2, the whole suite of SOPs, 13 to 15 of them at last count, and the QTF v.2 all together. And we are at a really exciting time because the governance structures stood up, which gives us a chance to really make this a collaborative set of decision making. I emphasize collaborative. We are in touch with the QHINs and some of the participants in TEFCA exchange on a daily if not hourly basis 24/7. It is exciting. It is hard and it is exciting because we are building, as Mariann said, the infrastructure.

As the person who talks to folks about TEFCA a lot, we are in a very odd place where we are trying to explain this thing that we hope nobody will have to know about in the future. This is just meant to be core infrastructure that works. It is the innards of the television. You use the clicker to turn it on and it works. That is where we are headed. But in order to get there, we have to explain it to people.

There is an envelope for TEFCA that is applicable law. You do not get out of your state privacy law obligations when you are responding to a query via TEFCA. You still have all those obligations. But you know that those who are asking for your data have signed a common agreement. That means that they too are tied to at least the federal HIPAA privacy and security requirements. They are all using the QHIN technical framework so that the data you get from them will be in USCDI standards to the extent that the data is from the USCDI canon.

And then you know that they have the same obligations to – not to pick a sensitive issue but to report in a cybersecurity incident. They are under the same obligations to use standards that are designated by ONC for public health reporting. That is where we are going to make it so that nobody even needs to know about TEFCA. They just magically can send and share data for the very important health care purposes that are the exchange purposes.

Here is the whole canon of documents that we put out in January. We know you read every one of the 200 plus pages. There are certain concepts that evolved. I think Mariann hit the highlights. One that I will emphasize on top of what she said is we got a lot of feedback from stakeholders that they did not want to be tied to just one QHIN. For example, if you are an integrated delivery system with 200 hospitals and 1000 clinics, you do not actually have to have all that data flow through one QHIN.

You can decide, just making it up, that your western division can go through one QHIN, your eastern division can go through another or your hospitals can go through one, your clinics can go through another. We have created that flexibility in version 2, which was very important to stakeholders because there is no such thing as one information system in a health care organization. What this means is that your individual information systems need to flow through a single QHIN so that we are not having duplicate data but different information systems can flow into TEFCA via a myriad of arrangements. Again, building from what we have today. Incredibly important foundational concept for TEFCA.

We do have a fire roadmap for those who are very interested in seeing FHIR expand and our intent is to have FHIR exchange live this year via TEFCA.

Spotlight on public health. I know this is an area you are interested in. Public health is one of six exchange purposes that are permitted in the common agreement. The others, treatment, payment, health care operations are essentially tied to definitions in HIPAA. Health care operations have a little bit of a narrower slice than what is the full definition in HIPAA. Public health is mostly about health care organizations reporting into public health agencies and allowing public health agencies to query for information, for example, when they are doing a case investigation.

Government benefits determination is like the Social Security Administration saying we have a disability application. We need medical records to determine eligibility.

And then individual access is really the idea that under HIPAA, individuals have a right of access to their health care data. There are third-party entities out there that want to help people get their data from across multiple sources. That is what this exchange purpose is about.

It is very important. TEFCA has raised the bar in this area where third-party applications that may not be HIPAA-covered entities are actually through TEFCA contractually obligated to follow the HIPAA privacy and security requirements. We are addressing through TEFCA one of those key issues of data leaving a HIPAA-protected bubble as I think about it and not having the same protections. Again, listening to stakeholders, using this contractual vehicle to address some of these key issues.

I am not going to dwell anymore on the exchange purposes. Public health, as you can see here. We borrow heavily from existing concepts, including what is a public health authority and then what does it mean to get data to public health or for public health to ask for data.

Again, this is all within existing law. If a public health authority in Missouri is asking for data, any state law will also apply in addition to all of the agreements and requirements of TEFCA.

I am going to let you take your time at a later date to look at this information flow. When I present this, I usually say everything in the middle should be invisible to the people on either end. Public health authority is asking for data. All they do is work with their QHIN to say I need data on this person who may have Ebola. Then there are all these QHINs, the crucial infrastructure that goes out and says who

has data about them, and the public health authority gets the data back. Of course, people want to understand everything in the middle. But our ultimate goal is that you do not have to.

When it comes to public health, we worked very closely with the public health community with ONC and with CDC and came up with an SOP, standard operating procedure, that addresses their needs or we thought it did. And then we put it out for comment and now we are working through the feedback that we received to sharpen that and make sure that it is in fact going to be supportive of their needs out of the gate.

What we are doing is really enabling message delivery within the existing QHIN framework. QHIN message delivery for public health will be the same as QHIN message delivery for treatment that allows reporting entities, for example, hospitals and clinics, and labs to report to public health through TEFCA rather than having a bespoke one-off connection to a public health entity. That is the ultimate goal.

And if you do not know, large health systems today can have hundreds and even thousands of one-off connections to different public health reporting repositories. The goal here is to streamline and create efficiency there.

On the flip side, very important to the public health community is to enable them to be able to use an automated mechanism to query for information rather than having to pick up a phone, rather than having to ask for a fax. They can query and get back data that they need when they are investigating a case. Today this is about individuals, but we are working towards solutions that might enable bulk FHIR query, in particular.

Some of the considerations. Participation in TEFCA is voluntary for everyone. But we believe it is valuable. Public health has an exception in the Common Agreement in the terms of participation from having to respond to certain queries that have required response because they have their own set of rules. They are encouraged to respond, not required.

All of the applicable laws still apply, including privacy and security. We are here too proposing to raise the bar a little bit on information shared for public help in that no entity could persist information shared for a public heath purpose unless they are the intended recipient of that data. That was important to the public health community to have that higher privacy safeguard for public health data.

And then we are looking at electronic case reporting, electronic lab reporting, and case investigation for both case reporting and ELR. We are building from the existing HL7 standards. That is really where we are going with public health.

Public health communities have multiple ways to connect into TEFCA. They can use existing, for example, state partners if they want to do that.

I have already talked through what was in our SOP. I will just leave you with the idea that you can visit the RCE website for a host of educational materials. I will stop there.

Michael Hodgkins: Thank you, Chantal. Just for the committee members and those participating by phone, I believe there are links to a lot of resource material that the panelists have provided that are available for anyone that wants to dive into this in greater depth. Thank you, Chantal.

Now, I would loke to turn it over to Steve Gravely. Steve, go ahead.

Steve Gravely: Thank you, Michael. Always a pleasure. I am Steve Gravely. I am going to try and take a brief but deep dive into privacy and security under TEFCA. I know there are lots of questions so bear with me.

A little change in color scheme. You already have my bio so I will not linger on this.

TEFCA's approach to data privacy. Some of you have known me for a long time. Some of you I have yet to meet. But I remember when Mariann and I started this a few years ago with the Nationwide Health Information Network that was several coordinators ago. We were both in kindergarten. We have been doing this for a while and this is really exciting now that TEFCA is live. I hope you share that excitement.

Data approach and security. We all understand that data moves at the speed of trust. Without trust, nothing is going to happen. Data approach and security is built into the DNA of TEFCA. I would say from the very beginning of TEFCA. Privacy and security information was recognized as a potential blocking issue to the success of TEFCA.

You have already heard some high-level discretion of how difficult it is to become a QHIN. We now have seven of them, I believe, with two or three more in the pipeline. But every one of those organizations has been through a very rigorous evaluation process, testing process, onboarding process. And part of that is privacy and security. When I say it is built into the DNA, that is not a hyperbole. It is a literal fact. No one can even try to become a QHIN unless they meet a set of pretty high bars. Even those who do try, not all will make it because the standards a quite high.

Mariann referred to that. I will not drill down on it. I currently represent one of the QHINs. I know what I am talking about in terms of health exchange and the process is very demanding and it should be demanding and it should continue to be demanding because we are part of the critical infrastructure. We are dealing with some of the most sensitive information that anyone has.

You have already heard about exchange purposes. I am going to try not to repeat what you have heard. But this is not simply sign up and you have the keys to the kingdom. That is not the way this works. That would be a disaster and there would be no trust. This meets a very high threshold, proves that you deserve to be able to participate in the exchange, and then follow a very set of prescriptive exchange purposes using very specific standards.

Let us talk about – as that as context, then what does this – how do we implement that? I am going to focus more on concepts rather than whether something is in the common agreement or an SOP or QTF. I think for this discussion, that is not really that important. It is more what are the concepts. You have already heard but I think it bears repeating that TEFCA recognizes that the ecosystem is very diverse. Sure. We have lots of HIPAA-covered entities that will be either a QHIN, a participant, or a sub-participant, a QPS. They are already subject to HIPAA and they have already – they may have been subject to HIPAA for a decade or more. That is right. That is wonderful. They are also subject to state law or territorial or tribal law to the extent that that law is more prescriptive than HIPAA. But HIPAA is the minimum requirement. But TEFCA is so much more than that. In all three of my previous colleagues spoke to that.

HIPAA is bringing in a lot of diversity to the ecosystem. Many of those organizations are not covered entities under HIPAA and they are not business associates under HIPAA. We embraced that and said how do we make sure that everyone is operating from the same base. We did that by – we have HIPAA-covered entities that we know what they are subject to. But then we have this universe of non-HIPAA

entities, NHEs, and the Common Agreement says that if you are an NHE, then you are going to comply with the HIPAA privacy rule and right now, I am just on privacy. The HIPAA privacy rule as a contractual standard. It does not matter if you are a QHIN, you sign the Common Agreement. But even if you are a participant or a sub-participant, you do not sign the Common Agreement, but you are subject to the terms of participation, the TOP, that are flowed down to every participant and sub-participant on down the line, which should be hundreds to thousands of Ps and Ss as TEFCA continues to evolve.

There will be many non-HIPAA entities. But everyone knows that these non-HIPAA entities are subject to HIPAA privacy as a minimum set. Now, there are some exceptions. Public health authorities, government benefit determination entities, SSA, for example, governmental health care entities, and then others as specifically identified via an SOP. Mariann talked about the change management process. But there are some organizations that are not subject to HIPAA today that are carved out intentionally. I realize public health is a little bit complex because sometimes public health is subject to HIPAA. You have hybrid entities. But we are really thinking about the non-HIPAA part of public health.

They are carved out of the privacy provisions. Why? Because they are already subject to probably more stringent requirements under either federal law or state law.

Then data privacy. That is really just set in the table. Every Q, P, or S has to have a written privacy policy that describes what its policy practices are for individually identifiable information. Now, you will immediately realize that individual identifiable information is more broad than PHI, and it should be more broad than – it is a subset of TEFCA information, but it is very broad.

When you hear Mariann and Chantal talk about how TEFCA is raising the bar, this is one very small example of how TEFCA raises the bar. Non-HIPAA entities are another pretty important example of how TEFCA is raising the bar when it comes to privacy and security of information. But everyone has to have a written privacy policy.

Now for those of us – I have been in health care for almost 50 years, and decades before HIPAA. But for those of us that are in health care, having a privacy policy is like that is a yawn. But for many others, it is a lift. They are required to have this.

Now, if you are subject to HIPAA and you have your notice of privacy practices, that is fine. TEFCA is not trying to make you do more work. The NPP will be deemed to meet the standard. But if you a non-HIPAA entity, then you are going to have to have a privacy policy and there are specific requirements for what that privacy policy has to say. We do not have time to dive into all those details today.

But as you heard earlier, why is this required? It is required in order to establish a baseline standard so that everyone in the ecosystem knows that everyone else in the ecosystem is following a common set of rules. That is really important to promote trust.

Now, IAS providers. You heard about those earlier, individual access service providers. They are special and there is an entire section of the Common Agreement that talks about IAS providers and the privacy and security requirements that they have to meet. I want to flag that for you. I want to encourage you to look at that in the resource materials.

But TEFCA hopes that we will bring in a lot of IAS providers but we also recognize that they come in all shapes and sizes and there was a lot of attention given to the privacy and security obligations of IAS providers in the TEFCA ecosystem.

Now, let us shift over to data security. Again, the Common Agreement requires HIPAA as a minimum standard for data security. If you are an NHE, this could be a pretty heavy lift. But that is the price of admission.

And then this obviously flows down to the terms of participation to all the participants and sub-participants. TEFCA is now saying if you are going to participate – yes, it is voluntary. But if you are going to participate, then you are going to adopt TEFCA security as your minimum standard for data security.

Now, we do not stop there. In addition to that as a contractual obligation, every QHIN so all seven of them today or soon to be maybe nine or ten, they have to be certified by a nationally recognized certification body in terms of their – do they meet the security requirements. Today, that is high trust. The RCE has designated high trust as its first approved certification body. Perhaps there will be more in the future. Today, everyone needs to be high trust certified. If you have been through that, you understand how rigorous that is. That is an objective third-party standard that all the QHINs have to meet.

And then in addition to that, QHINs also have to undergo an annual technical audit that is conducted by an independent third party, and that technical audit is intended to assure compliance with Security Rule, the NIST cybersecurity framework, and also the penetration testing. There is a lot here that QHINs sign on to when they decide to participate in TEFCA.

In addition to all of that, the RCE recognizes that security is an ongoing process. I think we all have been reminded of that recently with Change Healthcare. We found all these requirements but then the RCE has put on top of that ongoing security compliance and monitoring.

The Common Agreement requires that the RCE appoint a CISO and every QHIN has to appoint a CISO. The Common Agreement establishes something called the Cybersecurity Council, which is a formal body, part of the governance framework. And the Cybersecurity Council today is composed of representatives from five QHINs. That may be expanded in the future. And then the RCE CISO is the chair of the council. And that council meets, it is meeting, and they are focused on threats and addressing threats to the security of the TEFCA network and TEFCA information.

I hope you are getting the idea that when it comes to security, TEFCA's approach is a very layered approach, which I think it has to be given the ever-evolving threat surface that we have and the ingenuity of the opposition.

A couple more points and then I will wrap up so we can open the floor for questions. I would be remiss if I did not talk about data encryption. TEFCA does require that Q, P, and S are subject – they are subject to HIPAA and therefore they have to comply with the HIPAA Security Rule encryption requirements. I realize some people say that that is insufficient but that is at least a base level of compliance.

Now, for non-HIPAA entities for all of their individually identifiable information that is either in transit or at rest, that data has to be encrypted. Then for non-HIPAA entities, this is really raising the bar in a very meaningful and important way.

Then last but not least, this notion of restricted use. This really ties back to some of the foundational issues that you heard, Mariann and Chantal and JaWanna talk about and that is TEFCA is not a wide-open frontier. Once you get in, it is like whoopie. We can go find all this data. No, no. It is very locked down. There are exchange purposes. Not only are there exchange purposes but if you want to assert an

exchange purpose, you have to be the type of an organization that would be able to actually be involved in that purpose for treatment. If you are going to assert treatment, you are going to have to be the type of organization or individual that can be involved in treatment. I should not assert treatment if I were somehow able to get it, which I would not. Restrictions are really part of the DNA of TEFCA and that is also part of the DNA of privacy and security.

Any use of disclosure of TEFCA information by a Q, a P, or an S is also subject to the security rule and other applicable law. And that is so important because we now have a state law and some federal law that is more restrictive than HIPAA. Legislatures around the country are enacting privacy laws, some of which are exempt from health care, some are not that go far beyond HIPAA. That is part of the applicable law fabric that TEFCA embraces. I know I am talking a lot about HIPAA as a base. But I would be remiss to not say that in many cases, there are state laws that go well beyond HIPAA and that is part of applicable law.

With that, I think I am going to stop so we can get back to the schedule, open the floor to questions and discussions. I really appreciate the opportunity to be here. Back to you, Michael.

Michael Hodgkins: Thank you. Thank you to all of our panelists. There was a problem with people online hearing me. Are we still having that problem? Thank you.

I am going to exercise some moderator's privilege here. It occurs to me there is many a slip between the cup and the lip as the proverb says. We are still in our infancy here. But I want to direct specifically a question to Mariann and Steve. What keeps you up at night?

Mariann Yeager: What kept me up last night? I could tell you. It is quite specific. The ability for potentially well-intended actors to assert inappropriate exchange purposes is a real thing. It happens today all the time. What that means is having the right governance mechanisms in place so that concerns can be reported and addressed, investigated and resolved. Having good governance around dispute resolution remediation. Having good decision-making oversight compliance monitoring. Being proactive and understanding when you get once or twice removed from a QHIN that there are good processes for vetting these other parties who are new to this. We are not talking about health care provider organizations. We are talking about organizations that provide services that are on the fringe of that. That is really high priority right now.

Michael Hodgkins: Steve, what keeps you up at night about keeping your clients out of jail?

Steve Gravely: I was going to talk about my 2-year-old Newfoundland. Never mind.

No, fortunately, I do not have too many clients in jail. That is good news. I have not always been able to say that. No. I think Mariann is right. What keeps me up at night is just the fact that our industry is at the cross hairs of some pretty capable and serious threats. State actors, criminal enterprises, folks not to be taken lightly. And the data that we have is as the FBI continues to tell us is the most valuable data around.

That is what keeps me up at night is how do we protect the network and how do we prevent QPNs from going into lockdown mode because they are – at the tip of the sphere, they are the ones that are friends at OCR are going to looking to for state regulators and increasingly state attorney generals are going to come looking at and they understandably are worried about that. How do we prevent them from being

overly risk averse? And that is easy for me to say but overly risk averse and locking down their data when the threats are real.

Michael Hodgkins: I would like to open it up to questions from the committee and from those online. I see, Lenel, you have your card up. Why don't you go ahead?

R. Lenel James: Hello everybody. This is a great presentation. I finally got to slow down and hear everything about TEFCA. That was great.

This is to you, Mariann, but JaWanna, you may want to weigh in too. On your slide, Mariann, that talked about permitted exchanges, one of the things it said was the required response is for treatment. But when we talked about health care operations in public health, that is where SDOH and health equity comes in. As Steve just pointed out, a bunch of community organizations for which in full transparency I am a member of the payer-provider information exchange workgroup at HL7. And one of the laments I hear again and again from the payers is we are trying to do our best to get into health equity. We are trying to do our best for care coordination but we cannot the information because some people say that is not a required response. I am not going to give it to you. We cannot get some of that exchange going. What do you see in the future, Mariann, that might make that better?

Mariann Yeager: I will start and JaWanna and Chantal may want to weigh in. As a start, because TEFCA is new that it made sense to require responses for request for treatment purposes and when an individual request their own information. That was a start.

The other exchange purposes are permitted but the parties do not have to respond today but that is being revisited as a broader policy consideration for the reasons that you just mentioned.

JaWanna, do you want to speak to ONC's position on that?

JaWanna Henry: I do not know if it is too much detail we can say about that. But one of the things I do want to highlight is again just from a standard perspective in the work that we have been doing in USCDI. With USCDI between version 2 and version 3, we have been adding data elements that focus on health equity and addressing disparities. And within the USCDI version 3, you will see some of those SDOH data elements in there.

Where we are now is you will see that the USCDI aligns with the standards work that we are doing for TEFCA. More to come on that.

Chantal Worzala: I will just add. We are looking and working with the community on the health care operations exchange purposes. As you can understand, this is getting parties who have a somewhat adversarial relationship to come together to agree on what is the information that can be queried for and shared in an automated fashion.

We do need to think about things like minimum necessary. The reason treatment is required is because there can be an assumption that the data that you share for treatment is shareable under HIPAA. When you get to health care operations, you then step into minimum necessary. We have to have these conversations about what is minimum necessary. How do we scope the data that are shared for health care operations purposes so that everybody is comfortable so that the payer gets the data they need and the provider feels that they are not falling down on their HIPAA compliance obligations?

The intent is not for all of the exchange purposes to always be optional. The idea is that we are building trust and we are getting people to become comfortable with the idea that there can be automated query for information that is responded to and that you can step away from this highly manual process that we have today for sharing information. But you have to get everybody comfortable with the idea that only the data that is meant to be shared will be shared.

But I do think, to JaWanna's point, that as USCDI starts to incorporate more and more of these important data fields and we have information systems in place that are able to easily pull out the data that is in the USCDI standards. We will start to see much more of that data liquidity that we are all looking for.

Michael Hodgkins: Jamie and then Val.

Jamie Ferguson: First, thank you, all, very much. I really appreciate you being here and talking to us about TEFCA. My question is about the individual access service. I will paint a scenario. I am a provider, either a physician with a clinic or a hospital. I participate in health information exchange generally through my EHR vendor. Not all certified health IT is going to work exactly this way. But for the most part, when I get a request for health information from a third party that would be authorized by the individual, my vendor or their network has passed to me either a consent document or some other auditable indication of affirmative consent on the part of the patient and then in return for that, I am going to pass them back an access token that is time limited. But the access token – that is the keys to the kingdom. That gives this unknown third party really access to the entire record.

And then furthermore in that scenario, generally, the third parties that would be passing – that would get that consent from – they are known to the vendor and they are somehow registered with the vendor. I have some assurance that there are viable companies or something like that. I am going to pass them the access token.

But now in the case of TEFCA where you may get a request that goes from QHIN to QHIN and I get it and it is not from a known party that is registered with my vendor and do I get the same kind of – do I get a consent document or how do I get an auditable or adequate assurance that the patient has consented to give this access?

Steve Gravely: Great question. The whole point of TEFCA is to allow you to trust that at every step in the chain, the TEFCA rules, including but not limited to applicable law, have been followed. We are trying to get to automated processes. In order to do that, that is a big hill, as we all know.

As a provider, if you receive a request through TEFCA for IAS, then you have to have the assurance that before that is even gotten to you, there has been a demonstration of the requirement for consent. That is why IAS has its own dedicated section in the Common Agreement. I know that is – it is easy to gloss over that. But I really cannot emphasize enough how big a deal that is. Think about a national trust framework document and one entire section is devoted to IAS. We all recognize how challenging it is going to be for providers, in particular, to get comfortable given this information.

The short answer is that we are trying to get to the point where you do not need to lay eyes on the consent in order to be willing to provide that access. I am not convinced that we are there yet. Part of this is behavioral modification. But that is where we are headed. I will stop there.

Jamie Ferguson: Let me quickly have a follow up then. How do I audit that? Or if I get audited, how do I provide that assurance that the consent was real?

Chantal Worzala: I hear you, Jamie. I think this is one of the things that is keeping Mariann up at night and is this idea that we need the audit trails. You do not have the technical person here. I am quite convinced that Alan Swenson could walk you through exactly how you could get that audit trail should you need it because all those requirements for auditing are specified in the QTF. I will say that.

But I also hear underneath what you are saying is who is the sheriff and how are we doing enforcement. We have talked a lot about how the QHINs are the core infrastructure and Steve is probably about to kick me under the table. But the QHINs also have a sheriff role. They are responsible for monitoring the behavior of the entities underneath them. There are in these myriad SOPs and that is why we have so many of them. People are like what are you doing with all these SOPs. But we are really nailing down these kinds of issues in the SOPs.

The dispute resolution SOP becomes a very important vehicle for what I call a TEFCA-connected entity, somebody who is not a QHIN but is sharing data via TEFCA, to be able to say something looks weird to me and to know exactly how to be able to get that investigated and resolved. And the QHINs really do have a primary lift for making sure that what happens via their networks and what their participant networks are doing is in fact consistent with the rules of the road.

JaWanna Henry: I was just going to say just to Chantal's point that is clearly laid out in our QTF. If you take a look either at – I think we have the draft version that is available that can walk you through that process of what the access looks like in sharing consent.

I was also just going to highlight in the QTF as well, there is the authorization and exchange purpose that speaks specifically to that so really walking through --

Valerie Watzlaf: Thank you so much. I just want to commend you on your work that you are doing and thank you so much for being here. I just had a question and maybe this is for all of you. As you were talking, I was thinking about how each QHIN could possibly develop their own specific policies and procedures that would be different from maybe what is in the standing operating procedures or the common agreement based on their state laws or for other reasons. If that were happening, then how do you audit that? How do you look at that particularly if they were not complying appropriately or if they were not complying with the Common Agreement, what is the enforcement? What do you do to I guess enforce that or look at it?

Steve Gravely: I am going to talk about the terms of participation. I think that is probably the best example of the issue you talked about. The terms of participation are what a QHIN is required to flow down to its customers and then they are required to flow it down to their customers that are exchanging via TEFCA. There is one standard set in terms of participation and the TOP and that will be released shortly with version 2 of the Common Agreement. Maybe today. Maybe next week. And those TOPs cannot be changed. They are set in stone. They can be changed by the TEFCA process over time. But a QHIN or its participation or sub-participant – they cannot say we do not like that so we are going to block through that one.

What they can do is they can add additional requirements on top of the TOP so long as they do not contradict the TOP. I do not want to get too lost in the weeds on that.

We have assurances that people are not just going to take those TOPs and start editing them to suit their flavor. But we also have some flexibility and then of course the umbrella is always applicable law. Where there are state laws that go beyond TEFCA, those apply.

Now, we get into this very interesting and gnarly subject of extraterritorial application of state law. We all love to pick on California. And we are seeing this play out with reproductive health right now. And the Supreme Court is going to have to weigh in on this probably through multiple decisions around the extra-territorial application of state law. I am following that super closely because that is a direct corollary to TEFCA because we do embrace applicable law and that includes state law. I cannot sit here today and say that we figured that all out because that is a larger national issue that happens to be being played out now through reproductive health, but it could also be played to any other set of topics.

Mariann Yeager: I would like to clarify further. There were two parts to your question. One was from compliance monitoring; how would we know if somebody did something in conflict with their obligations under TEFCA. We do have and we have to map this out further ongoing attestations and possibly ongoing review going forward. We do not really audit all of their policies, but they are obligated by contract to comply. We are spelling out how and to what extent we will do monitoring and that they do re-verification of certain things on a periodic basis.

The second question was what do you and how was it enforced. If we discover an area of noncompliance depending upon how egregious it is, the RCE has the ability to escalate and take appropriate actions. If it is a threat to the network, say they are really doing something untoward not taking appropriate steps to address security – I am not using the right term in the Common Agreement, we can actually suspend participation. That means suspending their digital certificate. That is really the key to the kingdom if you are a QHIN and you have not – TEFCA digital certificate, that is how others digitally know that you can be trusted down the line. That would be enforcement that way of course and then removal from the directory.

There is also a dispute resolution process. If someone takes issue that maybe some other party is not compliant, then that kicks up a very formal process that is facilitated, brought to resolution, and then actions can include up to in terminating even their participation in TEFCA.

Chantal Yeager: I just wanted to clarify that the state law obligations are generally – the decision making there is about the person responding to a request. It is no different than your obligations today. You have to think about – I am in New York and this is sensitive information that I am not allowed to share because I am in New York. It does not change your obligation and it is not as if the state laws are being applied to everyone. It is the person in the state. I have information about a person in this state where I live and where I provide services. When I respond to a query, these laws apply to me.

The QHINs are in a challenging situation just because they support people across different state laws. But for any given TEFCA-connected entity, it is really no different set of obligations than you already have. It is just a different communication vehicle.

Michael Hodgkins: I think we have some questions from our virtual community. Is that right?

Rebecca Hines: There was a comment, I believe it traces back to your question, Jamie. I will just go ahead and read it from Jonathan Coleman. He wrote IAS providers must have a relationship with the credential service provider who must conduct individual identification verification to IAL2 prior to using a credential. There is a token in the specification that could be used to help provide the assurance that

the requestor is who they say they are. For demographics-based queries, the request must use verified demographic information that the CSP has verified per the individual verification process. Thank you, Jonathan Coleman.

PARTICIPANT: He is the RCE CISO.

Jamie Ferguson: I very appreciate that response. But if I am a provider with a record and my interpretation of HIPAA is that I need a consent. I may choose not to participate in the IAS.

Mariann Yeager: I was able to actually get clarification from a member of our technical team via text. They said the individual has to consent to use the app and what the app does with the data, for example. There is no consent shared with the record-holding organization. It is actually optional. Is that right, JaWanna? We were just looking at the QTFs. Since the request is coming from the individual themselves and not from someone who individual's consent to access the data.

Steve Gravely: I would just say that I understand what you are saying, Jamie, that you may choose to not respond with that information. That resonates with me. But we also cannot forget about information blocking. That is another dimension to the system now. Now I realize that for providers, there is no enforcement rule yet, but as some point, there will be. That will be something else that you will have to factor into your decision making.

JaWanna Henry: I think just to add to that point. One of the things that I highlighted and we have probably been talking about and kind of where we are and where we are going is there is this certain level of education that needs to happen again about what TEFCA is, what TEFCA does and how it works aside from figuring out where your role is in TEFCA.

I do not know if Chantal is trying to speak. But once we work through getting some of these newer documents out, we are really going to double down on our education and engaging different stakeholders.

Jamie Ferguson: I think part of what I am saying is that in the cases that I think we just talked about where an individual is using an app. The app is making a request. That is a direct request then to the record holder. Now, we are talking about two, three, four layers of indirection where it is not that direct request. That is the reason why I think some providers are looking for that assurance of consent.

Michael Hodgkins: Chantal, did you have something you wanted to add?

Chantal Worzala: At the risk of making it even more complicated, just note that when you go back to the exchange purposes that are currently allowed via TEFCA, none of those that require consent under HIPAA are actually yet part of TEFCA. For example, I know people are very concerned about reproductive health data and law enforcement. It is not an exchange purpose under TEFCA to be able to query for information for law enforcement purposes. There is no – those things that need patient authorization are not yet part of TEFCA.

Michael Hodgkins: I think, Lenel, you had your card up next.

R. Lenel James: Mariann, a question for you about the comments you made in the RCE directory. It is slide 14. It said specifically, the TEFCA exchange enables access to the electronic endpoints. I am curious about how the endpoints work now versus how you expect they may work when you have a FHIR

version because I am active with three of the FHIR accelerators and we are all having discussions about we are building this great stuff. How are we going – in the future. I am curious about how your endpoints work now and if you think that will have a role or some derivative for the future in FHIR.

Mariann Yeager: Definitely. I am probably not the person to speak to that at all but we can follow up with you all afterwards so someone can give you a more fulsome response. But the directory is being revised to accommodate FHIR – what we call facilitated FHIR, which is more point to point where the QHIN is not the intermediary routing them. Today, the endpoints are really the QHINs and their participants and sub-participants that they load into the directory associated with them – how it works with the facilitative FHIR, I do not know unless JaWanna or Chantal does.

R. Lenel James: But the key thing you said is it is an internal directory in the QHINs. It is not visible to the outside.

Mariann Yeager: No, it is the directory that is supported and hosted by the RCE and that the QHINs populate the directory and then they actually are accessed and maintain a copy of the directory data locally and it refreshes periodically.

R. Lenel James: Cool. That helps. Thank you.

Mariann Yeager: Okay. Good. I am so glad.

Chantal Worzala: One of those famous SOPs is in fact the RCE directory services SOPs. You may want to look at that if you are looking for all the nitty-gritty details of what are the fields and all that kind of stuff. And the QHINs are actually obligated I believe to load a new participant within 24 hours, I believe.

It is going to be an up-to-date registry. Under the facilitated FHIR mode of exchange, what would happen is that a participant would work with their QHIN to get the FHIR endpoint for the entity that they want to conduct FHIR exchange with and then they would have direct FHIR communication after that.

The QHINs can then offer additional services on top but with the QHIN facilitated FHIR model, what the QHIN is really doing is helping you discover who has data about a person that you are interested in and what is the FHIR endpoint that you need and then you take it from there.

Michael Hodgkins: Denise, I think was next and then we can go to Catherine and then Jamie.

Denise Chrysler: Thanks a lot. I really appreciate this presentation. I am fully retiring in September. I am trying to get out of the field before I have to learn a lot about this area. I did not read the 200 pages so hopefully I will not be too naïve.

I work in the public health field. When DURSA was around and we were working on IIS, Interjurisdictional Exchange, it was the jurisdictions were like no way on earth. First, it was like 42 pages. Sorry Steve. Very complicated. And public health is known for its system-by-system approaches because they have so many unique roles, so many unique laws and their systems.

I was trying to think about how TEFCA works with public health information systems. They almost always have laws that require user agreement. I am assuming TEFCA is not assuming the Common Agreement is going to be a one-all agreement. That if you are working with public health and public

health systems, you are probably going to have to have user agreements and you are going to have to deal with a lot of unique things in the clinical provider or health payer field. I just would like to know and then I have another question but I will ask one first.

Chantal Worzala: I think public health is an area where TEFCA has incredible promise accompanied by incredible challenge. No question about it. The good news is we have tremendous partnership between ONC, CDC, and the RCE to start to work through this.

I do think that one of the things that will be helpful is that under Common Agreement version 2, we are introducing the idea of a principal and a delegate relationship. You are probably aware that in public health, we have a couple of public health intermediaries like APHL that help manage some of that complexity and make the data more liquid. We are building TEFCA to be able to align with these kinds of approaches that public health is coming to. That is one piece.

The other piece is that the CDC and ONC are really working together to help the public health community understand that we can modernizing the CDC Data Modernization Initiative, modernizing the way that public health thinks about data and the CDC independent of TEFCA is doing things like building tools that can be used by multiple public health agencies. They are starting some cloud-based services. There is a lot of exciting work going on right now in the public health data space.

Where we see TEFCA really playing a role is to encourage first ways of reporting into public health that do not require one-off siloed data systems. A public health authority may get data through TEFCA and then internally figure out which of its data systems the reported data needs to go to. But the idea is there should be one TEFCA door that they can get some of this data through. But no question. These are really complicated, and it is going to take some time to work it all out.

Denise Chrysler: It seems like TEFCA would work well to push data to public health because you know whether you can or not and you know whether you are required to or not.

And then, Chantal, you said the issue when public health provides data whether it is through automatic functions or not is not – or any provider of data, the center of data, does not have – it is up to them to configure their system to know their own laws to not provide any information unless they are allowed to provide that information if you request it either configure automatically or for automated transfer or your manual transfer. But then what I see coming up a lot is states that try to control what happens to the data after it leaves their doors and it is with the recipient. And those recipients all have to obey every law. I do not know what we have with territories. I know we are over 64. And then we have a lot of even local public health regulations.

Thinking about TEFCA trying to simplify and how can I, no matter where I am, know that I am governed certain state laws or local laws and how am I going to – TEFCA says I have to comply and that is conditioned to get this data. How am I going to know what they are and how am I going to configure my own system to do that?

Chantal Worzala: That also – do not disagree. That is a challenge. I do hope that as part of the Data Modernization Initiative, CDC starts to think about policy harmonization across states. We operate TEFCA in the environment that we live in. All of these challenges are still there but folks are working on them. I see tremendous promise actually in the public health arena.

Steve Gravely: I just want to jump in real fast. Denise, it is great to see you. I think you put your finger on a really important issue for public health. We cannot think about public health as just one giant homogenous thing. Public health is many discrete things. I do not think we are going to have a single universal solution for public health. I believe we are going to have to tackle that. I am working right now on a project involving the vital records offices and NAPHSIS and the STEVE system, in which I really chuckle every time when I call. The people say Steve says this. I say I never said that.

Why did I bring that up? One of the principles, as you know, is that the send in jurisdiction's law survives and controls. I had to really wrap my head around that one. But for that particular provider records, it makes perfect sense. I feel like the public health is going to be very slow progress, but we are going to – we cannot just burn down the house. We are going to have to go into each room and maybe renovate a little bit to make it work. When I say renovate, I am not talking about just renovating the states. I am talking about renovating TEFCA too. It is a two-way street and make it all fit. I agree with Chantal. Very challenging but very exciting.

Michael Hodgkins: We only have a few minutes left so I would like to go to Catherine's question.

Catherine Donald: I will be quick. I feel like all my thunder or whatever has been stolen. Public health, 30 plus years, 30 years of that in vital records. I agree with everything that Denise has said. I agree with what you have said. It is a challenge. I was going to mention STEVE and I actually know the other Steve that was involved with that. The state and territorial exchange of vital events. When you were talking about the state, that is the first thing that came into my mind was whose laws govern it and it is laws. It is not necessarily policy. Legislation will be involved. And when you get down to it, especially vital records since you brought it up. When you get down to the level of I gave my birth certificate information to the Alabama Department of Public Health. Those state laws govern it. There have been some things that allow another receiver to see – Alabama says you cannot share that or yes, you can share this. I should use the positive example. You know your challenge. I appreciate all the good information. Thank you.

Michael Hodgkins: Jamie, it looks like you will have the final question.

Jamie Ferguson: Thank you. Staying with the public heath theme. I wanted to just ask if you could say a little more about the potential partnership with CDC under their Data Modernization Initiative any particular pilots. I noted, for example, we have paid attention to the fact that the safety reporting network in CDC now has approximately two dozen hospitals, using FHIR-based APIs to report the safety measures to the CDC. Is that on the roadmap for FHIR and TEFCA? What are those opportunities for partnership? This lets you leave behind all the state and local issues.

JaWanna Henry: Great. I am going to try and remember all the points that I have. As far as the partnership with CDC and ONC, the first thing is you referred to them as pilots. We are not referring to them as pilots. We are referring to them as early demonstrators. And one of the things that we are highlighting is looking at the opportunity to explore the use cases for public health but then also looking towards the future of being able to advance FHIR and the use of ABIs in that space. So probably more to come about that. I do not know if others have anything else to say but that is where we are in the beginning phases of doing some early demonstrations within states.

Chantal Worzala: It is exciting to see those demonstrations because I think public health is a community where they want to know what works because they have limited resources and they do not want to make the wrong bet. I think it is a really good idea to have those early demonstrators.

Our commitment as the RCE is to be really close to the public health community and to take the steps that will make them feel comfortable. We have talked a lot with the public health community about ensuring that we are enabling high value use to begin with, which is query and reporting but then have a roadmap so that over time we can expand.

The reality is that the public health exchange purpose allows entities to share data via TEFCA for any reason that fits within the HIPAA-defined definition of a public health so you do not have to wait, for example, for us to build out a sub-exchange purpose in an SOP. I do not think this is true. But if the CDC were to say you can do your surveillance reporting via TEFCA. We are a participant in TEFCA and go ahead and send us your data that way. You could go ahead and use QHIN message delivery today. As long as they understood what payload was going to be attached to that message, there is no reason it could not happen today.

What we understand though is that people need a lot more implementation guidance. That is where building out these sub-exchange purposes that do things like point to the IHE and FHIR standards for electronic case reporting or electronic lab reporting. That is really what we are doing in the SOP and that is the road we want to walk with the public health community. How do we systematically grow the number of more detailed, more specified use cases over time?

But today, if you and a public health partner understand what data you are going to share back and forth, there is no reason you cannot use QHIN message delivery or QHIN query for that today as long as you are all TEFCA-connected entities.

Michael Hodgkins: Rebecca, did we have any comments or questions from our virtual community?

Rebecca Hines: We do not. My parting thought first for the committee and then for the panelists is given your role advising HHS, what is the opportunity given what has been shared today? Is there something that needs some further encouragement? And from the vantage point of our panelists today, here is a group of people who clearly have some knowledge. We are at 50,000 feet and we have some folks who are down at the ground and everywhere in between. What would be helpful if you could wave your magic wand, as we like to say, to recommend to the department given where things are and of course that does not apply to you at ONC obviously.

The 21st Century Cures Act actually mentions NCVHS asked the HIT coordinate to take into account NCVHS' comments in carrying out the work. Just something to think about. You do not have to answer right now. It is not really a rhetorical question, but I think it is going to take some thought as to with the workplan development conversation coming up later today. If you could hang around, that would be great. If you cannot, we can obviously follow up. Thank you all so much.

Michael Hodgkins: We are open and receptive to comments from you where we can be helpful going forward to improve upon the great work you are already doing. I want to thank all of our panelists for a very interesting conversation today. As Rebecca said, you are certainly welcome to stay and listen in on other parts of the agenda but I know you all have busy schedules. Again, thank you very much.

Jacki Monson: Let us take a break until 10:10 a.m.

(Break)

Jacki Monson: Let us go ahead and get started. We are lucky to have Tim Noonan with us to give us an update on Office for Civil Rights. Tim, I will turn it over to you.

Office for Civil Rights Update

Timothy Noonan: Okay. Thank you. I appreciate the invitation to speak here. Alright. As I said, thank you for the invitation to speak today. OCR appreciates these opportunities to share some of our recent activities and get some feedback from NCVHS.

Today I thought to speak on OCR's recent policy activities such as the final rule on the confidentiality provisions, substance use disorder patient records part 2, the notice of proposed rulemaking to the HIPAA privacy rule to support reproductive health care privacy, and the updated bulletin on the use of online tracking technologies. I can also share some information on the trends that OCR is seeing in the large breach reports we receive such as the amount of large breaches reported, number of individuals affected, the types of large breaches reported and location of large breaches. And then finally, highlight some recent enforcement activity as well as some new HIPAA enforcement initiatives.

In late 2022, OCR and SAMHSA published a Notice of Proposed Rulemaking to modify the Part 2 rules to implement the CARES Act requirements to better harmonize the Part 2 confidentiality provisions with certain permissions and requirements of the HIPAA rules and the HITECH Act. Following a 60-day public comment period and review in consideration of the public comments, we should define a rule earlier this year in February. The compliance date by which persons subject to this regulation must comply is February 16, 2026, so a couple of years for entities to implement the changes required by this rule.

I am just going to highlight some of the major changes as this is a fairly lengthy final rule, which would easily consume all of our time today if we were just focused on that. The Final Rule creates a new option for patients to provide a single consent for all future uses and disclosures of Part 2 records for treatment, payment, and health care operations without the Part 2 program having to get consent from the patient for each future use for disclosure for these purposes. Upon receipt of such a consent, a Part 2 program can use the patient's Part 2 records for health care operations such as reviewing the competence or qualifications of a health care professional, evaluating practitioner and provider performance or conducting training programs, again, without having to seek the patient's consent for each use and disclosure. This continues unless or until the patient provokes the consent.

The Final Rule permits the redisclosure of Part 2 records in accordance with the Privacy Rule by recipients that are HIPAA-covered entities, which would also include Part 2 programs that otherwise meet the definition of a HIPAA-covered entity and business associates except for certain legal proceedings.

If a Part 2 program discloses Part 2 records to a patient's primary physician based on a patient's consent, if the patient's primary physician is a HIPAA-covered health care provider, then that physician could redisclose those Part 2 records as is permitted or required by the HIPAA Privacy Rule. It just allows the HIPAA Privacy Rule in essence to be a backstop for the redisclosure's Part 2 records just like it is for current HIPAA-regulated entities.

Now, a Part 2 program that is not a HIPAA-covered entity – they would be permitted to redisclose the Part 2 records according to the scope and limits of the patient's consent. Another example where a

residential Part 2 program discloses Part 2 records to a private outpatient substance use disorder treatment center based on a patient's consent and the treatment center is not a HIPAA-covered entity. They only accept cash payments for health care so they do not transmit health information electronically. That treatment center could redisclose the Part 2 records only for the purposes specified in the patient's consent and it would need to obtain a new patient consent to use or disclose records for a different purpose.

There are now some new patient rights under Part 2 for an accounting of disclosure of Part 2 records and a right to request restrictions on disclosures of Part 2 records. Patients now have a right to an accounting of disclosures made with the patient consent. This is for disclosures for treatment, payment, and health care operations made through an electronic health record and covers a period of three years. A patient now will be able to request an accounting of their Part 2 records to learn if there have been any disclosures in the past three years to, for example, other treating physicians.

The Final Rule also implements two rights really with respect to the restrictions on disclosures of Part 2 records. One is a new right for patients to request restrictions on disclosures of their Part 2 records otherwise permitted for treatment payment in health care operations.

A Part 2 program does not have to agree to the restriction. But if they do, then they must ensure that the requested information is withheld from disclosure. As an example, under the right to request restrictions on disclosures for Part 2 records, a patient in treatment for substance use disorder may ask their substance use disorder counselor not to disclose information about the history of childhood trauma when referring the patient for drug testing. And the substance use disorder counselor again is not required to agree with the restriction but if the counselor agrees, then they are required to hold that information.

Second is the patient's right to obtain. The first one was to request. This is to obtain restrictions on disclosures but it is to health plans for services paid in full by the patient. Where the patient is a member of their spouse's health plan and is receiving treatment in a Part 2 program, they can request and obtain restrictions on disclosures to their health plan of record about their substance use disorder treatment appointments when they are paying for the appointments in full out of their own pocket. The Part 2 program would not be permitted to disclose the Part 2 records about those appointments to the patient's health plan.

Next is a really significant change. It creates civil enforcement for violations of the confidential provisions of the Part 2 records. Previously, enforcement of this section was limited to criminal sanctions. Now in addition to potential criminal penalties for the first time, the Part 2 program can be subject to a civil money penalty for violating Part 2 confidentiality requirements.

Patients will have a right to file complaints of violations with the Secretary of HHS, similar to the program that is set up for HIPAA, in addition to being able to file a complaint directly with the Part 2 program.

HHS now has civil enforcement authority to investigate complaints and initiative compliance reviews of Part 2's program compliance with the Part 2 confidential provisions, again, similar to the department's civil enforcement authority for potential violations of the HIPAA rules.

The HITECH Act, which creates the tiered civil money penalty structure, which is based upon the knowledge of the regulated entity with regard to HIPAA violations – that penalty structure is now also

applicable to Part 2 violations. For example, willful neglect uncorrected, the highest tier in the penalty structure – it allows for now approximately a two-million-dollar civil money penalty for all violations of Part 2. The HIPAA, HITECH Act, C&P structure that is used that will now also be available for use in Part 2 civil investigations.

And then finally, there is a requirement for Part 2 programs to report breaches to the HHS Secretary in the same manner as the HIPAA Breach Notification Rule. Again, in the event of a breach of Part 2 records, Part 2 programs will be required to notify the Secretary, affected patients, and in some cases, the media. Again, we use the language that entities should already be familiar with from the HIPAA Notification Rule. That is now part of Part 2. Some of the structure will be set up just as HHS maintains a breach portal where large breaches of unsecured protected health information are submitted and posted. A similar portal will be set up for reporting breaches of Part 2 records.

Next, I want to speak a little bit about the Notice of Proposed Rulemaking that we did last year on the HIPAA Privacy Rule to support reproductive health care privacy. This proposed rule would prohibit the use or disclosure of protected health information to investigate, prosecute, or sue individuals, health care providers, and others involved in the provision of legal reproductive health care.

Under the proposal, the provision would apply where the relevant criminal, civil, or administrative investigation or proceeding is in connection with one of the following. Three scenarios here. Reproductive health that is sought, obtained, provided, or facilitated in a state where the heath care is lawful and outside of the state where the investigation or proceeding is authorized. For example, if a resident of one state travels to another state to receive reproductive health care that is lawful in the state where that health care was provided.

The second scenario is reproductive health care that is protected, required, or expressly authorized by federal law, regardless of the state in which the health care is provided. An example here is if reproductive health care such as miscarriage management is required under EMTALA, the Emergency Medical Treatment and Labor Act, in order to stabilize the health of the pregnant individual.

And then the last scenario is reproductive health care that is provided in the state for the investigation or proceeding is authorized and is permitted by the law of the state where the health care is provided. If a resident of a state receives reproductive health care such as pregnancy test or treatment for an ectopic pregnancy in a state where they reside and that reproductive health care is lawful in that state. Those are three scenarios where that applies.

The proposed rule would continue to allow regulated entities to use or disclose protected health information for purposes otherwise permitted under the privacy rule where the request for the protected health information is not made primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive care. What does that mean?

For example, health providers could disclose protected health information to defend themselves in a medical malpractice lawsuit or regulated entities could disclose protected health information to inspector general conducting an audit for health care oversight.

To implement the proposed prohibition, the proposed rule would require a regulated entity when it receives a request for protected health information potentially related to reproductive health care to obtain an assigned attestation if the use or disclosure is not for prohibited purpose and this attestation

requirement would apply when the request for protected health information in any of the following circumstances: health oversight activities, judicial and administrative proceedings, law enforcement purposes, and disclosures to coroners and medical examiners.

The proposed requirement to obtain a signed attestation – this will give regulated entities a way of confirming in writing that requests for protected health information are not for a prohibitive purpose.

While the department is still undertaking this rulemaking, the current privacy rule remains in effect. We have reviewed the public comments that were received in response to the proposed rulemaking and are presently working through decisions on what could be published in the final rule.

Next, I would like to speak a little bit about our online tracking technologies bulletin. Back in December of 2022, we published a bulletin on the use of online tracking technologies by HIPAA-regulated entities. To make sure everyone is on the same page, a tracking technology is a script or code on a website or a mobile app used to gather information about users as they interact with the website or mobile app. These tracking technologies are used to collect and analyze information about how users interact with the regulated entities' websites or their mobile apps.

The HIPAA rules apply when the information that the regulated entities are collecting through these tracking technologies or are disclosing to tracking technology vendors includes protected health information. The bulletin provides a general overview of how the HIPAA rules apply to regulated entities' use of tracking technologies.

We updated the bulletin in March. The bulletin now includes new examples of when visits to an unauthenticated webpage may or may not involve the disclosure of electronic protected health information, some additional tips for complying with the HIPAA rules when using online tracking technologies and guidance about OCR's enforcement priorities in online tracking investigations.

With respect to unauthenticated web pages, these are web pages that do not require users to log in before they are able to access the webpage. This could be a webpage with general information about the regulated entity like their location, their visiting hours, employment opportunities, or their policies and procedures. And tracking technologies on many unauthenticated webpages do not have access to individual's protected health information. In such case, the regulated entities' use of these tracking technologies is not regulated by the HIPAA rules.

However, there are some cases where the tracking technologies on unauthenticated webpages may have access to health information. And what the updated bulletin does is provide more examples to clarify that. For example, explaining that visits to unauthenticated webpage do not result in a disclosure of protected health information to tracking technology vendors if the online tracking technologies on the webpage do not have access to information that relates to an individual's past, present, or future health care or payment for health care. That is just the definition of individually identifiable health information.

Again, as an example, where a user visits a hospital's webpage that provides information about the hospital's job postings or visiting hours, there is not going to be any information that is transmitted or collected that relates to individually identifiable health information. Tracking technologies on that page would not be regulated by HIPAA.

But the bulletin does explain instances on unauthenticated webpages where it could. For example, if a student is writing a term paper on the changes and the availability of oncology services before and after the COVID-19 public health emergency. The collection and transmission of information showing that the student visited a hospital's webpage listing the oncology services provided by the hospital that would not constitute a disclosure of protected health information because even if the information could be used to identify the student, it does not relate to individually identifiable health information. It is the student working on something for a term paper. Compare, however, if an individual were looking at a hospital's webpage listing its oncology services to seek a second opinion on treatment options for their brain tumor. The collection and transmission of the individual's IP address, geographic location or other identifying information showing their visit to that webpage is a disclosure of protection to health information to the extent that the information is both identifiable and relates to the individual's health or future health care.

The bulletin then also reminds regulated entities of key provisions of the HIPAA rules they should be mindful of in order to ensure they are complying with all the requirements such as ensuring all disclosures are permitted by the privacy rule, ensuring there is a business associate agreement with the tracking technology vendor that meets the definition of a business associate, incorporating the security rules, risk analysis and risk management requirements, making sure the online tracking technologies are being routed through that and providing breach notification where applicable to individuals (?)2:31:33.

And then we also discussed our enforcement priorities, which is really we are prioritizing compliance with the HIPAA Security Rule in these types of investigations because our primary interest is ensuring that regulated entities have identified, assessed, and have mitigated the risks to electronic protected health information when using these technologies.

As you know, HIPAA-covered entities are required to report large breaches to OCR. We collect a lot of information through the receipt of these large breach reports. A large breach report is a breach affecting 500 or more individuals. Here, you can see a substantial increase in large breach reports that we received over the years.

We used to say that the average receipt of one large breach report a day. But as you can see, there has been a substantial increase from 2018 to 2023, a 99 percent increase.

Also notable is the significant increase in the number of individuals affected by large breaches. Last year it was nearly 135 million, it is a new record, compared to 2022 when it was 59.3 million. That is 127 percent increase. If you go from 2018 when it was 15 million, that is a 786 percent increase. You can see the trend is generally up as more individuals are being affected by large health care data breaches annually.

What is causing this increase in large breaches reported to OCR? Here we see the type of large breaches reported that OCR receives and how that has changed over the years. The pie chart on the left shows cumulative data from 2009 through 2023. You can see hacking is the largest percentage during that time period at 51 percent. Unauthorized access or disclosure is 23 percent. And theft at 18 is also significant.

The chart on the right just shows this data through March 31, 2024. You can see that hacking is by far the most common type of large breach reported to OCR at 77 percent and is really driving the increase in the reported large breaches to OCR. You can see the trend movement as theft has decreased significantly as a type of large breach reported. The data shows that hacking is the most likely type of

large breach that a covered entity is going to experience and therefore it really presents the greatest threat and risk to protected health information within the regulated ministry. This is consistent with what we have seen over the last two years where hacking was about 79 percent of the large breaches reported at OCR.

Here, taking a little deeper dive into what is causing the increase in large breaches reported to OCR. You can see the rise in hacking and in particular ransomware as the number of reported breaches to OCR have gone up so have the number of hacking incidence as the cause of the breach. Hacking, as you saw on the last slide, is the most frequently reported large breach of unsecured protected health information of OCR. It has been an 87 percent increase in large breaches reported to OCR involving hacking from 2019 to 2023. For ransomware, it is a 102 percent increase for that same timeframe. That is really what is driving again the great risks and threats to electronic protected health information – hacking and ransomware.

Next, I would like to look at where reported large breaches are occurring. Again, the pie chart on the left shows cumulative data 2009 through 2023. You can see that network servers are 36 percent and email at 22 percent. These are the largest locations. And paper records are a little behind at 14 percent.

In the pie chart to the right for ’24 to date, we can see that networks are even more dominant for large breaches at 69 percent. There is a drop in email at 15 percent and paper records are reduced at 9 percent. The two largest categories, network servers and emails, account for 84 percent of the large breaches that have been reported to OCR this year.

Here is another way of looking at the growth of network servers as location of a large breach. There has been a 319 percent growth in network servers as the location of a large breach since 2019. From 2022 to 2023, it was a 22 percent increase. And just as a side note, it is not just hacking that is causing an increase in network servers as location of breaches. We also see unforced errors where electronic protected health information is stored on servers without access controls or authentication requirements, the equivalent of an open door for someone to just come in and take health data.

Here is a list of recent OCR HIPAA enforcement actions. All these cases were resolved with settlement agreements, corrective action plans, and monetary payment or the imposition of a civil money penalty. The issues resolved include hospital employees snooping in patient’s electronic health records. That is the Yakima case. Health information left on unsecured servers. That is MedEvolve and iHealth. Unlawful disclosures of patient’s health information in response to negative online reviews. That is New Vision Dental and Manasa Heath Center. Mis-mailing of health plan ID cards. That is LA Care Health Plan. Ransomware. That is Doctors’ Management Services and Green Ridge Behavioral Health. Disclosures to the media. That is St. Joseph’s Medical Center. A phishing attack. Lafourche Medical Group. Malicious insider identity theft ring. That is Montefiore Medical Center. And securing patients’ rights to timely access their health records, the HIPAA right of access requirement. That is David Mente, United Healthcare Insurance, Optum Medical Care, Phoenix Healthcare, and Essex Residential Care.

Back in February 2019, we announced the HIPAA Right of Access Initiative as an enforcement priority. We expressed our belief that an individual’s right to access their protected health information is a cornerstone of the HIPAA Privacy Rule. It is a fundamental right to know about your medical conditions that you can make informed medical decisions about your health and share your medical information with whomever you want. And in the past, we have supported this right through rulemaking, guidance, technical assistance, professional training, and outreach.

However, it continues to be one of the largest volumes of complaint categories that we received in our HIPAA complaints. And the most common issues we see are untimeliness or no access and the charging of fees beyond the reasonable, cost-based fee limitation. We have completed 48 enforcement actions with over a million dollars in collections, including four in 2023 and 17 in 2022. This continues to be an enforcement priority.

The risk analysis initiative. This is a new HIPAA enforcement initiative that we have implemented. In certain HIPAA Security Rule investigation, we would be focusing primarily on compliance with risk analysis requirements. This has long been an area needing improvement. It is the building block or foundation in which all of the other security rule requirements rest. Regulated entities have to know where all the places where electronic health information is stored or what devices servers systems have access to that health information and what measures they have in place to protect against potential risks and vulnerabilities.

By prioritizing investigations focusing on this requirement, we can increase the number of investigations we complete annually, which should increase the number of cases resolved with technical assistance or settlements of corrective action plans. This will improve compliance for those regulated entities and hopefully see better outcomes for regulated entities and affected individuals in attempted cyberattacks, which every week as you open the paper so to speak, going to the internet and reading the news. You see the ubiquity of the cyber attacks particularly in the health care sector.

That is all of the presented materials I wanted to discuss today but happy to answer any questions folks may have.

R. Lenel James: It is actually a quick question, Tim. What are you doing in terms of outreach to some of the potentially underserved providers like federally qualified health centers that are now – again, the large federally qualified health centers are pretty sophisticated. I know one of the ones in Chicago got hacked. It was a real surprise to their leadership that someone went after them out in Chicago but it really up ended their operations for over a month. What has been the outreach to educate many of these entities that are not large health systems, are not large payers that have CISOs to help prepare them for that?

Timothy Noonan: Sure. It is a great question. We started something a number of years ago where we do a small entity outreach initiative. We have eight regional offices within OCR and we have a dedicated outreach slide deck. It has over 100 slides where in the past, it is like pre-COVID. We would go to areas outside of the big cities and try and get a number of smaller providers in those areas to be able to attend one of our presentations in person. Now, we can do that virtually. We do just a rough guess over 200 outreach presentations a year. We do have dedicated materials for the smaller providers that may not have the same resources as some of the larger institutions.

And then last year, we also made more materials available on our website. For instance, we did two videos in October. One is on common cyber-attacks. It walks through what we are seeing in OCR investigations as the most common cyber-attacks, how hackers are getting into information systems and try to present some lessons learned from some of our investigations in those areas.

And then we also did a video on the HIPAA risk analysis requirement where we walk through all the requirements and again go through some of the OCR investigations and identify some of the common deficiencies, what our regulated entities failing to capture in their existing risk analysis efforts that is

potentially leaving them vulnerable to these types of attacks. I think the individual outreach events that occur and then the push to put more free materials/resources available on our website particularly videos trying to reach more audiences that way. These videos could be used by regulated entities to train their own staff in addition to their own in-house materials.

Jacki Monson: Jamie.

Jamie Ferguson: Thank you, Tim, for coming and talking to us today. My question is on your enforcement initiative you mentioned, looking at the risk analysis. So many of the breaches are from third-party risks and business associate risks. How does that enforcement or how do you look at enforcement of the requirements for business associates and third parties to be secure?

Timothy Noonan: Sure. Great question. I try to hit it a couple of different ways. Business associates are required to comply with the HIPAA Security Rule. When we initiate an investigation, our primary interest is in response to a breach report. Our primary interest is where did the breach occur. What measures were in place prior to or at the time of the breach? What actions have you taken since the breach if there were some compliance issues?

You will have instances where a HIPAA-covered health care provider notifies us of a breach that occurred at their business associate. We will open two investigations typically. One against the health care provider notifying us of the breach as required under breach notification and then one against the business associate. But our enforcement interests are different between the two parties. With the business associate if the breach occurred there, it was their system, their responsibility. They are the cause of the breach, whatever the scenario. That is going to be our primary focus.

The investigation to the covered entity that had the relationship with the business associate where the breach occurred. Our interests are going to be primarily – did they have a business associate agreement in place with the business associate? They did complete breach notification? If they have done those things in many instances, then that is going to be the limit of our investigatory interest with respect to the covered entity and the investigation into the incident is going to be more focused with the business associate and again because they independently are required to comply with the security rule and will be focused on their compliance.

Valerie Watzlaf: Hi Tim. Thank you so much for being here. I just had two questions. One was a clarifying one. I think you said something about the accounting of disclosures for TPO is in the Part 2 rule. I just wanted to clarify that that has not been implemented or enforced in the general HIPAA Privacy Rule, the modifications to the HIPAA Privacy Rule. It has not. Is it something that OCR still wants to close off in the 2021 --

Timothy Noonan: Yes. What you are referring to – we have an accounting of disclosures as part of the HIPAA Privacy Rule, and then the HITECH Act added some additional requirements for accounting of disclosures. You will recall, we attempted to implement that a number of years ago with the Notice of Proposed Rulemaking. Based upon the comments we got back, we elected not to finalize it at that time because there are serious concerns by the regulated industry and their ability to be able to implement that.

We did receive comments in response to the 2021 NPRM. That is something that is still outstanding and that is something that we intend to look at and address at a future date. I appreciate the clarification. That is absolutely correct.

Valerie Watzlaf: Thank you. And my other question in which I think you might have addressed but I do not know if I heard you, when will the Final Rule do you think be out for reproductive health privacy? I know you said you are working on it. Can you give us any estimated time that we might be able to see that?

Timothy Noonan: No. Not really beyond what we said –

Valerie Watzlaf: I know you only had like 26,000 comments. But I just wanted to – I just wondered.

Timothy Noonan: It is a priority for the department and OCR folks are working very diligently on it. As soon as we are in a position to be able to announce something on it, we will. I am sorry I cannot give any greater clarity. But as you might imagine, there is a lot of different involved and that can sometimes obscure the ability to forecast accurately when there might be an actual landing or a publication date. I do think it will be soon.

Jacki Monson: Michael.

Michael Hodgkins: In your pie chart, you obviously showed that network server intrusions are sort of the big ones. But do you distinguish in your data collection between on-premise versus cloud network intrusions?

Timothy Noonan: No, in the materials we provided, it is not making a distinction between cloud service providers or in-house. It is something we could take a look at. It would be interesting perhaps to peel that back and see with more granularity if there is a difference in locations.

Michael Hodgkins: I guess I would think that there is an increasing movement to the cloud certainly by larger organizations, hospitals, and others with the thought that it is probably more secure than on-premise network server sites. It seems like it would be important to actually look at that and see if it is true because they are making big investments and moving the cloud in a way from on-premise.

The other question I had though was in your enforcement authority beyond financial penalties, especially in these on-premise network intrusions, it seems like in some cases certainly at least, there is just sloppy security. People have not made the investments required to bring their security apparatus infrastructure up to standards that I think what most people would considerable acceptable. Do you have enforcement authority that allows you to impose obligations to improve on-premises security infrastructure or only financial penalties?

Timothy Noonan: Sure. Our enforcement authority – there are really three options. One is technical assistance and that is how most investigations are resolved. We are providing guidance during the course of the investigation. The regular entity implements those changes to bring them into compliance with the different HIPAA rule requirements. At a certain point, that case is not going to be as interesting as another case where there are outstanding compliance issues. That is how that case resolves. We do not have injunctive relief as an available remedy.

We did send a request to Congress to give us that authority because that could be very helpful where you have an instance where health information is unsecured on a server. Anybody with access to internet is able to access that information and download it. And there is not anything OCR can do directly to remedy that situation. We do not have injunctive relief. All we can do at the end of the investigation was say that is a violation.

In terms of how we resolve cases, one which I think speaks to your concerns, most of our enforcement actions are resolved with a resolution agreement and a corrective action plan. And a corrective action plan lays out the steps that the regulated entity is going to implement over some period of time with OCR monitoring. And the OCR monitoring is really us providing technical assistance post-investigation on the things they have implemented. Have they done it sufficiently? Where do they need to clean it up, et cetera?

But there is a third option where a regular entity can say I do not want to make these changes, or I do not agree with you or I do want to be under federal OCR monitoring. We will just pay a civil money penalty. And when you pay a civil money penalty, you do not have to make any changes. If we found you have never done a risk analysis, you have been a regulated entity for 20 years and you have never done a risk analysis, if they do not choose to work with us to a settle agreement and a corrective action plan, then all we can do is impose a civil money penalty. They pay it and they still do not have a risk analysis. Now, we may come back at a later date and initiate another investigation. But there are limitations on how often that can occur.

To perhaps assuage your fears and concerns, the civil money penalty route is not frequently traveled. By far, most of our cases – and I do not have the exact number off the top of my head but it is 145 settlements and 9 civil money penalties, I believe, is roughly the numbers over the history of the enforcement program. That is not a problem that comes up too frequently but it does remain an option.

And then there are some instances too just to round it out. Entities – many of them have good folks working for them. They may choose to pay a civil money penalty for a variety of reasons, but they have taken their own steps to come into compliance. Even without the OCR monitoring, it is not as though they are just paying a fee and continuing to be reckless. They have made changes. It is not every instance that they just pay the fine and continue to travel blind without having a risk analysis.

Jacki Monson: Thank you. I have two questions for you, Tim. The first one is I just saw the NPRM for the cyber incident reporting for critical infrastructure active 2022 coming from CISA. How is OCR coordinating because it looks like it comes in some rendition to be a final rule? They are requiring a lot of reporting in a really short period of time, which I think for small entities, it is going to be an impossible task. But I was just wondering how you are coordinating.

Timothy Noonan: We have had some discussions with them about how that may look, what challenges might be presented by the timeframe to respond to that. That is about all I can really say at this point. It will continue to be the subject of ongoing discussions.

Jacki Monson: My second question is a little around the same topic that Jamie asked you a question about, which is third parties. I saw the data that you provided, which validates where I have been spending all of my time, which is in breach notification of third-party vendors move it, change health care impact. Is there any plan for OCR to even put a guidance out on the current HIPAA Security Rule?

I think it is really challenging today as covered entities and I heard you say that maybe with a covered entity, you are looking for a BA and you are looking for are we generally enforcing. But I think we, as a covered entity, look at it as are we sufficiently doing risk management to these third-party vendors. And that is obviously a challenging space because when we go through the assessment, they might tell us that they have all the security controls and then we find out during the breach that they did not actually have the security controls. Where do you see OCR's role and potential guidance see the third parties,

covered entities, or business associates in this space? Because I think I am going to continue to be spending my time where your graph show the increase of notifications to patients and dealing with vendors who have breaches.

Timothy Noonan: It is a great question. A breach at a business associate – there are instances now where the business associates have tremendous volumes of health information, and they are becoming attractive targets because you can get access to more information through the business associate than perhaps individual providers. Our focus will always be where the breach occurred. The investigation is going to be primarily focused on that. The parties that have the relationship with identity that experience the breach. There is a secondary interest. Because you have a party that can be directly held responsible for the Security Rule requirements, the business associate, we tend to limit the investigation for the covered entity that is connected to that business associate to really just the interest that we think are independent of the events giving rise to the breach.

In terms of what we can do with guidance, I think we have been very pleased with what we have done in the last couple of years. We have tried to do more videos. We did recognize security practices video to discuss the 2021 HITECH Amendment that gives you – as a mitigating factor, if you have implemented recognized security practices and that is the stuff under 405(d), NIST, and there is a third category, other.

We got tremendous response, a number of views and hits to our video on that. We have been pleased with the response we got on the common cyber-attacks. In the past, we have primarily done FAQs and written guidance. While that can be effective, I think the videos are a little more meaningful because it is something that regulated entities can use in their own environment as opposed to having a meeting and reading an OCR FAQ to folks that may not resonate as effectively as playing a video.

When we do the videos, we will often solicit questions in advance so we can then answer the questions in the video. That is then recorded for posterity and everybody has access to it. I would expect to see us continue to do more work in this space and your suggestion is a good one and certainly incorporate that into future ideas for how we can be more helpful.

Jacki Monson: Thank you. Any other questions?

Maya Bernstein: I do not think I have been read into the record so I am going to do that quickly. I am Maya Bernstein. I am the senior advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation. I am the lead staff to the executive director of this committee and lead staff to the Subcommittee on Privacy, Confidentiality, and Security.

Tim, I thought it might be helpful to the extent you are able to do for this committee – there is some information that has been made public like in the president's budget about enforcement. Are there certain things that have already been made public from the president's budget about enforcement that you could talk about? I think those would be helpful to the committee from previous years' budget that has already been made public.

Timothy Noonan: What are you thinking about:

Maya Bernstein: there are legislative changes that have been sought by the office that some of those have been made public already so that you could talk about how that would be helping the office and that might be interesting to this group.

Timothy Noonan: Sure. We have submitted proposals to Congress. You heard me describe one. Injunctive relief is just having to wait to the end of an investigation in order to effectuate relief where there can be instances on the front end that it is continuing to present a risk of harm to individuals and potentially more individuals could be affected again just using the example of due to a server misconfiguration and it does not require any authentication requirements for people to access it. Now, I think most entities would respond proactively but we cannot always ensure that.

We have had instances in the past where we have notified a regulated entity that we can see your data. They argued with us. They disagreed with us. It is not going to get any better for you. I can see your data. If I can see it – that is one.

And then the other – back in 2009, the HITECH Act created the four tiers for imposing civil money penalties. In 2019, the department issued a notification enforcement discretion, modifying as part of the general review of all of the regulations and laws at the time. The department determined that a better reading of the penalty gaps was to lower the annual amount that could be imposed for three of the four categories. For instance, willful neglect, unadjusted for inflation so willful neglect, uncorrected is 1.5 million. And that used to be the annual cap for all of the tiers. But after the 2019 decision, the other tiers were reduced. Reasonable cause is the most frequent finding by OCR. The cap for a reasonable cause violation went from $1.5 million annually to $100,000. The department made the determination that that is the better reading of the HITECH Act. Then we followed up with a request to Congress that really two things.

In 2009 – it was a long time ago. We do think there needs to be a revisiting of the caps and increasing them, in particular, in light of how the HITECH Act was interpreted.

And then when you look at other aspects of privacy entities, other agencies are able to secure more. The anthem settlement was the largest settlement in OCR's history. It was $16 million. But there have been instances where the FTCs have been able to collect $500 million for a settlement. It is just recognizing that the health care industry is vast and you have a huge spectrum. You have solo practitioners at one end of the spectrum and then multi-billion-dollar entities that cross state lines at the other. The question is does the existing penalty structure provide sufficient deterrents for these big entities keeping in mind that these numbers were set back in 2009. Now, it is 2024. Some of the changes that were made back in 2019.

We did put that forward because I think that is an important part of improving compliance. It is not the only part by any stretch of the imagination. We are not looking to impose penalties on everybody in the industry and that is the only way. But I think it is part of an overall program. We did send that forward to Congress seeking adjustments on that.

Maya Bernstein: Thank you so much.

Jacki Monson: We have one question in the chat, Tim. Are you seeing many third-party risk assessments being completed by business associates as added security?

Timothy Noonan: Say that again. I am not catching the last part, the added security.

Jacki Monson: It says third-party risk assessments being completed by BAAs as basically added security so basically the third parties doing assessments on their third parties or other entities and vendors.

Timothy Noonan: If I understand what is being asked where a business associate has an outside entity come in and perform – do their risk analysis for them – it is a mixed bag. I think there are some entities that do a better job of it than others. It is by no means a guarantor that if you hire an outside entity to come in and do your risk analysis for you that it will comply with HIPAA. We have seen instances where it has not.

Oftentimes those assessments – sometimes the assessments themselves will tell you essentially, it is not thorough. This risk analysis is only for these information systems. It does not cover all the information systems used by the regulated entity. The requirement is to be accurate and thorough, and you cannot be thorough if you are not covering all of the information systems where EPI is stored or has access to.

Many times it is like any sort of computer program or function. I do not want to say garbage in, garbage out. But if incomplete information is given to the third party that is doing the risk analysis or if they are not being invited to do other aspects of it, then it is not going to be complete and it is not going to meet the standard. It just varies. I cannot say it is always good or it is always bad. We have seen instances of both.

Jacki Monson: Thank you so much for your time today. It is always great to have you.

Timothy Noonan: Thank you very much. Again, I appreciate the opportunity to speak and interact and always enjoy hearing the questions and getting the feedback. It is beneficial for OCR too. Thank you.

Jacki Monson: Thank you.

Alright. We are going to move on. We actually need to officially read Denise into the record so we are going to do that real quick.

Denise Chrysler: Denise Chrysler with the Network for Public Health Law. I am on the Full Committee, the Privacy, Confidentiality, and Security Subcommittee, and I have no conflicts.

NCVHS Workplan Development

Jacki Monson: Thank you. And now we are going to pivot to the workplan, and we have quite a few things to cover in a short period of time. Tammy, I am putting my own pressure on today. Let us first start with the Subcommittee on Privacy, Confidentiality, and Security. Val or any of the committee have any thoughts?

Participant: (off mic)

Jacki Monson: Why don't we save that for this afternoon when we do more workplan planning? Let us talk about the Subcommittee on Standards and anything else you need to finish from yesterday.

Tammy Banks: I am fine with yesterday. I am basically where Val is, just going through the different sessions and pulling out different things for our workplan. The order – whatever makes sense for you.

Jacki Monson: Okay. Does that mean you do not have anything further to discuss right now?

Tammy Banks: I can always discuss stuff.

Jacki Monson: I was just checking. Let us go into then talking about the 75th NCVHS anniversary planning. Maya, I do not know if you can join us to talk about prior events and what we have generally been discussing.

Maya Bernstein: In the past, we have had a couple of anniversary events that were very well received and we have done it a little bit different ways both times. Once, I believe, at the 50th and then at the 60th. And one, we had a small symposium where people traveled to. I believe it was North Carolina because they had prior chairs all gathered together of the committee and one was unable to travel so they went to him, which was great. We traveled folks down there and had a gathering and there was a small symposium. People produced a history of the committee over those 50 years and association with that symposium and talked about the different issues that the committee had taken up over the years and the ways that things had changed over that time.

Things have changed very significantly since the advent of HIPAA. The name of the committee has this – here we are talking about HIPAA and Health IT but it has this name Vital and Health Statistics, which was the origins of the committee. With the advent of HIPAA and the additional statutory requirements for recommendations to the secretary that shifted a lot. We saw that I think in the 50th and 60th, maybe more the 60th anniversary history and you can find it online under the about the committee section.

There is a variety of ways you might go about marking the 75th anniversary of the committee. You do not have to do what we did before. You could invite guest speakers. You could pick a particular topic. You could look historically in retrospect. You could look prospective. I do not really have any strong feelings about what you might want to do. With the folks gathered around the table here today, you may have some particular ideas about what you would like to see or how you would like to mark the occasion for the committee. Some of you have been on the committee longer and have a sense – a more historical sense of the committee with your longer service. Some of you are more new and might have new ideas to bring to how we might mark that occasion.

I just wanted to throw out that I would like to talk about that and figure out what makes sense, what resonates for this particular instantiation of the committee at this time. What seems to be a way that you think would be meaningful to you in the current environment and would also be meaningful as a historical record going forward?

R. Lenel James: As a new member, my immediate reaction is it would be nice to go back to the beginning in the 50-year mark and just because I know outside of NCVHS and the regulars at HL7 and the regulars in the industry, a lot of what NCVHS does is invisible to big parts of health care. We could use the 75th anniversary to kind of help people understand the vital role this group has played over the years from the standpoint of the beginning, whatever was done at the 50-year anniversary and then what we are doing now.

But the thing I would like to recommend for consideration – I just sent you guys a link of just something I saw at HIMSS. I think there are some really interesting technologies that they are not going to be available any time in the near term but they are going to be coming fast, everything from AI to robotics. It would be an opportunity for us to highlight. There is a whole bunch of new stuff coming that is going to be important for this committee in the industry and for them to know we are aware of it and we are already thinking about it, not only some of the near-term changes that are important for the industry, but the visioning of the future is on our radar too.

Jamie Ferguson: I may be relatively recent on the committee but I actually have been providing testimony to the committee for over 20 years. And thinking back to some of the – having some of the previous chairs come. Unfortunately, Dr. Cohen has passed away. But Dr. Stead, Dr. Suarez – we could bring in some past chairs to get their perspective on where the committee has been and where it is going but also the committee has had different levels of involvement with different secretaries. I am thinking particularly of Secretary Sebelius and Secretary Leavitt who were around. Getting their perspectives might also be interesting if we can get some of them to show up.

Tammy Banks: They stole a lot of my thoughts. That is alright. There has been a lot of wonderful work that has occurred from chairs and the chairs of the subcommittee. Bringing them back I think is really important.

But I think even more important is all the great work that was laid out and where has it gone. It was wonderful yesterday to see when and where all that work developed and turn into something that is in operational today and just doing a review whether it be recommendations, whether it be other types of influence in different areas and what have we done in 25 years. That would be really meaningful I think to me personally and I do not know about the rest of you why we are here.

Maya Bernstein: Do I read you to say that you would like to focus on the HIAA part, in particular, when you say 25 years?

Tammy Banks: I mean overall. I can speak from the standards because I am more familiar just like Jamie. We have been testifying here for a long time, asking for change and change has occurred. Some area change has not and that is something that we may need to focus on. But I think doing a review of what we have asked, what has been influenced. That is an important piece.

Maya Bernstein: I will say that it is a time-honored tradition to recruit panelists to sit on a committee. Thank you for all of that service.

Jacki Monson: Now that I am not distracted from that. Val.

Valerie Watzlaf: I was just going to agree with Jamie and Tammy and also say that there are some reports and some recommendation letters back in 2009. I would love to meet the main people that wrote these. They are not there. We keep referring to them. I think they were light years ahead of everyone when they did this. It is amazing. I would love to bring them back. We keep talking about that.

What happens to our recommendation letters? Where do they go? Can we get people to maybe talk to us about that because we have been doing this now – we do not always get a response and we sit there and just really think what happened. Do they read them? What do they do with them? I think if we could add that as well.

Rebecca Hines: I also just want to say to that point, Val, that I think we do not totally appreciate or have a way to measure or track how the public benefits from this work because we hear from people. It would be very interesting to do and some of it is qualitative and some of it is quantitative. This committee is cited in peer-reviewed articles. The ICD Work Group when we had those discussions a while ago, there were people I did not even know who showed up to calls who had published papers who are now members of the ICD-11 Work Group. I had no idea. I actually think in many cases the influence of the committee is in a much larger sphere than the department. Although ironically, that is the stated goal in the charter.

But I do not want you to lose sight that we get a lot of traction, or I should say the committee gets a lot of traction in its work over the years does. To just remember that I think there are many cases where the value is more in that respect than directly to the department and that is not a problem. That is not bad.

I was talking to a vital statistics state director who said just having any kind of guidance even if it is not official from HHS helps with state legislatures. Here is what the department is talking about. Here is a report on this topic. Look what they are saying. It can be really helpful. States are noted as being an audience for the committee's work in the charter. I do not have the language committed to memory although I should. But just to keep that in mind that it is not the small little bubble. You actually have a website. You have public meetings. All of the transcripts and recordings more recently are all available and people draw on it.

Jacki Monson: We will go down the row. Michael.

Michael Hodgkins: I was just going to say if we are going to bring back past chairs, maybe we should also be considering bringing back designated federal officers, especially one of our outgoing because I think your perspective looking back over your service and perhaps even whoever your predecessor was would be as valuable as hearing from prior chairs.

Debra Strickland: I had my list before everybody went. Everybody stole my stuff. I think that we should see some of the highlights of what we have done in past presentations and some really cool things that we have done as a committee: inquisitive meetings, predictable roadmap, and some of the things that were before my time. Just big things that the committee has done over its entire duration.

As far as the chairs, I do believe we should bring the chairs that can come in and those who cannot because they are no longer with us as a remembrance. Create a table or something for them.

And I do agree with getting more of how our work has impacted public like the WIN Network and other things either directly or indirectly and maybe try to do a call to people to kind of feed us information about how they feel that they have been impacted by NCVHS.

Also, I think that will be a good guardrail to see what impact maybe we do not even realize some of the impact we have had on different groups of people out in the wild. Out of all the letters that we created, maybe we did not get responses to – we got responses but we did not have action to all of them but maybe in some way, we affected the industry, nonetheless.

Catherine Donald: I agree with everything that has been said. And what I have been hearing I actually came up with a theme. I might propose a theme. Past, present, and future. Maybe that will help keep us grounded in all these wonderful ideas and what has gone in the past, feeding off of all the impacts, what we do not know, what is going on right now, and then I like future looking. I also like that. What is coming up? What is AI going to be bringing us and all the other technologies? I would just offer past, present, and future maybe as a possible theme for the event symposium.

Jacki Monson: Jamie

Jamie Ferguson: I like the past, present, and future. This would fit right into that. We are talking here a lot about the things that are actually outside of HIPAA but let us not forget about the accomplishments of the committee in HIPAA. Electronic prescribing for the country was enabled by this committee.

Participant: ONC exists because of this committee.

Jamie Ferguson: Exactly. There are some big deal things within HIPAA as well.

Catherine Donald: I just wanted to add. Are we doing any dancing or anything?

Participant: Val knows that in another life, I am a swing dancer. That is why she is teasing me.

Catherine Donald: I was just going to say. I have been in another 75th celebration and there was a talent show and we are not doing that or I am not.

Jacki Monson: It is an executive decision. Should we vote on it? I think these are all great ideas and kind of in line actually with our brainstorming on the Executive Subcommittee.

One of the questions that I have is September really realistic to put something this great together. I do not know, Maya. You all have done a lot to make things happen. But one of the questions I have is does it make better sense for us to spend the rest of the year planning and planning for early next year so that there is plenty of time to pull this off in the way that we would want to and make sure that we give those that we want to come enough advanced notice that they can plan around it.

Participant: And you will have more members on the committee by then too.

Jacki Monson: I do not know what thoughts everyone has on that.

Tammy Banks: I was going to support it because we have a Report of Congress. We have things that are going to take up time and why not do it right, especially if we can bring back our former colleagues. I think it would be wonderful.

Jacki Monson: We are probably going to have to take a vote on that because Cathy is a hard no. I think we have enough brainstorming ideas to put a formal plan together and then we will bring it back for this group to review for consideration.

Rebecca Hines: We had an interesting comment in the chat that Naomi just pointed out from previous member Vicky Mays. She says I would suggest having story narratives from those we have had an impact on. It would be great to do five-minute videos for some of them. I think it would be good also to highlight special work groups and subcommittees that we no longer have and highlight them next year but not in the winter.

Jacki Monson: I agree. Nobody wants to get stuck here.

Rebecca Hines: And someone also said and a member of the public, just holding these meetings and making them publicly available is a huge service to the committee. I just want to point out the amount of work that members and staff put into organizing the panels for this meeting, it is paying off because it is on the website. The recording will be up in about a week, and it is there in perpetuity and the transcripts as well. Thank you for that comment. We are getting some claps over Zoom so just to reinforce that.

Jacki Monson: The exciting world of Zoom clapping. I think that is present, not future.

Thank you for the great conversation. Let us break for lunch and let us reconvene at noon. Thank you.

(Luncheon recess.)

Exploration of Privacy and Security in AI in Technology and Health Care

Jacki Monson: Val, we are going to turn it over to you to start.

Valerie Watzlaf: Thanks, Jacki. Welcome everyone. We are going to start the panel on Exploration of Privacy and Security in AI in Technology and Health Care. We are going to make this a little more conversational. Feel free, committee members, to interject during as the panelists are presenting. We will be throwing out different questions and so forth.

But just to start, I am just going to briefly introduce you and then if you would like to say a little bit more about yourself too, you can pick any two interesting things you would like to add. You can do that. First, we have Jennifer. Welcome. Jennifer Goldsack. She is the chief executive officer for Digital Medicine Society and she is also a member of the Board of Directors for Coalition for Health AI.

And next to her is Jonathan Jungck. He is the commercial healthcare technical lead and HIPAA security officer for Palantir Technologies. Welcome.

And next is Von Nguyen. He is the clinical lead in Population Health at Google.

Last but certainly not least is Garrett Adams. He is the lead EpiCare Ambulatory Research and Development, a division for Epic Systems. Thank you, all, for being here.

Jennifer, do you want to start with saying a little more about yourself?

Rebecca Hines: These mics are particular. You have to be directionally pointed at them. You cannot talk with them over there because then the people on Zoom, which there are many believe it or not. Just make sure you remember to do that.

Jennifer Goldsack: Terrific. Apologies in advance, everyone, as I do have an outdoors voice. Sorry folks on Zoom.

I think a couple of important things. First of all, the Digital Medicine Society. We are a global nonprofit. Our mission is to advance the ethical, effective, equitable, and safe use of digital technologies to redefine health care and improve lives. We have the same philosophy at DiMe as we have at CHAI, the Coalition for Health AI, which is we are not here to shoehorn digital technologies into every nook and cranny of health care and then declare victory. But rather what we think about is that there are pressing, persistent, and emerging challenges in health care. That using the tools that we had in the pre-digital era, we have been unable to address. Our focus is how do we develop and deploy this new generation of tools in the toolbox to actually address those issues.

We are not a hammer in search for a nail but we are not tech determinists and I think that is a really important lens to bring to this discussion. What are the problems that we are solving for, how can we use these new tools, and how can we make sure that they work for everyone? Because what we do not have a history of as an industry is actually going back to make sure that innovations apply to people we

do not bring with us in the first line. I think the equity piece from the get-go is also really important as we digitize health care. That is the lens that I will be bringing to our discussion today.

Jonathan Jungck: Awesome. Great. Hi everybody. My name is Jonathan Jungck. I work for Palantir Technologies. I have been in the company for about 20 years and in commercial for about 10. We started in health care with a number of federal different projects. One of those was the deployment of the COVID vaccine and distribution across the country. I work for a commercial health care sector. I lead or work with health systems and hospitals in the United States.

A big part of my focus has been around ethical AI and how we think about actual workflows that work in the health system in terms of being able to surface the right information to the right people at the right time.

Before I did that, I did get to do a brief stint on our sexiest project, which is probably Formula 1. That was a lot of fun too.

Von Nguyen: I am Von Nguyen. I am an internal medicine doctor who works at Google. And I think the other thing I would add is that in addition to thinking about health care, I think there is a realization that when you think about health, we spend the vast majority of our time outside of the walls of a hospital system. Thinking about health in a broader context in terms of what is a consumer to do as well as how do you think about communities in addition to health care as a perspective. We would love to bring it in the conversation as well.

Garrett Adams: I am Garrett Adams. I am with Epic. We are a small little EHR shop out in Madison, Wisconsin. We have a lot of deep expertise with both technology and with the needs of our health care systems that we work with. We see a lot of opportunities to bring technology together into workflow at the point of care to help reduce things like our improved clinical efficiency, address documentation burden and improve or advance patient care.

I think for your comment about we are not looking to – I was thinking of the sledgehammer on every nail problem. But there are certainly new opportunities that we can provide significant value when done correctly. Thanks for having me.

Jacki Monson: Great. We really planned this to be conversational. We encourage the committee as you like to participate in the dialogue with these individuals. They also provided us with some questions. We are just really looking forward to a great dialogue.

Let us start off first with an overarching question for each of you to answer if you would like, which is will you start by just describing the landscape of AI and health care. What are the trends that we are seeing right now and what are you worried about?

Jennifer Goldsack: This is a really big question. I think given the – I am going to use a word that is not sure is fair but I think will resonate with everyone. Given some hype that we are experiencing right now, I think the automatic way that you may expect us to respond is to talk about what are we seeing in terms of the uses of generative AI in health care because that is the leading edge of innovation. But the reality is we have been using a variety of different AI machine learning approaches at various levels of health care for the best part of a decade if not more at this point.

I think that we have to recognize that the automation of guidances and rule-based decision making – I think we have to recognize that some matching and risk-reduction tools have been used safely with great intent and partnership with the connections on the frontlines for a long time now.

Notwithstanding that, what we have seen in the last I think year or so is an enormous groundswell of interest and adoption that may be a little bit less than you think compared to the groundswell of interest of some of these more cutting-edge products. And when we do see these models, certainly from what I have seen and I am curious of what my colleagues think is much more on the operational and administrative sides when it comes to actually touching patient care as it exists right now.

We have certainly seen the application of these in the development of new medical products in ways that are really interesting whether it is brute force to try and identify new antibiotics, whether it is other sorts of innovations that does not yet touch patients on the medical product development side of the house but there are some deep roots with more traditional technologies and then perhaps my colleagues will weigh in on the leading edge.

Jonathan Jungck: I think that is a great point. Honestly, when we think about workloads that use generative AI, it is only a piece of it. It is the co-pilot. You think about these rules-based workflows of how do you determine if a patient is eligible for hospital at home where it is more clinical operational type workflows.

A big piece of that is going to be you know a lot of structured information about that patient. But we are able to access the notes now. We are able to access the pieces where you have a nurse sitting behind the desk saying I do not understand why this order was placed. That is why when they are going through the notes and they are trying to do their job. That is where we are seeing this is really improving the workflows.

Von Nguyen: I am going to push us in a slightly different direction and to think again outside the health care system. When we think about artificial intelligence or just technology in general at Google, we think of it in these three C's or these three buckets. There is the idea of the consumer, what is the consumer need, how are they thinking about health. There is the idea of caregiver. As you think about that, there is the health care delivery system. And the third idea is about the community and what are the needs there.

But let me take an example in each of these buckets. The consumer is really interesting. Google is a consumer company. From a YouTube perspective, in 2021, there were over 100 billion views of health-related content on YouTube alone. Just remarkable numbers. Every day there are a 100 million searches that occur on Google Search.

As you think about that, consumers are looking for information. They are trying to understand their health especially on YouTube. They are not looking for an answer. They are looking for someone who has experienced cancer, experienced diabetes and this understanding of their health and how it relates.

Within this context, there is a new tool that we have developed called Allowed, which actually dubs videos into other languages. It might be in English but you might dub it into French or Spanish. There are a handful of languages now they will be expanding but that is AI, the ability to dub into different languages so that you are actually able to reach more people in the language that is appropriate for them. That is a consumer example.

When you think about caregivers, this is what we frequently speak of here. There are lots of great technology sort of AI in terms of radiology, computer vision, predicting sort of -- reading of film or helping a radiologist reading film, helping a radiologist or a pathologist read a slide, a lot of opportunities within the context of workflow. Working with partners like HCA or other organizations to develop tools that are helping them become more efficient and we will have lots of time to talk about that so I am not going to spend a whole lot of time on that but clearly lots of tools for caregivers.

Then also think about the community as well. How do we think about artificial intelligence for communities in different ways. Part of this is thinking about what information do we need for communities to make better decisions. As an example, we just went with Stanford to produce a data set called SCIN. It is the skin care – I forget exactly what it is. I forget the acronym because there are too many acronyms. What it is is it is about 10,000 images of different types of skin conditions that we work with Stanford to label and to identify so that not Google but the community can actually develop tools.

The community researchers can build off of that data set to actually train their own models in a way to understand the differences between different skin tones because if you look at many of the data sets now around skin, they are of cancer data sets, what is malignant and what is not malignant and frequently not representative of the true population. Underrepresented minorities are not clearly represented. We put together this skin data set for that expressive purpose of making data available so that the community of researchers that is reflective of the community can begin to do their own – to build their own tools that are appropriate for their communities.

I would push us to think about that context of AI, not just in the context of health care delivery, but in the broader context of what are consumers looking for. Definitely a place for health care. But what communities need as well.

Garrett Adams: I can echo that health care AI is not something that is new. We have had AI in various forms, even going back to – if you consider something as simple as a Meds interaction alert that prevents harm every day. That is under some definitions of AI. But then things like predictive algorithms for predicting the risk of either readmission or deterioration or operational efficiency or even machine learning algorithms for just workflow optimization. If you search for something, you get the thing that you were really expecting floated up to the top, things that are just kind of commonplace across many applications that we use every day. That stuff has been around for a while. I think what is new is the advent of or the advancements in generative AI and in the ability to stand up and train other evolution of other data sets becoming available.

I think in terms of trends, what this means is more momentum, more potential for it to help solve some of the challenges with staff shortages across health care, low operating margins, and reducing provider workload.

I think something that – on the flipside of that, what health care organizations and other providers need help with being able to validate and identify what is good, how is it good, how can we use it effectively, how can we know that it is working as designed as intended. Does it perform on my local patient population the same way that as it was designed for the standard data set that it was originally trained on? That is where I see some of the trends. I could go on for a while but I will pause.

Participant: It is the Skin Condition Image Network.

Von Nguyen: Thank you. I was going to say Google it but –

Participant: That is, in fact, what I did.

Valerie Watzlaf: Thank you for that. Anybody have any questions? If you do, interject at any time? But I will ask you this one. Do any of you have any other specific case examples to bring forward to illustrate additional – some of the trends that you all talked about?

Garrett Adams: Just in terms of actual use case application, one of the areas that I personally focus on a lot is clinical efficiency, helping with staff shortages and just reducing workload wherever we can. AI is just one of many tools in that tool belt. But there are some unique applications that it can help with whether that is helping either draft communication, saving some time writing that accumulates over time or summarizing information to help you get up to speed more quickly.

I think one of the very promising use cases is in documentation help, needed documentation to capture but how can we make it lower cognitive effort, easier to do, reducing duplication. We have seen the feedback that we have gotten with the folks that are using it. I do not know, Jennifer, what your perception is of the use, but there is fairly broad use of some of the early generative AI use cases.

Some of the feedback that we get. Stanford published an article in one of our tools recently. Mayo wrote a piece on the impact on nursing efficiency. The feeling is I love this. I cannot wait for more of it. This is really helping me.

One of the really interesting anecdotes that I see as roll out these tools and groups like Stanford do analysis on it, they get both quantitative and subjective survey feedback on it. Time and time again I see that the subjective feeling of this feels like it has saved me 40 minutes a day. The data might show that it saves ten minutes a day. But the fact that it is helping them out, feeling like a virtual assistant has an outsized impact on their mentality. I cannot help for anything more with a focus on helping out with clinicians.

Jonathan Jungck: I think you are totally right there. A lot of things that we hear from nurses are my nursing handoff process is hard. It is the same two nurses oscillating back and forth, night shift, day shift. I cannot remember what I told them yesterday was what I need to tell them today.

It is also things like doctors spending their entire weekend writing appeal letters. Things like that are no fun. But how do you prevent them in the first place with good utilization review notes? Those are all really good forms of documentation.

I think two other use cases I would say outside of those that are pretty important especially from the health side is how do you identify benefits for a patient or a potential individual based on characteristics about that patient. How can you determine their eligibility to receive certain help? They may not be a US citizen but the fact that they were pregnant came up on the call and this makes them eligible for a particular benefit. How can you identify things like that more easily?

And then other things that we think a lot about is in the cancer research space and working with MD Anderson for about five years now. One of the things that comes up is how do you map a staging outcome. How do I get the TNM out of this diagnosis that came out? And some of that is just an abstractor spending a lot of time doing this but also as you start to abstract that are things for cohort building. You are looking at millions of fields that need to be mapped to standard concepts whether it is SNOMED or something that they have. It just takes time and it is not the fun part of your day like Garrett

was saying. It feels a lot longer than it is. But how do you actually do that in a more efficient way that allows them to look at the harder cases?

Von Nguyen: A couple of use cases that I have not heard here. Another place where I think you are going to see AI both generative as well as other AI sort of more traditional AI is within drug development and research so things like AlphaFold where we have been able to build this tool, the database that understands how proteins fold and subsequently understanding interactions between those but really incredible tool that helps researchers both in the academic medical centers as well as in industry more effectively, more quickly sort of understands what drugs will be possible so driving innovation in that context.

Also in the context of just quite frankly running clinical trials from an efficiency perspective, being able to translate information into different languages as they are running global clinical trials. But those types of use cases are also important. But research is another opportunity where driving innovation will be important and AI will play an increasingly important role.

Garrett Adams: One thing to add on to translation, because I think you are spot on for improving equity and access for patients. Even just beyond language-to-language translation, there is literacy level or level of background knowledge translations, being able to go from high fidelity, medical jargon rich language to something that is easily understood and approachable for a patient.

I have gone through some health journeys of my own, gotten some information I did not fully understand and that can be panic inducing in those moments so anywhere that we can help create that translation layer to make it more understandable I think goes a long way for how patients feel as they go through their health journey.

Valerie Watzlaf: Outside a sort of the hospital/clinic ambulatory setting, where is AI going to impact consumers in other contexts from your perspective?

Von Nguyen: I can take a swing at this. It already has is the short answer in terms of things. Let me give a Google example. When you think about Fitbit, we can actually use the Fitbit tools or actually on a Pixel phone to actually understand using light sensor – it is called PPG, to understand someone's heart rate. And then we could use that, and look at that is my heart rate compared to all the data of everybody else's heart rate to see if my heart rate is irregular regular, which is atrial fibrillation.

This idea of actually using consumer tools, remote sensoring is a place where I think there will be a lot of innovation in the coming years and a lot of that will be built upon artificial intelligence tools to understand what is normal, what is not normal. Lots of validation will need to go into that to make sure it is right. FDA will play a very important role in this. Like the PPG tool that I mentioned, it is FDA cleared. It went through the appropriate regulatory process. But that is one way in which consumers will be impacted.

Another thing I think is that when you think about ubiquity of mobile phones whether it is an Android phone or an Apple phone, we looked at these things all day long. I do it. I try to stop my kids from doing it. Failed miserably but tried my best. The question is how do we harness that in a way to actually help people manage their health more effectively?

I am a clinician. I see a patient four times a year for 15 minutes. Quite frankly, ten of those minutes is staring at the screen, typing as I try to talk to them, which drives me crazy. I hope the AI tools will help me with that.

But the rest of the time they are in the communities, making decisions, trying to get information about health. How do we ensure they get the right information with the highest quality content that is authoritative in a meaningful way? How do we make sure that that information is delivered at the right time in the right language?

As Garrett mentioned, this is something that I always thought was interesting. I spent a lot of time in public health. There is always this perception that I had to raise the health literacy of my patients. What if that premise is wrong? What if the premise should actually be I should get my medical content and meet them where they are rather than trying to raise everybody's health literacy. Health literacy is really important. Don't get me wrong. But they are in tools now that allow us to do this. It is going to be really important for us to think about health care from a consumer perspective in meeting people where they are in the environments that they want to be seen in and with the tools that are effective and efficient that will use their time in an effective way.

Jennifer Goldsack: I cannot help myself. I am just going to temporarily hop on a soapbox and then jump off. Which is I personally really struggle with this notion of the consumer when it comes to health care. I do not care for quadruple bypass is two for a dollar. I do not want one. I think we have to be careful a little bit in terms of how we blur the lines between folks who are undergoing clinical care and have clinical need and then something that should be public health and social initiatives in order to keep people and the workforce and children healthy and well.

While I ultimately think that the digital future of health and health care is actually can we change to a health care system from a sick care system. Can we evaluate ourselves by how good are we at keeping people out of the hospital as opposed to evaluating how good we are at doing a patch-up job once they cross the doors of the clinic further along with their diagnosis with poorer outcomes and more expensive than they needed to be?

But I also think that sometimes this notion of consumerism because in order to consume, you have to have resources to spend on things. Your three C's I thought were excellent. I think this notion of community as opposed to patient can really serve us well.

I do think if we collectively decide that the only way that we are going to manage things like health care costs, the only way that we are going to move away from having the worse health outcomes in the developed world is to think about a health care system instead of a sick care system.

Then I think one of the really powerful things that AI begins to do for us is to be able to look at different streams of data beyond just clinical streams of data and maybe triangulate off those things. We can look at things like environmental conditions. We can look at things like food deserts. We can look at things like – we could do a DIS survey right now and I absolutely guarantee you if we did a heat map of poor internet connectivity, if we did a heat map of clinician shortages and if we did a heat map of health outcomes, there are areas of the country where it is on fire. We can use these sorts of analytic tools to do search resource distribution. We can think about where we need to be piloting new programs. I think it allows us to move beyond just doing clinical care in order to improve people's health because we triangulate off these different data sets. We can be intentional and we can be targeted. All of that is

predicated on the availability of data and parameters around the use of that data so it is used to help and not harm.

Valerie Watzlaf: I think we have a couple people that have some questions. Michael, you were first and then Deb and then Jamie.

Michael Hodgkins: There are obviously a lot of wonderful opportunities here. Let us talk about some of the risks and not to pick on you, Von. But most recently, Google had to withdraw an AI application because of the issues that arose. Microsoft just had problems as well. I think in terms of the Gartner Hype Cycle, it seems like we are on that up slope right now. The next step is the trough of disillusionment.

All the excitement is wonderful and there are some obvious instances of things that are really quite exciting like AlphaFold and the opportunities that it presents to develop new drugs, maybe lifesaving. But how do we manage all these downside risks?

I do not really think the government is ever going to catch up with this from a regulatory perspective. How do we deal with it?

Von Nguyen: When I think about this, let me acknowledge the risks are real. There is no doubt in my mind about that. In terms of the opportunities are real but the risks are also very real. Let me sketch two general approaches and ideas. One is this first notion of starting with what are we trying to do. What are the principles behind this?

As an example of this, Google put together something called AI Principles in 2018, way before this generative AI wave. And the first one is basically be beneficial but it is the same thing as do no harm. But there are also seven of these. Starting from this, these are sort of our guiding principles within the organization. We try our best to adhere to these organizations. That is sort of a starting point. Being very clear about what the guardrails are and the boundaries are I think is a first step.

What is interesting about this is if you look around the world both – there are other versions of this. The Biden administration – they put a couple of guardrails or principles around AI. The World Health Organization has done the same thing. They are all actually pretty similar, which is really great. But that is a starting point just to make sure that everyone knows what these are and that they try to –

The reality is that principles are not enough. It is great to put them out. You can point to them. You can talk about them in venues like this but you have to structurally put things in when you are building a software in a systematic way to do this.

Let me talk – I think one of the biggest risks is equity and sort of biased data sets. Clearly, it is something we all worry about quite a bit. One thing I would argue is that data sets are kind of biased because we collect data in a biased way because we are the health care system. As you think about that – when you look at any data set, I suspect compared to the real-world population, underrepresented minorities and rural populations are underrepresented largely because they do not have access to health care. That data set in and of itself will likely be biased. Understanding the bias is really important as the first step.

The second step is as we are building solutions, being very clear in the evaluation process with reinforcement learning with human feedback to make sure you actually do that with humans that are diverse and be very clear about the criteria you are evaluating the model by.

An example is within our Med-PaLM 2 or medically 2 model, we actually had evaluated from all of the world lots of different races, lots of different -looking at this because we recognize that Von looking at the model, it is not the same as someone from the UK or someone from Sub-Saharan Africa or Asia looking at the model because there will be different cultural biases. Picking the group as you are developing the model, making sure that you have checks and structural ideas and principles in place to actually mitigate the bias and risks associated with it.

The last piece is that when you are actually in deployment, you are not done. You have to continue to monitor the model to make sure that the results are unbiased. And the point here I highlight this is because this is – when you think about the bias and the risks associated with equity, you have to think about the entire value chain.bi You start with the data set, understand the biases in building the process. Make sure you put the structural pieces in place to understand it and then at the end of it as the models and production continue to monitor and make sure that you do not have the drift that is creating problems but that is the systematic process that you have to go through beyond just creating principles.

Garrett Adams: I think, Von, you captured that very well. The evolution from the design development and then into the deployment phase. Something that Epic has recently developed is what we call the AI trust and assurance suite, which when you think about health care organizations/providers, they are being inundated with AI that they can deploy and how can they both understand how it works on their local patient population.

I think the Biden Bill of AI Rights that you referenced, referenced the need to have the validation of AI done on a representative local data set. What we have developed is a tool set that organizations can run to validate both AI solutions that we may provide, that they may custom develop, that they may bring in, that they are deploying at the point of care and to not only be able to see validate how it applies to their patient population, how it performs but also how it performs over time with continuous monitoring.

I think one of the keys here is some groups have amazing data scientist teams that they can do amazing things to do research and validation on their own. Other groups do not have that opportunity. They do not have those resources available to them.

Part of what this does is it automates the collection of the data and of the monitoring, displays it on a pre-configured, easy-to-build dashboard that gives you the slices by things like sex, things like race so you can see how that model performs across different patient populations for the individuals that you directly serve.

We are open sourcing that monitoring template and data schema so that it will be easy for others to plug in and play with it and be able to have this ongoing continuing evaluation at scale to prepare us for what is already coming and what will continue too.

Jennifer Goldsack: Really good question. One of the things I find most helpful sometimes in these situations is asking myself what is the same and what is different for these sorts of AI models compared to every other health innovation that we have evaluated.

And the reality is that medical products get recalled all the time. We have the sentinel system for tracking drugs because we recognize the RCTs are the gold standard, but they do not tell us everything we need to know about how they work in real life. We have the MAUDE database for medical devices

and more traditional medical devices get pulled from the market all of the time. Is it ideal, something we should aspire to? No. But I also do not think we should have a zero-tolerance approach to the AI-derived devices when the reality is that we have a level of tolerance with other medical products.

I also think that medical decision making is based off risk-benefit analysis. You are the clinician at the table, so I am going to be very careful as I say this. The reality is when we say first do no harm, we do harm in health care all the time. We amputate people's legs when their diabetes is not in control in order that the necrosis does not kill them. The side effects from immune oncology – we sit with the risk of cytokine release syndrome to administer IO therapies to save people's lives. The side effects of chemotherapies are horrendous because we might save someone's life. We do harm all the time, but it is within a very thoughtful risk benefit framework that defines decision making in medicine.

I would encourage us if we can, instead of saying what should we do about the downside risk, I think the right question is more along the lines of as we face the health care system that is on fire, how do we make sure that we are doing more good than harm as we move these forward and how are we intentional? Fifty percent of black Americans live in a county where there is no cardiologist. One in five Americans of any background live in a county where there is no mental health care provider, yet we find ourselves in a mental health care crisis. We continually forget until we remember and then feel a bit sick and then think about something else, there is a looming antibiotic resistance crisis and there is absolutely no incentive in the current paradigm to develop any antimicrobial products. If we are not using AI to just brute force some new molecules, what is the plan?

I do not want to dismiss the risk. I do not want to miss our need to be committed to moving forward in a way that these tools work for everyone. But I think we have to be realistic about what the health care system is right now. If we do not want to use a robot in a nursing home, then how the heck are we going to look after everyone because no one wants to work there. A pragmatic approach I think will serve us really well, especially given the pace at which we are moving and especially given that health care has existed for centuries with a general rubric for decision making that has served us well through many innovation cycles before and I do not think this one should be different.

Garrett Adams: And now we have the opportunity for that innovation cycle to be more and more informed by data and close the loop on it. Absolutely.

Jonathan Jungck: It is completely right. I think also along the risk benefit metrics, there is a validation framework that we teach a lot our perspective customers and customers when we start just to get the education out there because I think the education is one of the most important pieces here.

When we think about a program like Hospital-at-Home program, it is potentially can I get a patient to go to the safety of their own home. I come by a couple of times a day to check on them. When I am looking at that list of 150 patients in the EHR, I am like how am I going to pick ten patients today to go into this program. It can be difficult.

One of the things that we did was we found 108 different identifiers that we wanted to use to qualify someone for this program, some of which are very structured fields, some of which are I am looking for things like IV drips and things like that in the notes. And then what we did was we said what if we could produce a short list that is 20 patients. And of those 20, there might be 10 who are eligible for this program. The doctor is well educated and understands and knows that I need to go check and I need to talk to the patient and have the interview, determine if this patient is eligible for this program. But they

are only looking at 20 patients instead of 150. That was a very appropriate and applicable use of AI where I was able to make a decision faster because the information was surfaced to me, knowing full well that it was not going to be entirely correct.

Garrett Adams: You might not even think about AI in this context but once you have those 20 patients, the route that you choose to drive to go visit them in order to make the most of your time, that is also AI.

Valerie Watzlaf: Deb.

Debra Strickland: I know. AI has huge advantages. Get it. Duly noted. However, there are bad actors and can bad actors influence the things that you are building for the greater good and things like reviewing drug products that the reviews are not even real. They are just auto generated over and over again. This is like the next best thing. Awesome. Saved my life. All of a sudden this person who is easily swayed does not understand to be very filtering of perhaps bad data. Does not know to make a wise decision and do some additional research and all of a sudden takes – it is just that the AI technology can sway a population. How do we do diligence to try to protect our population?

Von Nguyen: Let me maybe talk about this in the context of how do we think about security and privacy within the context of AI because it is not just the large language model and scamming. It is broader. If you think about new technology, as you think about our data, especially around health, it is really important. Financial data is really important as well, but this is HIPAA-protected information that we are talking about.

A couple of things I would say from a principal perspective. We actually have pretty good tools already to think about data protection. When you think about most of the places where we have had intrusions of different sorts, it is usually someone turning over or clicking – like a human clicking on an email somewhere that results in someone – that results in an intrusion within a system. The weak point is not the AI. It is actually the human in that process.

The tools that we have now to protect against that are things like two-factor identification. You have all done this where your bank account – they send a text message to your phone and then you use that or if you are a government employee, you probably have a PIV card that you are putting into your computer to make sure it is you.

From a base perspective I would say when we think about security within AI, start with the basics. Do not think about new, fancy, crazy stuff yet, but start with the basics first because they are important and they are useful. This goes for things too as you think about some of the mechanisms that bad actors will use, there is something called SQL injection of access where basically you are entering an SQL code into a piece of software that will subsequently create an opening later on. It turns out that the code that you see in AI now, it is now SQL necessarily. It is prompt. So prompt injection attacks are something that you are going to see more. We have ways to deal with SQL injection attacks. We take that knowledge and transfer it to prompting attacks that are current. Again, use the tools we have now, evolve them in a meaningful way to continue to have privacy.

To the point that was made – one of the places as we think about bad actors, what we are seeing is not – we are not seeing generative AI at this point, developing new ways of attacking people. What we are seeing is toward your point like messaging campaign, human engineering sort of efforts where you are changing the language, changing the conversation. This is where it actually takes a village to do this. It is

not the big tech company. It is not the hospital system or payers. It is all of us working together and understand what is authoritative content, raising the authoritative content, making sure it is easy and accessible and gets there first.

For health for instance, what we have done is we worked with the National Academy of Medicine to understand first what is authoritative content, because in today's day and age, there are discussions about what is authoritative and what is not. We go to the source and work with the National Academy of Medicine to first understand what it is and then we make every effort to highlight that and raise that. As you think about search, there are ways by which we can highlight authoritative content in these boxes that pop up on the side of research. You get a bunch of stuff. But the authoritative content will pop up first and may be easily accessible and easy for you to see. But those are the types of tools that you can use to short circuit these processes where people are using human engineering and using some of these new technologies to change the way or change the conversation – but again, it is not one organization's responsibility. I would argue it is all of us together that must be together.

There is a piece of this where convening the right group together is really important. As much as Google can do that but I do not know if – I think you would be more trustworthy than us in that context. But that is something to think about as you are doing – who are the right people in this space and how do you bring us together to make sure that we are aligned in a meaningful way?

Jennifer Goldsack: I completely agree. There have always been bad actors. We can look at historical propaganda campaigns. We can look at things like redlining. That was a travesty of policy decision making and it was data driven and it achieved exactly the goals that the people making those decisions wanted it to do.

I think we also have to be a bit honest with ourselves. We can use AI to solve all sorts of problems. At the end of the day, the definition of success, what we are actually trying to do here, what the desired outcome is, there is a very – we will go back to the word that I railed against earlier, there is a very commercial or consumer-driven way, which is if the buyer of a product or a user a product sets the parameters for success, there is an industry that will build to it. Let us decide what we are actually trying to do here.

If we are trying to reengineer a health care system and in my opinion, it is moving towards a health care system instead of sick care system, let us define what good looks like in front because otherwise if we are just doing these various small, tactical steps, we are going to struggle. The system can perform whatever intent we articulate. Let us articulate a common and shared intent and that is something that I think we need now more than ever because of the pace of change.

I also think that to your point about authoritative content, I think that is really important because while we have had things like propaganda campaigns going back to the Second World War with early movies, there were cassettes being burned in Eastern Europe. I am not sure if you burn a cassette. I blew a lot out when I would listen to them again and again. The point now is that we can do it at such scale that that is what is I think nerve wracking about this and how do we wrap our arms around that challenge.

But the reality is and I will use an example and this is a personal opinion and I hope it does not offend anyone but we pulled off a modern medical miracle when we produced, tested, and were confident in the performance of COVID vaccines on the timeline that we did. We absolutely blew it when it came to the messaging campaign. We absolutely blew it. We had six to nine months to have the messaging

communications, trust-building campaign of a generation that recognized that under no circumstances were people just going to take something because people in an ivory tower said so. And we did absolutely nothing about it, which also brings us back to this notion of intent. Von, you gave really good examples about how we actually now need to reestablish authoritative content. It pains me that maybe the answer to that is an influencer. So sad. But if that is what works, that is what works. Let us meet the people that we are trying to care for where they are. I think that is part of the responsibility.

And again, I think it all comes back to what is our North Star here. What are we actually trying to do? And then the power of the technology as long as we are driving in the same direction and have appropriate guardrails, which ironically can be the AI itself. There are really good examples of GPT-4 that can be used to check on GPT-4. And that forges a pretty nice Swiss cheese model to stop hallucinations and other crap coming down the pike. But what are we doing here? What is our North Star and what are our parameters around risk and benefit? That is what I think we have to define as a community because the technology is – it is largely there. We might not quite understand all of it but it is largely there.

Garrett Adams: Got a pretty good grasp on it. I think your comment about having AI that can validate and test AI under human-defined parameters and guidelines I think is spot on and is also how we scale this.

I think, Von, you touched on it is not up to just one of us to define this. I think across health care providers, industry experts, government, health IT developers. It is up to all of us to lend our expertise to come together, help define these best practices, using both our knowledge of the risks, what the technology is capable of, and where it is headed to be able to have a common dialogue, common language about how it is performing, what it can do, what it is capable of while also fostering an environment for innovation to allow it to achieve the value that we all see that it can.

Debra, just one tongue-in-cheek comment for the beginning of your question. Yelp reviews for years. Amazon reviews. The influencer comment. I do not know. The amount of junk I see on TikTok ads. The reputable or trusted institutions having – when you cannot just validate based on trusted data that we know is good, I think that is always going to be the best source. But there is certainly a role of trusted, reputable institutions that are also commenting on it.

I think that might be a little bit of a risk of what you were getting at initially with consumerism. Consumerism absolutely does not mean only that but it could mean some of that. It is something that we will adapt to as a society.

Valerie Watzlaf: Jamie and then Tammy.

Jamie Ferguson: Thank you all for being here. I really appreciate it. I want to ask about your perspectives on risk management, but I am coming from a different angle. I want to ask really what do you see in terms of practices on the ground for risk management and health care and where do you think that is going. Put more context on my question.

I assume that you all have some familiarity with the NIST AI risk management framework. But this committee is charged with advising the Secretary of HHS on health information policy. We have also some specific responsibilities with regards to HIPAA. In HIPAA, there is a requirement to do risk assessments. Any time any health care covered entity puts in a new system, you should be doing a risk assessment on it. We have heard that sometimes that does not always happen when AI products are purchased and installed.

And at the same time, in my home system as well as others I am sure, there is a lot of excitement about augmenting the large language models with our own data to provide better context and precision by augmenting with RAG data. When you do that, of course, you have just changed the product or the system and you have to actually go back and revisit your risk analysis. I am sure that is frequently not happening. And then if you change your RAG data, again, that is another material change. Are you seeing awareness of this kind of on-the-ground system risk analysis and where do you think that is going?

Jonathan Jungck: That is a great question and I am glad that you are thinking about it. At Palantir, we hold a really high bar for making sure our customers understand where their data is flowing, where it is being stored, where it is being retained, what is being used to train.

One of the first things that happened when Dr. Karp told us that we had to go turn on AIP – all of our AI functionality everywhere. Everyone said I have to go do another technical risk assessment with every IT that I work with. Part of this was guys, just so you know, we want to turn on this new tool but it is going to involve egress to this new Azure instance that has this open AI model that we want to use. There is zero retention on prompts and responses. There is no training of your data externally. There is not even auditing for CSAM and such. We will do that on our side.

We kind of go through that training and education exercise with our customers proactively. I would say if we were not doing that, probably 70 percent of them would not even know the difference and would say, oh, you are just turning on your AI functionality and that is in the same control plan. It is often not, and a lot of folks do not know that. It really is up to the good actors to give that education right now. Some health systems do know this and some health systems are well educated in it. But it is important to go through that risk review and to really make sure that they understand where their data is flowing, how it is flowing.

I think HCA hospitals, which were deployed on top of Google Cloud, they have the concept of innovation hubs or innovation sites. It is hospitals where they are particularly used to new technology coming into the hospitals and health systems. Those have been great places to get started because they are totally aware of how these things work. It is made for much easier onboarding of those new tools.

Jamie Ferguson: Let me just also follow up with part of my question that I forgot to ask. Is there any additional policy or guidance that you think would be helpful to improve risk management?

Jonathan Jungck: It is a great question. I think that on the policy front, I think the two most important things are – on the education front, it is important that they understand where their data is flowing and where it is being retained, where it is being used and stored. Is there a BAA with every entity that is involved in the chain of the process? Do they understand this is going to another third party as part of that risk there?

I think the other piece is do they have a validation framework of some sort in the works or in place for the workflows that they are building. An example of how you do this – I like the large language model the eager intern. It is so obsessed with giving you the right answer that even when it does not have enough information, it will try. How do you write it first of all in a way that says it is okay to not have an answer when we talk about the TNM cancer classification diagnosis that we were talking about earlier. To say if you do not know the answer, it is okay to not put it there. It is a seven-centimeter

adenocarcinoma. At the bottom, there is a note that says the doctor does not agree with this diagnosis, so I am going to say it is a Stage 3, not a Stage 2. Sometimes it is okay to just say could not classify.

You then have to look at two different metrics sort of combined with each other. One is for each actual classification when you think about what did it actually end up as. In this care progression, which department did they end up in or did they get discharged? Based on that final decision, how often did it attempt to make an answer and then how often was the answer correct? If you are constantly intention of that duality, you can get to a place where both are at about the 90th percent mark. That is when you are at a really good state.

Garrett Adams: I will draw one distinction between fine tuning of training and retraining a model with more specific data and RAG, where you are supplying it to the prompt at run time. But the actual binary of the model under the hood does not change, which I think that would invoke the need for a reevaluation if you were changing the underlying model binary. RAG, retrieval-augmented generation. I asked Maya to ping me if these terms – retrieval-augmented generation rate dynamically pull in contextual data at the time of calling the API or building a prompt to get a response.

I think what Jonathan mentioned about the way to make this an easy question to answer, is to have the prompt not be stored, the model to not being trained dynamically by (inaudible). so just really prompting against the foundational model and getting responses back.

I would add in the need for good evaluators once you get the response back. Rather than a single call-in response, you might think about your ChatGPT experience. If you ask a question, you say – it might have told you something great. It might have told you something kind of dumb. But you might dialogue with it more. You might ask clarifying questions or give it more guidance and then you can refine it down to something that is precise and is reliable.

The way that we have designed workflows is primarily embedded directly and not chat experience. We are controlling the way the prompt is designed, the way the responses are presented. But before the response is presented, you can run a series of evaluators to check – some of that what Jennifer referred to with the language model, checking the language model or other more traditional techniques, checking the output to see is this of the quality that we are expecting before presenting it to the user or for whatever the workflow is.

What is something that we would ask for or what – I think my answer across the board is continue to engage the experts in the field that work with this day to day for what policy could look like, what advice could look like or even what additional research should be done into the capabilities.

Participant: Anybody else want to respond?

Tammy Banks: -- inspired me. Think outside the box. I know that you were looking at population health. One of the issues that we have in health care today is obviously the exchange of information. And one thing that AI makes as data becomes more and more important and the lack of data and the data being named in different ways. If you pull it, it does not necessarily mean we can go into all that.

Just thinking outside the box, we have a national infrastructure that even though we have standards, there are always proprietary endpoints. Garrett, you know exactly what I am talking about. We could talk about X12, NCPDP, all these standards. I know we have been focused more on population health efforts and community efforts. But in your expertise, do you think there is anything that can be done

coalition – you did some amazing things with getting data ready to be used by others and not make this a for sale product because we have community centers, all these other people that need to get access and send this data in a way that is not so costly. Do you have any ideas on how to move to different versions of exchanging of information whatever the syntax be?

Von Nguyen: Actually, I would argue that the government is actually moving in the right direction already. As you think about the requirements of FHIR, which have come down the pike in the last couple of years, I think the rules are definitely hitting in the right direction to create that interoperability that ONC and other organizations talk about.

I think the challenge sometimes is the implementation in terms of actually getting it done in a meaningful way. The switching cost associated with many of these actors is not small so just practically speaking. It will take some time is my suspicion in terms of that.

But the building blocks are there. To your point, I think there seems to be a consensus that FHIR is the place we want to be and begin the exchange of information. And the question is that data mapping exercise to get to FHIR as you share information across the board.

When you think about that, there are actually states that have done a really good job in terms of creating these all-payer claims databases. There is significant variation. Like Massachusetts is a great one. Other states not so much. What I would say there is that there are some exemplars that we could learn from and there is that opportunity to highlight those exemplars to understand what happened in specific states that you can point to.

I spent a fair amount of time at CDC. I always found that states were the bedrock of understanding innovation and what works and what not. You basically have 50 places where you can test new ideas in a different way. And to what extent do best practices where the system is working can be shared with others? I always found it is a valuable mechanism to both identify what works but also provide real-life experience but how to get there from an implementation perspective.

Jonathan Jungck: One thing I would say about FHIR in particular is I think FHIR has done a good job at bringing us a lot of the basics that a lot of systems outside of EHR need to know about. It is things related to billing and claims and events within the hospital with the movement of a patient.

But when we start to talk about large language models and some of these other things, there is a lot of other contexts that it starts to need to know, things that become more unstructured and a little bit harder to get at. Those are not always going to be solved by a very structured format.

I think a piece of this is FHIR but a piece of this is also how do you start to think about just more broadly how do you get access to the core of the raw data in a more accessible fashion.

Jacki Monson: I am going to ask you a question from the chat. Are there specific concerns around the use of thresholds that users may not understand that the yes/no answer they see is actually a 92 percent or an 87 percent likelihood, et cetera, depending on how the threshold is set?

Jonathan Jungck: It is a great question. One thing that I would say GPT models, in particular, is one example is a percentage. If you ask it that same question ten times in a row, you will get anything from a 70 to 90 even if it is the same answer. I think less so than giving it a threshold, giving it context is probably the most important thing. When we think about why are we giving a patient a particular

medication and they want to understand the context for why that order is on their list is can you pull the snippet from the note verbatim, show a highlighted piece that shows this is where they contracted pneumonia six hours ago, which is why they are on this. It is really about providing and servicing context in a way that is shorter and easier than the way they do it today. I think that is where you get success.

R. Lenel James: Lenel James with Blue Cross Blue Shield Association. Jennifer brought it up. Social determinants of health, health equity and that role. But yesterday we had a panel that talked about value-based care, fee for service in HIPAA standards, and then we had a variety of experts talking about SDOH. I am the payer advisor to the Gravity Project so you understand a little bit of the context.

Garrett and Jonathan and anybody else who wants to answer the question, just trying to make sure I understand from a privacy and security standpoint when we have these new community groups. Federally qualified health centers are in the community but they are HIPAA covered. But a lot of the food banks, a lot of the community groups – they are not HIPAA covered but they are also very leery about AI. What is your vision of that world where we are looking at SDOH and we have new actors that are not HIPAA-covered entities but are going to be critical to improving health of the system outside of the normal typical health care?

Garrett Adams: I believe my colleague, Prerana, was out here on the panel yesterday. I would love to tee her up with this question. I think similar to – there has always been the – where the data is used within the organization within the walls of HIPAA, if you will. There have always been entities that they work with outside and there are existing ways that they have already learned how to interact with those groups. I do not think there is a direct transfer or exposure of information unless it is something that is agreed upon and consented to by both patient and health care system.

Jonathan, do you have other thoughts on that?

Jonathan Jungck: I was going to say the same thing. We work with New York Health and hospitals doing a lot of their SDOH work like benefit counselors, for instance. First of all, if you can reach the patient in the first place, calling and calling and emailing, writing letters, every form of outreach you can think of. But if you can get in touch with them, of course, they are incentivized to see what are benefits that they may well need if they have an upcoming birth or something like that where they can be of assistance there. I think that is important to them but also these other educational pieces are equally important, and they have partnerships within the city where they are already finding ways to be able to share this information.

Jennifer Goldsack: Two tremendous answers and I am so glad that you asked this question. I am an enormous fan of HIPAA. I think it is a tremendous piece of legislation and I think when it is implemented as intended and not hidden behind, it does so much good work to every single person that our health care industry exists to serve.

And I think if we are serious and you can tell what I think a good future state looks like that we want to move beyond a sick care system that is defined by clinical care to a health care system that is defined by keeping people healthy, we are going to have to grapple with the fact that our current definitions of what health data is or health data are when I speak American are not appropriate for the digital era.

There is a flippant example I can give but it is a good one, which is we can look at your health record and we might be able to run some models on that for predicted health risk.

I could also look at the GPS data on your phone that knows every day after work, you pull up at a liquor store. I could then look at your credit card data and know that you buy a handle of Jack and I can look at your OnStar data from your car and know that you are enormously overweight regardless of what your height is. That tells me an awful lot more about your current and future health status than probably most things in your electronic health record and yet none of that is considered protected data and it is flying around, and I tell you this right now. Many people are making decisions back to your good actors/bad actors. They probably would not even describe themselves as bad actors because by their letter of the law, they are not doing anything wrong whatsoever.

I think if we are really interested in there are all of these social determinants, we actually are genuinely interested in maintaining people's health. We need to think about this really differently.

I will give a couple of examples of things that I think stray from that clinical/non-clinical boundary particularly as it relates to where data comes in. Our organization, the Digital Medical Society – we currently under a different grant-funded projects have tow initiatives under way to build risk prediction models, one for relapse for individuals battling with opioid use disorder, specifically derived from consumer grade sensor technologies that they might be wearing and can we actually identify when they might be at risk of relapse so that we can intervene in time because we know that it is that moment of relapse when most of the overdose deaths happen.

It is actually not a hard model to train because there is a gold standard reference standard. It is a urine test. We know there is a yes/no very clear answer for whether you are using or not. This is a very solvable mathematical problem. But how we think about the protections of that data, how we think about who has access to that data and information, how we think about funding interventions, that is the bit where it gets hairy. It is much less about the AI. And to your question, it is about the data that is input into it and the lack of any protections around it. It is consumer-grade wearables intentionally because we want them to be really accessible. But it is also about who has access to that information on the back end of it.

We are doing something similar with serious mental illness. If we think about where we find most people in America with serious mental illness, it is in the prison system because there will be an exacerbation when they are out in the community and the only person that we know to send is a police officer. There is absolutely no reason for that. We can think about different psychoses. We can predict – we are confident that through the same kind of training of models, we can use sensitive-generated data maybe supplemented through some use of GPS data and other things that we could get a pretty good read on when someone is about to have some kind of serious mental illness episode so that we can help them. But none of that data under current knowledge is actually protected nor is whether information goes after the fact.

It is exactly the right question and I think we might need to start redefining what we mean by health data as more and more care leaves the walls of the clinic and more and more data we can access that is relevant but is not clinical data per se.

Jacki Monson: Jamie, did you have a question?

Let us round out with a couple of last questions. If you are sitting in our shoes as the National Committee on Health and Vital Statistics, what do you think we should do with all that is transpiring in the AI world particularly in health care? How can we help?

Garrett Adams: I will again say engage the experts. We are at the leading edge of it at the front lines and have a deep understanding of both how it is going to be used, how it is being used, how the technology works. Please continue to have these dialogues, have an open collaborative discussion about it. We can define best practices together. I think that is a general advice.

Getting down to some other considerations for just the perhaps overall regulatory landscape around AI, I would say there could be some additional clarity on jurisdictional boundaries or jurisdictional separation between FDA, ONC, and CMS for what part – who has jurisdiction over what in AI in health care? What entities do they – should they have coverage over?

Another one. Perhaps advice on – advice or guidance on what effective localization, localized testing for a model validation looks like and how to scale that effectively.

Thirdly, helping – and I do not know if this is advice, but it is perhaps a desire that many of us in industry have. It is helping define a common dialogue. I think you mentioned the many different groups or lists of similar ethics or similar guideline principles.

When we say accuracy or usability or bias, let us get a common definition that people can work on, quantify, develop against. I think that is something that groups like this have the perspective to be able to bring together.

Finally, I will say continuing to have an open, collaborative environment for discussion that fosters innovation and helps us adapt and be ready for how the world is going to change.

Von Nguyen: Just for me, I would echo Garrett's comment about creating a forum for discussion so this group but the private sector but also community groups, making sure there are academics in there and government at all levels where local, state, and federal but that forum and that space to have this discussion is important both for us to share what we know but quite frankly for us to hear what people are concerned about. That is really important. There are never enough opportunities to really hear from people and communities about their concerns. That would be really helpful.

The other thing I might add is what I started with. When talking to the secretary and making recommendations, think beyond just health care alone or beyond the 15 minutes that I spend with my patients four times a year and think about the context of what do consumers need, what is the, how do you information think about authoritative content. Also, thinking about the community needs as you think about communities. What are the decisions they make? What is the information they need to be more effective to serve the people who live within the context of some geographic area and the broader definition of community. It could be a group of people who have a common characteristic. It does not have to be geographically defined but think about that context of communities in addition to the brick-and-mortar health care delivery system.

Jonathan Jungck: I think those are all really good points. I think the only one that was not mentioned that I would like to add is as an influencer, I influence in board games. There was a rule in the last year about – we kind of had to start putting in that paid sponsorship type promotion thing even if it was just a free review copy or whatever it is. There needs to be sort – not necessarily a standard but an encouragement of appropriate language to identify when AI is in use, when something is AI derived. What we find a lot of is that nurses will read something and go yes. It sounds right. Discharge. And that is not necessarily the right approach.

And I think how you build these even user interfaces to say this is a predicted or estimated decision and how you actually surface the information for them to say okay and I feel good about that, I think is probably one of the most important thing that the health systems in general and other AI-driven workflows need to be educated on more broadly.

Jennifer Goldsack: It is a tough one to bring up the rear on. Riffing off what you were just saying in terms of how we actually communicate current state, I think whatever technological innovations or frankly whatever quality innovations there are, we have to make sure that we are continuing to support the appropriate skill development in the current workforce.

I think your example is perfect. If there is not another side of the coin, which is actually educating whoever is looking at that decision, then the language that we use I think with good intent like human-in-the-loop, we are just punting responsibility and we are doing it in a way where we are not actually taking seriously the consequences of some of these decision making moments and we actually need to position our clinical colleagues for success. We need to position our colleagues who work in health administration for success as we do this.

I want to go back to the jurisdiction piece as well. I was at the ONC annual meeting in December of last year and there was a tremendous panel and a variety of different data standards obviously. We were tackling some AI security issues and NIST had a framework and NIH had a framework. FDA had a framework. ONC had a framework. And they were all good but they were not the same. You sit there and – isn't that a tremendous panel? Isn't the government doing a lot? Yes, but wouldn't it be great if we could harmonize and align a little bit more.

I think that given the consternation that we see in the field right now and given the pace at which we are moving, I want to recognize that the question about risks is real. Why are the risks higher with these sorts of tools? Because of the speed and the magnitude with which they can impact. I do not think there is time for us to be parallel processing on redundant issues. There is more than one right answer. Having four A-grade papers is not the way we do this. We need to unify. We need to harmonize that informs best practices. It is clear for industry to build to. It is also clear for folks who need to upscale what that looks like and what they are dealing with.

And then I think the last piece, and this is hopefully a bit of a theme that has come through today. You are exactly right that we need to engage the experts in how we are doing this. I think what I would look to the secretary to hopefully really coordinate and champion is what. What are we doing? How do we want to set the goal post or the North Star for what this wave of innovation, the generational wave of innovation even does for the health care system? What is the problem that – these things – it is an overused word but these technologies can be truly transformative. Great. What are we trying to transform? If we were to sit down, for example, maybe some AI would even help us in this. We could project out what health care shortages look like in different areas and in different specialties over the next few decades. Great. Let us find information there. Let us actually think about what we think drug shortage crises may hit us. Great. Let us funnel some AI information there.

We know that everything we are doing about the way that we manage the clinician experience by burnout through early retirement and through the fact that it is the career where more people commit suicide in the US than any other career is not sustainable. How do we actually create a hierarchical roadmap of what we go after first? I think that could be incredibly powerful because it is going to yield the greatest ROI.

And back to our risk-benefit decision making, if we could yield some real benefits, we are going to build trust. We are going to garner more investment so that we can build things right and we can earn trust as we go to lower tier sorts of instantiations.

Jacki Monson: Thank you so much for your time today. It was a great, active conversation and it probably will not be the last time we talk with you so thank you.

Let us take a five-minute stretch break and then we will get at it. Thank you.

(Break)

Jacki Monson: First, I want to turn it over to Rebecca, who has something to give to our new DFO, who is sitting at the end of the table.

Rebecca Hines: In case you did not get the memo, this is my last full committee meeting and I will be here for about another month but I thought since – I feel like I have just been a steward and a caretaker or running the race for this period of time. I thought what better way to reflect this than a baton. We have the new NCVHS baton in our theme colors. Naomi, I am going to walk over and hand this to you. Get your cameras going, folks, so we can show that because we are now diving into the workplan, which is the future, I want to make sure everything that you all want to see happen in the future ends up with our wonderful new acting DFO for probably a long time, until they hire – sorry, there is my boss over there. Sorry. Here we go, Naomi.

NCVHS Workplan Development (continued)

Jacki Monson: Alright. Thank you. We are going start with Standards and both our esteemed co-chairs of the different subcommittees have told me they are going to run efficiently fast. We will start with Tammy to cover standards and then we will move over to Val to talk about the workplan.

Tammy Banks: Why does that not seem like a new directive? I do not understand. What our goal here is in the next probably 10 or 15 minutes is we want to take advantage of the newness of the presentations that we have had over the past couple of days. As we talked about yesterday, the four items that we are going to add the workplan, I will be adding them before our next meeting and we will be able to talk about them. Just consider that is going to be done.

The first topic I want to talk about is the examine mature and emerging standards and how they co-exist to support current and future business needs and their workflow. The Standard Subcommittee identified areas of learnings that we were looking for and we held two sessions yesterday. One is TEFCA introduction as well as the value-based care. I would like to start with the value-based care panel. Anybody in the room here, is there anything that we should be adding to our workplan or any lessons learned that we need to document in future discussions?

Jamie Ferguson: One of the things that we heard about in the TEFCA panel was the importance of the TEFCA implementation specifications for the use of FHIR for the non-treatment use cases, including both health care operations and payment-related purposes. I think that an examination or our consideration of those TEFCA implementation specifications for the FHIR-based APIs for the non-treatment use cases has to be on the radar screen of the Standards Subcommittee.

Tammy Banks: Thank you. That correlates to the value-based care where they actually laid out the use cases that are needed. It would be interesting to see if it translates.

Debra Strickland: I kind of kept resonating with the exception process or bringing willing partners together to do good things even if they are small and just trying them out and see if it is going to work. I think that that is probably a worthy strategy for us to look at and talk about, kind of brainstorm that out a little bit more because maybe that is how we get to what other evolving standards are out there, what other alternatives are there for us to consider, trying to get our toe wet first before we jump in without floaties.

R. Lenel James: -- the mixture we add, exploring not pilots but early demonstrations because it is really clear that one of the – we had a lot of discussions about what are tools to validate the standards. Well, there are not any. Many of them are not going to come overnight but we can be trying to make sure we are including – trying to make more early demonstrations more appropriately funded, more appropriately considered because the best way to find out if something works is to try it and then we can go back to somebody and say we just did that. It did not work the way you thought it worked – please fix it or assess it may be quicker than we can get better tooling to test the standards.

Tammy Banks: Anybody else? Kind of related to these two committees, one thing is the prior auth lack of enforcement and obviously under TEFCA, I would assume they are probably going to use as similar as the covered entity approach where they will have in their contract protections. But if that is used outside of TEFCA, the alternative to the prior auth, are there any protections to it if there is no enforcement being made on the HIPAA standards? I am thinking that that is something we need to understand a little bit more and I am sure we will hear more with the guidance that is coming out. Is that worth putting on the workplan? Okay.

Anything else under TEFCA or under the value-based care that we do not already have on our topic for this area? In the interest of time, we are going to move on.

The third panel we had was the – and the other thing I wanted to just relate and just give a notice of is we are looking at having a – developing a session about the HIPAA exception process outcomes and present that to the executive committee after it is developed later this quarter.

Rebecca Hines: Are you saying that is for the September Full Committee Meeting?

Tammy Banks: Yes, but again we have to present it to the Executive Board and go through the –

And then the other areas. Review relevance of HIPAA in the current health care system. Val and I had discussed – this is one of those topics that we were wondering exploring if we should have a joint workforce or have an independent workforce and we talked and came up with a proposal if you do not mind me just laying that out just to be quick. Val and I thought it made sense to keep these separate and then meet maybe once a month or so on this topic so that we can share those questions that intersect and make sure that it is a unified approach to address those. Does anybody have any questions on that topic or concerns in regard to the review relevance of HIPAA or beyond HIPAA?

Rebecca Hines: Are you saying that at the monthly executive subcommittee, that is where you would have your intersection or are you saying you would have the members involved meet monthly?

Tammy Banks: I was meaning have the members meet monthly. But of course, we will touch base of the executive and Val and I continue to touch base on this topic and as well as other topics. But for the members, I just wanted to see – because we had raised the idea of having a separate workgroup if that touch base was enough in order to move this forward during the staff transition and during our limited membership. It seemed to make most use, best use of our time. Any questions or concerns?

Rebecca Hines: This is specifically to the tenth item in the eAgenda book, which is the joint proposed project scope where it is still a lot of conceptual and there is not an actual here is what we are going to do laid out. There are some ideas. If you are not familiar specifically with where Tammy is, could I see a few questions on people's facial expressions? Go on your way home on your airplane ride, read the tenth item in the eAgenda book to see where this is at the formulation stage I would say.

Tammy Banks: What happened when we were talking about the joint project scope, the Privacy and Security Committee and the Standards Committee came up with the same topic. Because we came up with the same topic and there are cross overs – Nirvana would be to create another workgroup. But unfortunately, after we brought it here before and had a conversation and asked for willing volunteers, while people were interested, no one really had the time to commit. We had staff turnover. We wanted to discuss it at this meeting, and we were just thinking again to be more efficient since these are topics that are discussed in our report groups already that we would just touch base monthly or as needed in order to continue to touch this highly – everybody is excited about this topic but we were hoping that that meeting structure would meet everybody's needs.

The scoping document is what got the conversation going. It is that Beyond workgroup. Is HIPAA going to be sufficient for the innovations that are moving forward from both a Privacy and Security and Standards? Anybody have any questions? I know I am trying to be quick so that sometimes I am a little bit too brief.

The other topic we had was SDOH, which also came under the Beyond HIPAA. Other secondary uses of HIPAA data. With that in mind, anything from the SDOH session that we should be putting on our workplan to be considered or look into further?

Seeing none, I have a suggestion. I think SDOH and the secondary uses of SDOH are extremely important. With the information that was conveyed, there are a lot of issues for us to look at from what is the North Star to steal our eloquent Jennifer's language. What are the data points that are most important? There are so many wonderful efforts going on. Are there any lessons learned between all of those efforts? I am just wondering if actually taking time to dissect this presentation instead of discussing all this and form an ad hoc workgroup for those who are interested in looking at this from a standard, privacy, and public health perspective makes sense. Is that anything that anybody would support or entertain?

Jacki Monson: I would support it. I think there is definitely a need. In the last couple of years, we have made some efforts in this area but it has not been as focused and I would say set up for success. I would like that too and I think we will just have to be really thoughtful about how we set it up for success this time.

Jamie Ferguson: My view is that is an item for standards and not for PCS. I think it is important but I think it is a standards issue.

I also think that rather than moving straight to the secondary use, I think that the standardizing the original data capture of the SDOH is critically important and is highly divergent today. This is an area where actually standardization really is needed, not just on what are the data elements, but on how are they captured and managed from the point of capture before secondary use.

I would provide a friendly amendment to add original capture of SDOH to the scope or charge of this activity and I would put it as really under the Standards Subcommittee.

Jacki Monson: I would counter that a little bit because I think that the issues are broader than standards. I think there is health equity and I think there are a lot of good things that came up during the conversation that should be considered holistically. Standards is a component of it but I think we should look at SDOH holistically more than privacy and security as well. I am thinking from a whole population health type lens.

Jamie Ferguson: If we had a Population Health Subcommittee, it would be joint of that with standards. I just do not see the PCS angle as much. I agree completely about health equity. The population health purposes are very important.

Jacki Monson: I believe we have the right to have an ad hoc population health group and have the opportunity to look at this.

Michael Hodgkins: I was not here in the past but it sounds like there have been starts and stops around the topic. You were talking about setting it up for success. I guess from my perspective, I would argue for taking a small bite and being successful and then moving on as opposed to being over run and risking not accomplishing very much.

Jacki Monson: My comment on it was not successful. It was not because there was not good intent. It was that we did not have the staff support that we needed. We did not have the focus I think on conversation. That was led by Vickie Mays. I think there is still a lot to be uncovered that is broader. I am a big fan of looking broader and then narrowing where we think the most benefit is from NCVHS. That is what I am suggesting is we take a broader look at it and then we go more narrow.

Tammy Banks: Jamie, I think we need to put that on our workplan regardless of this ad hoc workgroup. The original capture of SDOH and the impact on our Beyond HIPAA and then we can talk about that broader ad hoc workgroup and how that could feed into it as it makes sense.

R. Lenel James: I will just say I want to be careful that between the work of USCDI and the Gravity Project, a lot of the standard data elements have been defined. In fact, they have been so well defined, most of them are sitting on the shelf and not getting used. It is less an issue of the data and more the issue of how does it get used, how does it get implemented, how do people build the protocols and workflows, which is broader than just standards but a lot of it does come to standards and then probably auditing to make sure we do not find some missing data elements.

Jamie Ferguson: I was just saying that Lenel is talking about these standardization efforts, including under Gravity and things sponsored by ONC. Of course, they are creating standards rather than using standards that exist such as ICD-11, which has greater granularity for what they are already trying to do. I think that needs to be looked at from the Standards Subcommittee perspective of how can existing international standards be used rather than just creating it and other standards for the same thing.

Valerie Watzlaf: I was just going to comment too that I think it is important that we also – because I was on the SDOH, I think. Was it a workgroup or something that we started? And I thought we did some work. I do not know if we cannot throw that out and do not forget about it and bring it forward.

Participant: There is no reason why you could not dust that off.

Valerie Watzlaf: I do not want it to go away.

Rebecca Hines: And I wanted to remind the group because not everybody was here for all of it that there was no population health subcommittee when you got two letters done by having ad hoc groups of volunteer members who got together. You self-organized. You met. You drafted the recommendation letter. You brought it to the Executive Subcommittee, discussed it with the Full Committee and you got it done. And you are perfectly welcome to do that. You do not have to do things within the subcommittee. Those really help you organize yourself. And over time they, I think, really reinforce and strengthen the way the committee operates but you do not have to have a subcommittee in order to get the work done.

Just off the top of my head, the 2021 ICD-11 recommendations were an ad hoc group of members and the tribal organizations having access to their own data. The tech letters, as we call it, for short. That happened through an ad hoc group of members who self-organized with staff support, met regularly, developed a draft, brought it to the Executive Subcommittee, brought it to the Full Committee and got it approved. I just want to remind you that there are many ways to crack the nut as we say.

Tammy Banks: And maybe we could put this on the Executive Committee agenda to kind of figure out what needs to be included within the scope of this type of ad hoc group regardless of where it lies.

Jacki Monson: That sounds good.

Tammy Banks: With that, that is all that I was hoping to capture so that we can make sure that we can go through on Thursday. Thank you.

Jacki Monson: Thank you.

Val, I will turn it over to you.

Valerie Watzlaf: We did meet our PCS Subcommittee to go over our workplan. This is really just to summarize that. But before I start, I just want to thank everyone who was on our subcommittee. It was Angela, Denise Chrysler, Cathy Donald, Jamie Ferguson and Jacki too always provides us great input and special thanks to our staff. Of course, Rebecca, Maya and Shirley and Naomi. Maya also helped me with some of these slides. I want to thank her for that.

This is just – on the next slide, we wanted to start with building on our most recent work and I am not going to go through each one of these. These are all up on our website. But we do tend to go back and use these as very good resources that we continue to use and build on, one being the Beyond HIPAA work that Tammy mentioned and then also some of the data considerations within a PHE, public health emergency. Also, our recommendations to strengthen cybersecurity. We have a couple of those recommendation letters. And then our very detailed response that we had on the Privacy Rule, the NPRM HIPAA Privacy Rule to support reproductive health privacy.

We are going to build on some of these and I will just come back to this slide. This is pretty much what I am going to be talking about and I will try to go fairly quickly. But it is really looking at our past, some of the work that we did and what are doing now and what we anticipate to do in the future.

This is what Tim really went over so I will not go into it again but just to refresh your memory. This is the NPRM and reproductive health information privacy. This is a future focus area for us because the Final Rule has not come out yet, as he mentioned. But the NPRM – we were actually asked. The committee was asked to respond. We did. We got our response and right on June 16, I think, right at the deadline. You can see there that they did receive almost 26,000 comments. That is what they are going through right now and hopefully we will get the Final Rule probably sometime this spring.

These are some of the proposed Privacy Rule amendments. And Tim did go over these so I will not go over them again. But I think some of the things to remember is if this rule were finalized, it would be the first time that the HIPAA Privacy Rule protected someone other than the patient. It would protect anyone providing reproductive care and it would protect those facilitating care. For example, it would protect the Uber driver who takes the patient to the abortion clinic, or it could protect a family member who would go to the pharmacy to pick up a prescription and so forth.

Here are a few more just to refresh your memory and to summarize. There is a proposed attestation requirement that I think Tim also went over these that you would – the CE or the BA would have to obtain a signed attestation if the PHI is requested for any of the following purposes that are listed there.

As I mentioned before, we were asked to specifically comment on the NPRM, which we did. Our comment letter is right there if you want to take a look at it with the QR code. But we also – as I said, we know that there is probably more than that we would have liked to put in that letter. But due to time, there are some things that we were not able to do. We are hoping we can do that in the future.

These were some of the comments that we made. I am just going to briefly summarize these. We had four major comments and the response. The first two were on the scope of the prohibition. We felt that again the HHS should consider not making a distinction between care provided that is illegal versus legal. Again, our major consideration here was that without broader protection, this distinction would continue to cause people to fear seeking care and it would cause fear in physicians to provide necessary care because it is not always clear in the moment whether that care would be legal or not legal. You should not have to ask. Doctors or patients should not have to call up an attorney before performing, for example, a stabilizing emergency abortion or before having to document in their records. And legal counsel may not even be available and obtaining counsel may be very costly and seeking counsel could also delay necessary care.

The second comment that we had on there on this slide was to prohibit obtaining PHI for investigations of any type of health care, not just reproductive health care. Our idea here was that being that no one should be investigated or subject to any liability for the mere act of seeking, obtaining, facilitating, or providing any kind of medical care.

There are a few more here. This was just in relation to requiring attestations again for all requests for PHI, again, because the definition of reproductive health care that was given in the NPRM was very broad and we thought why couldn't you just extend that to all types of health care.

And then we also finally – this is the last comment I will just summarize. Our committee suggested that HHS should require that attestations include a redisclosure clause for the prohibitive purposes. We

thought that if you could add that phrase that further prohibits redisclosure for the same prohibitive purposes, that might be useful as a defense in court.

These are some other ones that were not as I guess broad that we did not spend a lot of time on. But these are some other comments that we did have in here that you can take a look at.

Now what we would like to do and this will depend on what the Final Rule shows when it comes out but we would like to extend our further recommendations to other health care entities, for example, including the patient's phone app that is not used as part of a covered entity or covered practice, looking at location data, tracking non-prescription data such as prenatal vitamins and pregnancy tests, and also look at data analytics that are being used by some organizations to predict pregnancies. For example, Target – I think you might have heard of this. They actually use modeling and data analytics to identify women as being pregnant before those same women were able to tell their closest friends and family members. And then we also want to go into a little more in telehealth and telemedicine.

Other areas. And these came up in our July 2023 panel briefing that we had in which there were some wonderful very detailed stories of what has been happening around reproductive health, health information privacy, one being in the documentation and coding gaps where health care providers are not always documenting reproductive health information for fear of prosecution and also they are not always using the appropriate clinical codes for things like miscarriages and ectopic pregnancies because the word abortion could be in the code description. Physicians are not always including these for fear of prosecution or litigation.

Another area we would like to explore further is some of the professional repercussions. One of the stories that came out again in our July briefing was in response to laws prohibiting abortion. One hospital had a new policy for terminating life-threatening pregnancies that actually required the obstetrician or gynecologist to go and get another signed statement from another physician stating that the pregnancy actually threatens the life of the mother. They also required that they get an additional signature from a neonatologist stating that the fetus cannot be resuscitated. And these statements were required for any termination of a pregnancy, including surgery to remove an ectopic pregnancy.

This new policy was really – it was designed to protect the hospital from prosecution but obtaining these statements delayed treatment for potentially life-threatening conditions. It took neonatologists – it took them away from being able to care for their critically-ill newborns to go and sign these statements and it also created an environment that eroded trust in the profession of obstetrics and gynecology and implying that they had to go and get other authority.

Another area we wanted to focus on was reproductive justice and racial inequities. This also came out of our panel briefing. I believe it was Monica Edwards who said – she is from In Our Own Voice, the national black women's reproductive justice agenda. In that, she actually urged lawmakers and federal agencies to use all means available to protect the rights and health care access of black women and gender-expansive people, including privacy protections. She specifically urged our committee to approach relevant issues such as privacy protections from a reproductive justice framework that would then focus on people most impacted by the Dobbs' decision.

Some of our next steps. Again, we have to wait until we get the final rule that hopefully is anticipated. I tried to pin Tim down on a date, but I could not get that. I just said probably in spring of 2024 of this year. And then we have to prioritize areas that would not be included in the Final Rule as well as what

we were not able to include in our response. We hope to then formulate a project scope outline and develop a recommendation letter.

Another area that we were thinking of is the accounting of disclosures. This was also one that Tim had brought up. I think that they actually are going to include an accounting of disclosures, including disclosures made for treatment payment and operation purposes within the Part 2 role. That is why I wanted to clarify with him that that has not been made in the Privacy Rule modifications though.

We thought that we could look further into this because we were finding – I did take a look at some of the comments that they received. Some of the comments did talk about how much this is a great industry burden for those organizations that would have to do this if it did come to a Final Rule. OCR did say it continues to be an area of interest that they would like to close off.

Our next step here would be to again review the comments. We could go in and review more comments that OCR received from their 2018 RFI and also their 2021 NPRM and then discuss further with OCR, and also we could hold briefings from industry to get more input on the accounting of disclosures issue.

The next areas are privacy and security and AI. Again, I want to thank Maya for putting together a fantastic panel that we just heard from. I think we need to go back and review the previous briefings that we did have from our previous ones. I think we had two others as well as this one. I think, Jacki, you were saying that possibly we could even have a workgroup that would be developed around privacy and security and AI, which I think would be great.

Jacki Monson: I think it would be a good idea just with the evolving space and – the group. I think we can work to shore something up to bring for discussion at the Executive Subcommittee.

Michael Hodgkins: To use your earlier comment of going broad and then going narrow, I am comparing what we heard about SDOH to what we heard about AI today. AI is a runaway train and the implications for a variety of things whether it be standards, privacy, et cetera, I think are very serious. If we are talking about an ad hoc workgroup for SDOH and you had to choose between an ad hoc workgroup for SDOH versus AI given limited resources, where should we be spending our time?

Rebecca Hines: Although not focused on health care, there is a relatively new AI FACA. In fact, they reached out to us for advice because they needed some help just with the basics of setting up a FACA. The website is AI.gov or something. It is really simple. You can just find it. I think it came out of an executive order. Do I have that right, Lenel, Jamie? I spoke to their DFO and some of their staff. They just needed help with some basic things. They are actually – we coordinated with them on some ideas for how to get the work done. I was thinking you might want to invite them just like you have this idea for a session at the September meeting. I do not know if they would be willing to come because they are still so new but a previous NCVHS member is on that FACA, Frank Pasquale. You might want to invite them to come talk to you about to what degree they are focusing on health care so that you are not duplicating efforts.

Jacki Monson: And because of that, we might want to go more narrow to specifically privacy and security because I think that is unfettered territory where there is not – they mentioned lots of different areas of governance around it but not one single aspect of that guidance, et cetera. I think it is just a ripe area.

Michael Hodgkins: I would not limit it to privacy and security. I would add equity because that is a big – that is going to be just --

Jacki Monson: We do frequently go a little broader.

Debra Strickland: I think that if there is this new AI group that the information that we heard from our group and that we would think that we would want to act on, we probably would want to be in lock step with them, not only inviting them to us and vice versa. But I was kind of thinking some of the things that resonated with me was that they were looking for think tanks, getting a lot of really knowledgeable people plus grassroots community people together in a room to vet out where can we protect our communities, how can we protect people from themselves, that kind of stuff. At first, I was thinking that might be a nice place for us but then I am like if there is an AI group, then that might be a better place for it to live.

Michael Hodgkins: If they are looking for advice, actually, some of the conversation that we have with the panel I think would be very good input for them because some of those comments were limited to health care.

Rebecca Hines: I just sent you all the link. It looks like they have a whole – they are not wasting any time. It looks like there are a dozen recommendations that they have gotten right out of the gate, including implementation of the NIST AI Safety Institute, their most recent one from December. You guys might want to check that out as you think on this.

Participant: It is a new committee. They have already met 15 times.

Rebecca Hines: They also have a budget.

Debra Strickland: That is awesome. They should probably even reference past testimony that we have heard from in the government AI groups if they have not already because we did get a lot of good information from them as well.

Valerie Watzlaf: Any other comments on this?

Another area that we of course heard about today as well – was that today? It was today, I think. I think we need to again with TEFCA personal and public health data sharing. Some of the next steps might be to just – and we could do it here if you have comments. How do we decipher the input from the panelists if we focus on personal and public health data sharing?

I did think, as Tammy mentioned, that this might be an area or our Full Subcommittee thought we could make this a part of the Beyond HIPAA possibly one of our first areas that we could focus on as well. Any additional comments?

And then this is just the Beyond HIPAA work. Our two focus areas that I thought we – our subcommittee thought we could focus on included TEFCA, personal and public health data sharing, and also the reproductive health information, privacy and security just to get us started because I know there are many areas that we could include. But we can see. It just all depends. We could probably put some other areas forward if we do not hear back from the Final Rule on reproductive health and so forth.

And then I know Tim brought up a couple other areas that I thought were interesting that they were interested in. Right of Access Initiative I think was one where there is such an untimely or no access or very large fees for individuals that are trying to gain access to their PHI medical information. And then there was another one where I think he mentioned revisiting caps for the civil monetary penalties, which I think he had talked to us about that before that it was just so old back in 2009 or something like that. Those are some other areas.

Michael Hodgkins: I thought Jamie brought up a pretty important point in the IAS discussion. There are a lot of privacy and security consent implications, liability implications. I am wondering – I would not suggest not having a focus on reproductive health, but I am wondering if we need to pay more attention to the IAS area.

Jamie Ferguson: That is really an issue of consent and authorization because whether you call it a consent document or an authorization token that comes from the app that a patient logs into, the current situation is that the individual who is the subject of the record is directly logging into an app that is directly asking the provider for a copy of the record. Pretty clear. We know how that works.

Under TEFCA, there are all these intermediaries, and it is like just trust us that it is there. Just trust us. Well, no. How are you going to audit that? I heard about a four-hop audit of different intermediaries. Forget it. No. This is why providers are actually not signing up for that. That aspect of TEFCA frankly is going to fail if they do not fix that. That is an area for us to figure out.

Michael Hodgkins: But in addition to the consent authorization, which I agree, talk about a quagmire. The consumers are going to be signing up for apps that have no – there is nothing that covers them. There is no HIPAA rule that extends to them. We know already historically that these folks are selling people's data. They are violating people's privacy left and right. I just think it is an area that is ripe for attention and recommendations.

Valerie Watzlaf: Could that fall under what we have there for TEFCA? We could put it right under there.

Michael Hodgkins: It fits in here. I just do not want to lose track of that.

Rebecca Hines: I sent this to you by email but someone on Zoom said FTC might want to be involved with AI due to health applications transmitting information. Breaches have occurred with wearable AIs that were not covered entities.

Michael Hodgkins: Actually, FTC is about the only agency that has been going after these app developers over violating people's privacy and selling their information. I think it is ripe for us to be advising HHS on this topic.

Valerie Watzlaf: Thank you. I think that is all I have. This was just more of what we were planning just very briefly. And this could certainly change. Currently, we have heard from many expert panels on those areas of reproductive health privacy, TEFCA, AI, and so forth.

I think what we really need to do though is prioritize which projects we are going to focus on in the next coming few months and so forth. We could hold briefings for accounting of disclosures or for other areas that have come up today. I think it is very important that we develop a project scoping document, first an outline and a document because I think that keeps us very focused.

Participant: And keep it to two pages if you can.

Valeria Watzlaf: and then bring it to the subcommittees and then to the Full Committee for approval. And then hopefully, we will be able to get a couple of projects out, I think, drafts or recommendations hopefully by next year. I think that is it.

Jamie Ferguson: This is not PCS but this is – it is maybe an addendum for the workplan. It is just to update you all that following the approval of the recommendations for ICD-11 yesterday, I have gotten from Rebecca some additional input that came in over the chat. I am in the process of drafting the rationale to support those recommendations to form a letter.

My current plan is to draft something up, send it out to all of you for input and then we can bring it to the Executive Subcommittee to form up the letter.

Participant: That sounds great.

Rebecca Hines: Make sure those on the Executive Subcommittee are available. It is on your calendar for May 15.

Participant: It is going to be a very important meeting.

Jacki Monson: Are there any other items for discussion today? People were worried about us not finishing on time.

I just want to again recognize our two members who are coming off. I think we are going to rope you into one more go around to get the RTC done. Denise, I think stepped out but just want to thank both Deb and Denise for all your service to NCVHS. We are very lucky to have had you for as long as we did. We just really appreciate it.

And then I want to thank Rebecca for all you do and you did. I said last night at dinner that she is the spine of NCVHS, and I believe that to be true. Big shoes to fill but just appreciative for everything that you have done at least in my time as chair but also before that because we certainly are going to miss you and know that we will probably be calling you too because the knowledge gap is going to be missing in between meditation. Thank you so much for all that you have done.

Rebecca Hines: I just want to say it is all about the partnership. Naomi, Shirley, and Gwen. They are with you. As I like to say, it is a team sport. We are all on the same team and help each other. They will have ideas for you. Naomi already has some fabulous ideas that I am just too tired to think about and she is ready to come. Put me on time out. Put her on the court. I think you will be happily served and just help each other out. And yes, you can always text and call me. You know all I want is for this to be a thriving voice into the bureaucracy because that is what we need.

Jacki Monson: And hopefully by our 75th anniversary, we figured that out and we can invite you back to show you that. Thank you again.

I just want to thank all the staff. It is not possible to do this without everyone who is in the room helping us put this all together, not just the last two days, but all the days in preparation for the extra service to go pick up meals. Just thanks for all of the work that you have done. It is just deeply appreciated.

Rebecca Hines: Lorraine Doo, Maya Bernstein, Gwen Mustaf and RLA. I just want to make sure everyone understands it is not just the names and the faces you see. There is so much that goes on behind the scenes. I just want to make sure everyone really gets that. And I just want to publicly thank RLA for being so outstanding to work with. Thank you, all.

Jacki Monson: Great. We are officially adjourned.

(Whereupon the meeting was adjourned at 2:30 p.m.)