National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Catherine Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Tammy Feenstra Banks	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Angela Alton	City of Hope	Member
Melissa M. Goldstein	The George Washington University	Member
Michael Hodgkins	Healthcare Consultant	Member
Richard W. Landen	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
Vickie M. Mays	UCLA	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
Gwen Mustaf	NCHS	Staff
Donna Pickett	NCHS	Staff
Marietta Squire	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Robert Anderson	CDC, NCHS	Chief, Mortality Statistics Branch
Sara Rosenbaum	George Washington University	Professor Emerita
Lisa Satterfield	ACOG	Senior Director
Monica Edwards	In Our Own Voice	Director of Policy and Advocacy

Elizabeth Mosley	University of Pittsburgh	Assistant Professor of Medicine
Jake Laperruque	Center for Democracy and Technology	Deputy Director
Richard Salgado	Stanford University Law School	Former Director of Law Enforcement & Information Security
Deven McGraw	Data Stewardship and Data Sharing	Lead

Call to Order/Roll Call

Rebecca Hines: Good morning, everyone, here in the room. Good morning everyone with us online, members of the public, members and staff of the National Committee on Vital and Health Statistics, NCVHS. A warm welcome to everyone joining us here today and a special welcome to our newest members today. We look forward to hearing from you this morning on the agenda. My name is Rebecca Hines. I serve as executive secretary and designated federal officer for the committee. This is our first in-person and hybrid meeting of the Full Committee in a fully equipped conference space. This is a new experience for all of us. Very exciting. Pre-pandemic, we had a whole setup with mikes and a different kind of arrangement. As our team reminds us, anything you say in this room will get transmitted. Please keep that in mind.

So much in the world and in health and in health data in particular, has changed since we last met in person on November 13 and 14, 2019. It is a new day for this committee in light of all the circumstances.

Grateful to you all, our members. You have done so much work getting us to this point, your thoughtful planning, your preparations for the meeting today and tomorrow. I want to use this opportunity to let the public know about another upcoming meeting if you have not seen it on the website coming up on August 3. It will be a working session of the committee's ICD-11 Workgroup on Timely and Strategic Action to inform policy. Actually, it will be here in the same room. Also, hybrid format. More to come this morning on that.

Today's agenda is posted online. I will put it in the chat for everybody. All of you on Zoom, there is the agenda. If you have not already, you can sign up to receive email notices from us. That is on the home page of the website.

Let us start off. Let us take care of roll call now. We will start in the room with our chair.

Jacki Monson: Good morning, everyone. Jacki Monson, Sutter Health, Chair, Full Committee and no conflicts.

Rebecca Hines: Why don't we go this direction?

Tammy Banks: Tammy Banks, independent consultant, chair of the Standards Subcommittee, member of the Full Committee, member of the Executive Committee, and no conflicts.

Jamie Ferguson: Good morning. Jamie Ferguson, Kaiser Permanente, member of the Subcommittee on Standards, the Subcommittee on Privacy, Confidentiality, and Security, and a co-chair of the ICD-11 Workgroup. I have no conflicts, but I will note that we might discuss the ICD-11 RFI this morning. Kaiser Permanente did submit a response on the RFI, and so if there is any discussion on that, I will recuse myself from that discussion.

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

Catherine Donald: Good morning. Catherine Donald. I work for the Alabama Department of Public Health. I am a member of the Full Committee. I am also a member of the ICD-11 Subcommittee. Because I do work for the Alabama Department of Public Health, I will be recusing myself from any discussions around reproductive health care policy or reproductive health.

Rebecca Hines: Thank you, Cathy.

Over to you, Lenel.

R. Lenel James: My name is Lenel James. I work for the Blue Cross Blue Shield Association. I am a member of the Full Committee and a member Subcommittee on Standards. I have no conflicts.

Wu Xu: Good morning. My name is Wu Xu. I am a retired state health (inaudible). I am a member of the Full Committee. I have no conflicts.

Richard Landen: Good morning. Rich Landen, member of the Full Committee, co-chair of the Subcommittee on Standards, member of the Executive Subcommittee. I have no conflicts.

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

Vickie Mays: Good morning. I am with the University of California Los Angeles. I am a member of the Full Committee, the Executive Subcommittee and Privacy, Confidentiality, and Security and the ICD-11 Workgroup.

Rebecca Hines: And your name?

Vickie Mays: Good morning. My name is Vickie Mays and I have no conflicts.

Michael Hodgkins: Good morning. I am Dr. Michael Hodgkins. I am an Independent consultant. I am a member of the Full Committee, member of the Standards Committee.

Denise Chrysler: Hello. I am Denise Chrysler. I am a senior advisor to the Network for Public Health Law, which means now I am semi-retired. I am a member of the Privacy, Confidentiality, and Security Subcommittee, the Full Committee, and I have no conflicts.

Valerie Watzlaf: Good morning. I am Val Watzlaf. I am with the University of Pittsburgh. I am a member of the Full Committee. I am the co-chair for the Privacy, Confidentiality, and Security Subcommittee. I am also a member on the ICD-11 Workgroup and I have no conflicts.

Rebecca Hines: Great. Over to online. Melissa Goldstein is with us on Zoom today. Good morning, Melissa.

Melissa Goldstein: Good morning. My name is Melissa Goldstein. I am on the faculty of George Washington University. I am a member of the Full Committee, co-chair of the Subcommittee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Thank you, Melissa. We are still sorting out the audio in here.

Melissa Goldstein: Do the individuals in the room have microphones? It is a little bit low, the audio, when individuals are speaking.

Rebecca Hines: That is helpful to know. Thank you. We will try to work that out. We did a sample meeting a few weeks ago and it was much louder. We will try to figure that out in the next few minutes. Thank you, Melissa.

Steve Wagner, you are with us online? You are muted, Steve. Steve, are you with us? I can see you. We will circle back to you.

It does appear we have a quorum so we will continue with the meeting. Let us move over to staff, starting off with Sharon Arnold.

Sharon Arnold: Hi everybody. I am Sharon Arnold. I am the Executive Staff Director of the committee and I am also the Associate Deputy Assistant Secretary ASPE, Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.

Maya Bernstein: I am Maya Bernstein. I work for Sharon in the Office of the Assistant Secretary for Planning and Evaluation where I am the senior advisor for privacy policy. I am co-lead staff to this committee and lead staff to the Subcommittee on Privacy, Confidentiality, and Security. Good morning. It is nice to see everyone in person.

Rebecca Hines: Lorraine, are you with us? I see you are unmuted. Lorraine Doo is with the Centers for Medicare and Medicaid Services and she is the lead staff to the Subcommittee on Standards.

And I see Steve. Good morning, Steve.

Steve Wagner: Good morning. My name is Steve Wagner. I am a retired Enterprise Architect. I am a member of the Full Committee. I serve on the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Great. We are going to try to sort out the possibility of you being here in person, Steve. Give us some time to work on that. Thank you for your patience.

I also want to acknowledge Marietta Squire. That you all know on email and Gwen Mustaf, she has been escorting you here to the room. You will see them around today. If you have any questions, Gwen has been gracious enough to handle travel for us even though she is not officially a member of the team.

I wanted to mention public comment for those who are online. If you could bring up that public comment slide. Just a note on today's agenda and tomorrow. Today, there is a public comment period scheduled for around 5 or 5:15, depending on how the afternoon goes. The timing for the public comment could shift so please stay tuned. And for the majority of you who are on Zoom, we will put this information up to help you plug in and get an open line. You can also email us comments in writing at NCVHSmail@CDC.gov. And of course, we will have public comment in the room if there is anyone who would like to do that. I think that is it for the opening ceremony.

Jacki, over to you.

Agenda Review

Jacki Monson: Great. Let us go through the agenda. It feels weird to have a paper agenda – really long time. First, we are going to do a new member welcome. We have a series of interview questions for each of the new members. Next, we will move on to an update from Sharon and move on to Workgroup on Timely and Strategic Action to Inform ICD-11 Policy (inaudible) discussion of the August 3 expert roundtable as well as the RFI. We are going to take a break and then move on to the implementation of ICD-11 for Mortality reporting in the US. We will take a lunch break. We are going to move to the Subcommittee on Privacy, Confidentiality, and Security, a briefing on privacy and reproductive health. We have a number of panels. Panel 1 will start at 1:15. We will take another break at 2:45. We will

reconvene at 3 o'clock. We will continue the panel conversations (inaudible) with updates. We are going to take some directions on (inaudible). We are going to make some updates for the workplan development, specifically with Privacy, Confidentiality, and Security group. Then we will (inaudible) 5:15 (inaudible) take a couple of comments and we will wrap up and adjourn for the day.

Rebecca Hines: I just want to do a sound check. Melissa, can you hear us any better?

Melissa Goldstein: Yes. You and Jacki are very easy to hear. Maybe if someone down the rows could check. That would be helpful.

Rebecca Hines: Can you hear Lenel?

Melissa Goldstein: Much better. Thank you.

New Member Welcome

Jacki Monson: Let us start with the new member welcome. We have several new members with us today. Steve is on Zoom with us although in Washington, DC. We appreciate that. We have a few questions they are going to respond to. You are going to talk about your current organization and role, their favorite project or work experience and why they enjoyed it, and then what excites them (inaudible) part of NCVHS, which is probably the most important interview question.

Let us start with Angela, who is looking at me --

Angela Alton: (inaudible) expanding a system-wide – is to be part of developing new – that are going to be – as well as --

Jacki Monson: Let us go next to Catherine.

Catherine Donald: Good morning. Catherine Donald. I go by Cathy. I work for the Alabama Department of Public Health. Currently, I am the CFO and the chief operating officer. Prior to that, I spent 30 years in vital records. I would have to say that my most exciting project – I have always been implementing electronic systems. We implemented an electronic birth registration system, an electronic death registration system. And those things have really helped the public and those experiencing deaths of loved ones, be able to get their records faster and more accurate, less mistakes, things like that. We have also recently implemented an EHR. I would say that just implementing systems that make life better for the public, for our workers, and reduce the manual tasks are things that I really enjoy.

I would say that what really interests me about NCVHS is the opportunity to help shape things at the national level and to advise the secretary of HHS to let them know what is going on out in the real world for a lack of a better world and how it can be implemented. Thank you.

Jacki Monson: Thank you and welcome.

Let us go to Michael next.

Michael Hodgkins: I am Michael Hodgkins. I am an internist by training (inaudible). I am currently a consultant in health care. My last full-time position (inaudible) currently chair of the Sequoia project. For those of you who may not be familiar – most exciting project – probably initiating – medicine strategy at the AMA – effort – why am excited – associated with all of you and to also represent the physician perspective –

Jacki Monson: Thank you. Welcome to the committee. Last but not least, Lenel.

R. Lenel James: My name is Lenel James. I am with the Blue Cross Blue Shield Association (inaudible) Health Information Exchange and Innovation (inaudible) at the association – HL7 – my favorite – experience. It would be – leadership role in putting together the – task force for using – for SDOH. Those three projects – what excites me about being at NCVHS is an opportunity to – some of the planning and leadership and expectations – technology and standards – federal government perspective and how do we move the industry forward realistically – health care takes a while in trying to merge those two things – advance technology – health care – in the context of the federal government. Thank you.

Jacki Monson: Thank you – last but not least is Steve, who is on Zoom.

Rebecca Hines: Steve, are you up? We are not able to hear you. Is your phone on, Steve? It looks like your phone is unmuted. There you are. Great.

Steve Wagner: I started working in health care back in '73 when I joined the Air Force because I became a health care administrator. I also started working in government since it was the Air Force. From there, I evolved into – when I left the Air Force, I actually became a government employee. I started working for the Navy Medical Department. Then I started working for the VA, working on – that is when I mainly started working on standards, which was about 1988. I have been working on standards since then. I evolved into software development, managed software developers and eventually into doing enterprise architecture.

When I retired from government, I took a job working in Australia as an enterprise architect, developing enterprise architecture for Queensland in Australia. It was a nice 13 months. That is something I really enjoyed. When I came back, I was a contractor and started working for the Federal Health Architecture Office, which is part of HHS. That office existed – after I joined it, that office existed for about 11 more years and then they basically shut it down. At that point, I retired for a second time.

The main thing – I guess the best thing that enjoyed was the work at FHA in that we were looking at trying to do standards harmonization in a little different way by harmonizing at the most basic levels, which is down at the data element and terminology area. We did that by doing models, information models, terminology models and looking across all the government organizations that use the information and terminologies and looking across all the standard organizations and then modeling that in a single model that pulled all that information together and harmonized it across all of those organizations. That project was fairly successful in doing that.

We ended up dividing health information into about 40 different domains and we finished modeling about 30 of those domains before FHA was closed. That model was – everything we did was for the government so it was all public domain, freely available to anybody.

At this point, I am interested in working with NCVHS particularly on their convergence area, which is also getting at trying to do some harmonization.

Jacki Monson: Thank you and welcome to the Committee.

That concludes our new member welcome so we will move on to Sharon to give us an update on the Office of the Assistant Secretary for Planning and Evaluation.

Office of the Assistant Secretary for Planning and Evaluation

Sharon Arnold: Thank you so much. I am so delighted to see all of (inaudible) first time since November 2019. It has been quite a while. We have many new members that have come on since that. This is really the first time that I have seen most of you for the first time –

As you know, much has changed with the committee. We have gone through two chairs since then. Only seven of you were members in 2019 when we last met in person. I want to particular welcome the give new members from today: Angela, Cathy, Michael, Lenel, and Steve. I really look forward to getting to know you and having you join our discussions.

We have a sixth member who will be joining us. She has been confirmed and she will be fully onboard with us shortly. Mariza Hardin. We are very grateful for your service and hope that you will find working with the department and the committee both challenging and rewarding.

I want to start by reminding of the department's strategic plan and our top goals at HHS. These are to protect and strengthen equitable access to high quality (inaudible) health care, safeguard and improve national and global health conditions and outcomes, strengthen social well-being, equity, and economic resilience, restore trust, and accelerate advancements in science and research for all, advance strategic management to build trust, transparency, and accountability.

As you well know, HHS is a big, vast, sprawling organization with lots of different – pieces. But we use these goals – priorities even challenges arise. We still do not have an FY24 budget and we are in the midst of planning for the '25 budget as you probably have concurred. Financial conditions do not look great for the federal budget. We are planning on all our priorities while recognizing that – constraints –

We continue to work in this uncertain environment and push forward on all the goals and I am happy to share with you some of the highlights of what we have been doing. Among many activities, the – since the Supreme Court's decision on Dobbs v. Jackson Women's Health, last week FDA announced – over-the-counter birth control pill – provide millions with access to safe and effective birth control without a prescription, lowering barriers for women.

Secretary Becerra officially declared on January 31 the end of the COVID-19 public health emergency that would be May 11. But while the PHE has concluded so the public health emergency, the department is still committed to strengthen our preparedness and response efforts and safeguard the health and well-being of all Americans as a public health priority and certainly COVID is not over but the public health emergency is over.

We can report that deaths – declined – according to the CDC – tracker. FDA's vaccines and related biologic – advisory committee met on June to discuss any recommendations to FDA – for updated COVID-19 vaccines for use beginning in the fall. FDA – updating your COVID – develop vaccines – composition as opposed to the – most recently recommended.

In April, HHS announced initial investment of $5 billion collectively, referred to as Project NextGen to accelerate and streamline the rapid development of the next generation of vaccines and treatments through public-private collaborations.

We currently have a number of COVID-19 therapeutics, including an anti-viral drug, immune modulators, and oral anti-viral pills. Other products are available for COVID-19 under emergency use authorization. You may be particularly interested to know that the end of the public health emergency has had

significant consequences for our COVID-19 surveillance program because the authorization to collect certain data ended along with the expiration of the public health emergency. Some metrics will still be available going forward like the weekly COVID-19 – levels and the percentage of all COVID-19-associated deaths – also report emergency department visits and percentage of positive SARS-CoV-2 lab test results and national genomics – identify and monitor -- wastewater surveillance will continue and monitoring vaccination coverage and vaccination effectiveness and safety will also continue. Many other surveillance data sources and corresponding metrics and geographic levels will continue to be available and updated weekly on the CDC COVID Data Tracker.

The end of the public health emergency has also meant changes in coverage for testing in vaccines. The requirement for public insurance companies to cover COVID-19 tests – both for over the counter and lab tests ended with the expiration of the public health emergency. The administration is encouraging private insurers to continue to provide this coverage moving forward.

Up until May 11, residents will be able to assess COVID-19 vaccines and treatment at no cost due to the requirements of the vaccination program provider agreement. However, now that the Federal Government is no longer purchasing and distributing COVID-19 vaccines and treatments, payment coverage and access may change.

Medicaid programs will continue to cover COVID-19 treatments – through September. After that coverage and cost sharing – by state. For those with most types of private insurance, vaccines recommended by the Advisory Committee on Immunization Practices, ACIP – preventative health service – fully covered without a co-pay. Persons without insurance, CDC announced the HHS Bridge Access Program to maintain broad access to COVID-19 vaccines and treatments after the transition back to the traditional –

Analysis about the long-term effects of COVID is starting to come in according to the CDC. About 6 percent of adults currently have symptoms of long COVID. This represents about 11 percent of persons who report ever having had COVID-19. But this figure luckily is declining.

Maya Bernstein: Sharon (inaudible) the audio – we have about 62 people on Zoom who want to hear you. I think we are all going to have to try to keep our voices up, which is difficult throughout a whole day. Sorry to interrupt you.

Sharon Arnold: That is okay. My kids accuse me of having a quiet voice. That is surprising. On April 5, HHS released a fact sheet – responding to long COVID and actions the department is taking. In June, the department built on this with a new advisory from SAHMSA entitled Identification and Management of Mental Health Symptoms and Conditions Associated with Long COVID.

COVID-19 is not only the infectious disease requiring the department's attention. I want to touch briefly on others. On June 8, the department released the inaugural Sexually Transmitted Infections Federal Implementation Plan, outlining several federal actions to combat STIs in the US. The implementation highlights more than 200 actions that federal, state, and – and emphasizes collaboration, expanding access to care, and developing new tools and therapies to combat STIs while focusing on health equity and measuring progress toward set goals.

Last summer, we faced an unprecedented outbreak of mpox. This summer, thanks to the combined efforts of HHS and the LGBTQ+ community, we have an average daily case rate of one or fewer down 99 percent from the peak.

For the first time in history, people 60 years and older can now receive a single dose vaccine against RSV. FDA has approved medication for the prevention of RSV – and infants born during or entering their first season.

Turning to our work on opioids and overdose prevention, on July 7, the secretary renewed the opioid public health emergency for another 90 days. In March, FDA approved Narcan, the nasal spray for over-the-counter, nonprescription use. This paves the way for life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores – stores, et cetera.

We have had a number of analyses that looked at opioid overdose and CMS just released an evaluation report on the maternal opioid misuse model. Collaborative research by CMS, CDC, and NIDA revealed expanded availability of opioid use disorder telehealth services and medications during the pandemic lowered the likelihood of fatal drug overdose on Medicare beneficiaries.

In the spring, Secretary Becerra declared two natural disaster-related public health emergencies on March 27 as a result of severe storms in Mississippi. The secretary declared a public health emergency in June. There was a public health emergency in the US territory of Guam as a result of a typhoon –

There are a number of other activities of the department related to health coverage and access. In May, CMS approved a state plan amendment, allowing South Dakota to expand Medicare coverage to adults with incomes of 233 percent of the federal poverty level. And under the ACA, states have the authority to expand Medicaid coverage. With the addition of South Dakota, 39 states plus the District of Columbia –

Maya and other staff have prepared quite a long list here so I am going to pick and choose. Since last December, CMS – additional states and the US Virgin Islands to extend post-partum coverage for a full year to individuals enrolled in Medicaid and CHIP. This brings the total number of participating states to 35.

The Administration for Strategic Preparedness and Response released a second version of their Cybersecurity Implementation Guide this March, developed in partnership with the Health Sector Coordinating Council Cybersecurity Working Group, which spoke to NCVHS last year on the cybersecurity panel. This guide is intended to help the public and private health care sectors to prevent cybersecurity dissidence by providing specific steps that health care organizations can take immediately to manage cyber risks.

We have a number of rulemaking actions that may be of particular interest to the committee – the rule that would amend HIPAA to enhance access to reproductive health care. This committee has provided comments to rulemaking. The department received almost 26,000 comments on the rule, including those of this committee. It will be a while before we see a final rule as we assess all those comments.

Earlier this month, the Office for Civil Rights and the Assistant Secretary for Financial Resources announced a Notice of Proposed Rulemaking to affirm civil rights and equal opportunity for people nationwide in HHS – programs and services. The rule is Health and Human Services grants regulation that if finalized would protect people from discrimination and PRN built on HHS' efforts to ensure access to services and furtherance of President Biden's executive orders.

OCR and SAMHSA announced just after Thanksgiving, proposed changes to the confidentiality of substance use disorder patient records under 42 CFR Part 2, which protects patient privacy and records

concerning treatment related to substance use from unauthorized disclosures. The comment period closed at the end of January and the rule has not yet been finalized.

For new data releases, HHS just publicly released ownership data for all Medicare certified hospice and home health agencies in line with Biden-Harris Administration's commitment to competition and transparency. Families can review detailed information on over 6000 hospices and 11,000 home health agencies on the CMS website.

The Assistant Secretary for the Administration for Children and Families, ACF, January Contreras has announced her departure. We do not yet know who will be nominated in her place. Dr. Mandy Cohen, the new head of the CDC, started last week.

A lot going on in the department. I just picked out a few highlights. I am happy to take questions or comments.

Vickie Mays: Thank you for the (inaudible) updates – the question – update is we were concerned – this committee was concerned about data collection efforts during COVID. We also expressed some concern about things that needed to be fixed in terms of disaster – I am wondering if there are any updates on what the fixes are, what our preparation is in the event that there is a COVID 2 or whatever the next –

And then my separate question from that really has to do with whether or not in terms of the budget we are going to see our ability to really still do – and I am concerned about that. I do not know whether we should write something or express that concern because the data fixes are expensive. I would hate to see them drop off.

Sharon Arnold: I am not prepared at this point to detail all of the efforts that are undergoing but there has been a concerted effort across the department to look at data collected under the public health emergency and ongoing efforts to collect data for surveillance purposes and make sure that that data is accurate and complete and useful and timely. CDC has been engaged in a very comprehensive data modernization initiative to accomplish a number of those activities.

I think there is a lot of uncertainty about budget environment going forward. As you know, we operate on annual budgets and we often do not know until well into the fiscal year when our budget is for that year. That makes planning difficult and especially multi-year initiatives difficult. I think right now there is commitment to continuing those activities but depending upon what the budget situation is, we are going to have to make some really difficult decisions --

Rebecca Hines: For the new members, the protocol – lift your tent card up and then Jacki will know --

Sharon Arnold: As Maya alluded to, I also want to say that we have some new information about the committee on our website, including a section for the recruitment of new members. We always welcome ideas and suggestions for new members for the committee. We are continually trying to identify appropriate new members. If you know of anybody, please do direct them to the website and either nominate them or have them nominate themselves according to the protocol on the website. We rely heavily on word of mouth and we do do some outreach but I think that the best recruitment mechanism is by word of mouth by people who have expertise – thank you very much.

Jacki Monson: Thank you. We are ahead of schedule. Jamie, I am going to turn it over to you to talk

Workgroup on Timely and Strategic Action to Inform ICD-11 Policy

Jamie Ferguson: I will give an update on the ICD-11 Workgroup and our upcoming expert roundtable. I just wanted to note that (inaudible) half of the committee members actually had been involved. About half of the committee members have been involved in this workgroup – particularly for those of you who have not, I wanted to encourage discussion and questions during the presentation rather than waiting until the end if you have questions –

As you can see, ICD-11 was first adopted by WHO in 2019. Its used was effective starting in 2022, which was the beginning of a five-year implementation support period of the WHO. We are considering three components here. One is its use for mortality reporting as we have a separate presentation on that that will happen after this one.

Then also, the use of ICD-11 for morbidity coding for health care and public health. I want to note that that includes use of the classification system for population health, for – management programs, social health, community health, and health equity programs. It is a very important set of use cases.

And then we also of course are concerned especially with the committee's responsibilities under HIPAA about the adoption of ICD-11 as a HIPAA code set for health care billing and –

The goals that the committee has discussed for US implementation are frankly seeking to avoid some of the problems that occurred in the transition from ICD-9 to 10 by sharing lessons learned, understanding the differences of ICD-11 versus 10 and then reaching consensus on what information is needed to provide sound policy recommendations.

We really want to understand the costs and benefits from a wide variety of perspectives and all different interest areas of different kinds of stakeholders.

We are interested --

R. Lenel James: (inaudible) and morbidity in the context of ICD-11.

Jamie Ferguson: Sure. Thank you. The use of ICD-11 for mortality reporting is basically cause of death reporting that is done within the NCHS and we have our expert here to talk about that. And then morbidity would be other than for cause of death, it is used in – health records –

We were also interested – just the final goal on the page here. We are interested in identifying everything that needs to be communicated because obviously the country and the community, the health care sector and government needs to have communication and a communication plan – great interest to the committee.

The focus that we have on the committee is to develop recommendations for US policy. Ultimately, the committee will advise the secretary on adoption and implementation of ICD-11 as a HIPAA code set as well as its use for all the purposes outside of HIPAA in the US health information ecosystem such as the population health purposes –

The committee has been working on ICD-11 for several years. In August 2019, there was an expert roundtable meeting, which informed an NCVHS letter to the secretary in November 2019. Back then, the committee identified a number of different research topics that should be studied. I have actually quite

an extensive list of research questions to be answered and evaluated. The committee also recommended a timely outreach and strategic communications to various stakeholders.

Of course, right after that letter was sent, what happened? Well, we have a public health emergency. We had a few other things that came to the top of the priority list. Recognizing that there had been essentially no action on any of those recommendations, the committee revisited this over the last two years and sent a letter in September 2021, reiterating the call for conducting research and emphasizing the need for timely action. At this point, we are now going about to enter the WHO support period for implementation. It was very important to both to have a communications plan and a research plan.

Lenel, is your card up again?

R. Lenel James: Yes, it is. In an earlier slide, you mentioned that WHO had five (inaudible). Because of COVID, has that timetable changed? Is it still five years?

Jamie Ferguson: To my knowledge and we do not have a representative of WHO here today, but we will on August 3. Please come to that. To my knowledge, that is the timeframe for implementation support of member nations is the five-year period that started in January of last year.

R. Lenel James: -- implementation support be in the US, given the size and scope of our operation?

Jamie Ferguson: Again, I am going to differ that to the August 3 roundtable where that will be addressed more fully.

Some of the more recent history. The committee then last year voted to establish an ICD-11 workgroup. We finalized the workgroup charge in January of this year. We invited members to the workgroup and we have now over – I think it is 17 external workgroup members. And we also have representation from I think eight different federal agencies and offices participating in the workgroup on a regular basis.

ASPE very kindly provided resources to conduct an environmental scan with the research on looking at the published materials that had been published mostly outside the US on ICD-11 use cases and implementation –

The committee also through the – and then the committee also issued in the Federal Register a request for information about a list of ICD-11 issues.

We are not prepared to discuss RFI results today. Again, I will defer that to the August 3 meeting where it is a central part of that and invite all the committee members to participate in that.

Upcoming two weeks from tomorrow –

Participant: July 27.

Jamie Ferguson: That is – I think two weeks from – basically, two weeks from now, we will have an expert roundtable here in the same room to update the ICD-11 analysis and discuss the findings.

And then following that, we will have not only a meeting summary report but we will use the – the committee members, the federal participants and the external participants to develop a report. The workgroup will have a report to the committee. Obviously, the committee makes recommendations to the secretary. The job of the workgroup then is to provide observations, findings, and analysis that will inform the committee's recommendations.

And actually, with that – a little more on the RFI. An RFI was issued on June 13. We received 18 responses. Unfortunately, because of the timing that it took to get the RFI out in the Federal Register, we have a relatively limited time period for responses. We received 18 responses but from a wide variety of organizations, including large membership organizations across the health care spectrum. The RFI is posted on the committee's website.

In the roundtable meeting, there are two main objectives of the roundtable. But we expect to get input not only through analysis of the RFI responses and the environmental scan analysis but we have identified experts from truly across the entire spectrum of different kinds of stakeholders and interest groups, essentially people with any interest in adoption and implementation of ICD-11 and its use for all those various different purposes.

As I started to mention, we have two main objectives for the August 3 roundtable itself. First is considering the range of studies that have already been done of ICD-11, the results of the environmental scan, all the information and discussion and analysis that has happened thus far. What is left? In other words, what are the gaps? What are the remaining research questions and what are the priorities for additional research that need to be done in order to inform sound policy recommendations by the committee? What is most critically important?

And then the second aspect of the expert roundtable is to get input on how to sustain work through a collaborative setup. It might potentially be through a public-private partnership, something like that. But what options do we have for laying out a timeline to get the information that the committee needs? The committee is going to need additional information before making policy recommendations for ICD-11. It has to happen timely. How are we actually going to sustain the work to get it done?

Rebecca Hines: One of the issues that has been brought to the committee's attention is that the WHO right now in its implementation period is accepting requests for revisions. People in this country are sending in revisions that they think are needed to ICD-11, which may or may not actually be the best looking at the system as a whole. That is one of the concerns I have heard the workgroup discuss is can there be some coordination. Otherwise, different organizations with competing priorities potentially when you think about reimbursement and so forth could be making suggestions that actually are counter to what would actually make sense. This is one of the issues.

And the reason why there is a bit of a time concern just in that – it is a moving target. I do not know if you are going to get into the clinical modification and that whole question in the presentation, Jamie. I have forgotten. But there are just a lot of very complex issues that need some time and need attention.

Jamie Ferguson: -- the perfect -- person because this was actually on our next slide so this is actually in the next slide. Not only do we want to bring together the diverse improved coordination and collaboration of the research efforts but also improve the coordination of the US work with WHO in terms of requesting those changes that are needed in advance of US implementation. And then we also want to discuss the possibility of having public-private collaborative to coordinate the research agenda.

What are some of the study questions that we know still need more work? One is what are the benefits? What are the benefits of adoption and implementation of ICD-11 in the US? Most of the studies that have addressed this question are outside the US in different health systems that have substantially different use cases for use of the classification. What are the costs of implementing or the cost of not implementing it?

And then the question of clinical modification comes up because as I think everybody knows with ICD-1, the US created its own version essentially, which is a full clinical modification, which is costly and causes delays. WHO is recommending that countries do not need a clinical modification in ICD-11 because of its inherent flexibility, the structure of it, and the fact that there is a facility within WHO for updating, adding to and modifying the classification system on an ongoing basis. In fact, they believe that ICD-11 would be the last version because it will be updated ongoing into the future.

There are different ways that ICD-11 can be used in order to avoid a full clinical modification. One is using the existing stem codes as they exist. ICD-11 also allows extension codes so when extension codes that exist can be used. ICD-11, unlike ICD-10, is structured in a way similar to SNOMED and other terminology systems that allow post-coordination otherwise known as cluster coding so the codes can be clustered to achieve the needed level of specificity.

What is the proportion of all the different classifications that US needs that could be achieved through cluster coding or post coordination using the existing codes? What extension codes would the US have to request or what base or stem codes would the US have to request in order to achieve the needed level of coverage of the classification system?

Finally, another option is to create a mini organization on the foundation level of OCD-11, which is also possible. In fact, the National Library of Medicine has been studying the use of all of these different techniques to achieve the needed level of coverage for the US. They will be presenting that on August 3 in the roundtable. Again, put in another plug for participating in the expert roundtable.

And all of those different options are intended to give the US the needed level of coverage of detail and specificity that we need for the coding system and all the different kinds of categories of use cases that I described earlier.

Michael Hodgkins: I was just thinking (inaudible) describing the ICD-10 – in its entirety --

Jamie Ferguson: That is a very good point. In fact, the US did not adopt ICD-10 from the WHO. We created our own version, which is the clinical modification and the procedure coding system. In fact, with ICD-11, again using those different – that I just described, it should be possible to avoid – we would actually be on the same coding system that is used internationally.

Just a couple of additional discussion points expected on August 3. I think the first one I have already covered in terms of what are the remaining priorities for research. And then considering the studies that have been done by NLM and others, what else is needed to confirm that the US does not need a full clinical modification for ICD-11? The committee is going to have to have that information.

And then what benefits of adopting and implementing ICD-11 are most compelling for key stakeholders? We anticipate having representation of, as I mentioned, all different diverse kinds of stakeholders on the third. That is going to be very input to find out what will be compelling benefits from all those different perspectives.

I am happy to take any other questions.

Tammy Banks: This may be premature but are they talking about automated coding – talking about SNOMED and the National Library of Medicine. Is there any conversation of how to automate the use of this --

Jamie Ferguson: In fact, because the foundation layer of ICD-11 is the same as SNOMED and SNOMED having been adopted as a requirement for problemless coding in the electronic medical records by ONC and CMS, it is possible to have a fully automated one-to-one correlation for – you will have to study again based on the modifications to ICD-11 that are needed but certainly for the foundation layer of the stem codes that that correlation is possible for that to be fully automated. And then depending on the US linearization and the US specific extension codes that are needed, there may have to be an additional crosswalk to enable that automation.

But the kind of automation from the original clinical data capture in the electronic medical record to the classification system for all these reporting and other program purposes should be primarily if not completely able to be automated.

Richard Landen: -- excellent report, Jamie – to see the amount of the work that has been done since the last recommendation -- a couple of points I want to bring up. First is the difference in the approval process for the mortality versus the morbidity. Mortality, as I understand it – Jamie, correct me if I am wrong. Implementing the mortality reporting for ICD-11 is not voluntary. It is a condition of our US membership – health organizations whereas as Jamie mentioned, adoption of morbidity within health care is a HIPAA-designated medical code set and will require new rulemaking by the Department of Health and Human Services.

Jamie Ferguson: That is exactly right. Because of the requirements of WHO members to use it for mortality reporting that we consider it a UN treaty obligation. That is not voluntary. Obviously, it is used for billing and payment is voluntary and require the rulemaking that you talk about. And it is used for the other purposes that may not require rulemaking also as voluntary.

Richard Landen: The second point. I am channeling Margaret Skurka here is just to remind us of some of the difficulties with our transition – ICD-10-CM that Jamie has incorporated in his presentation – was among the last of the countries in the world to implement ICD-10. It was a stumbling, painstaking process. We hope to avoid that. We hope to be – last year of international doctors. We hope to do a better job this time around.

Vickie Mays: You mentioned something that stirred a question for me and that is what is our relationship with WHO in this work. They are attending the meeting and they are just listening or is it we are going to send something to the secretary and then the secretary is the voice.

Jamie Ferguson: In terms of WHO, we have a representation from the collaborating centers in the workgroup. And we are inviting a WHO representative to the August 3. It sounds like your question is more general about how does the US work with WHO. I do not know. I am not the right person to answer that. I do not know is Val is here – insights on that.

Robert Anderson: -- involved with the collaborating center for family international classifications for – years. We – the delegation. It was – Donna Pickett up until just a week ago or so – going forward.

We do participate with WHO and the other collaborating centers in the maintenance of ICD-11. We have representation – mortality and for functioning disability and --

Vickie Mays: Will you do – the Donna Pickett – you would bring information and share it with us and listen to things we say – I am just trying to get a sense of where our work is going – so that when we are in the meeting, we have an idea of what --

Robert Anderson: -- it is just happened this past week.

Rebecca Hines: Bob, are you able to attend August 3?

Robert Anderson: I am pretty sure yes. I have to move a couple of things around but – I will let you know – but I am pretty sure.

Jamie Ferguson: I will also mention that, Bob, for you and all committee members that we have a virtual pre-meeting on July 27 that you are all welcome to attend – it is a two-hour – meeting. That is not open to the public but it is open to committee members.

Rebecca Hines: Jamie, there is a question that I think is worth looking at if you have time. Is there a standard cluster coding? I think the person – model that is understandable to a non-health person. I like the one about the right hand and the left side of the body and --

Jamie Ferguson: The idea is you could add – for example, you could add a body site and a morphology and a disease stage together.

Rebecca Hines: Or a new drug shows up.

Jamie Ferguson: You could add those different characteristics together to describe the disease.

Rebecca Hines: Rather than creating a whole new separate –

Jamie Ferguson: -- creating a new, single, pre-coordinated code that adds together. Maybe it is your left kidney and you have a tumor of a certain morphology and disease stage. But you could add those things together rather than creating a single code for those things.

Val, did you have a question?

Valerie Watzlaf: I was just thinking when people were asking questions – and if they are going to join – I do think it would help to view those past recommendations – that we had because I think some of that information about WHO and the history and all of that is in there. I think the 2019 and really just to follow – trajectory of what we had done and then I think you will be able to see some gaps and why we are now at this point.

And I think the other thing is we are reviewing – reviewing literature, which really is finding – issues there as well and gaps and so forth. I was just trying to think how do we get that together and give that ahead of time so that people would be able to understand some of the questions --

Jamie Ferguson: All those materials of course are on the committee's website.

Rebecca Hines: The letters are. The two letters to the secretary, 2019 and 2021. The environmental scan is a work in progress, as I understand it.

Jamie Ferguson: That has been provided to the workgroup members.

Rebecca Hines: The workgroup members but not the external ad hoc experts. That is correct.

Jamie Ferguson: That could be provided to all the committee members.

Rebecca Hines: That could be. Yes. That could be provided to you all. And we can also send you a link to the 18 responses for a whole range of organizations. It is actually on the August 3 meeting page of the website but I can shoot it around by email as well so you can see the whole gamut of input. And we were fortunate enough to have an AI expert take the 18 submissions and press a button and come up with a summary that is pretty helpful so you can see we post 12 questions to the public and it is sort of parses out what is the general consensus so far or where there's not consensus from the 18 organizations.

We have also talked about possibly having an RFI post-August 3 and giving people 90 days because it does seem like – this is a long-term proposition and people need more time to even digest what is I-11 and how it is so much different. It is just fundamentally, structurally different from 10.

Jamie Ferguson: That is exactly right. Thank you for mentioning that. We are hoping that the workgroup be reauthorized. The workgroup currently is authorized only for this fiscal year. We are hoping that it will be reauthorized. If that happens, then I think that reposting the RFI with an extended period would be very useful for the next phase of work.

Richard Landen: For those who want to learn more about the ICD-11 – World Health Organization does have a pretty good robust website with information and training and videos on ICD-11. Just Google World Health Organization and ICD-11 and – introductory stuff --

Jamie Ferguson: Thanks for mentioning that. And in fact, many of the pertinent materials from WHO links to those are posted in the committee's letters that are on the committee website.

Tammy Banks: As you were identifying these research questions, what is the appetite for public funding or private funding to --

Jamie Ferguson: That is actually one of the reasons why we want to have a discussion about coordination and ongoing sustainment of this work. One of the objectives of the expert roundtable is to provide the committee with information on options for developing a community of interest that would be ongoing that would provide both public and private input to that ongoing communication --

Tammy Banks: I do not think I heard you. It was August 3.

Jamie Ferguson: Yes. Thank you. And that meeting will be open to the public and it will be here.

I think then that is it for the ICD-11 discussion on morbidity today. And now, we are ready to go to the discussion on mortality.

Rebecca Hines: Just a reminder to please keep your voice up. We have 60, 70 plus people online. Even though this room is filled with microphones, it is still helpful to speak up if you can and project as best you can. Thank you.

Implementation of ICD-11 for Mortality Reporting in the US

Robert Anderson: -- pulling up the slides, I will just introduce myself. My name is Bob Anderson. I am chief of the Mortality Statistics Branch at the National Center for Health Statistics – space for almost 27 years – for a while. I am old enough to remember the transition from ICD-9 to ICD-10 – occurred in 1999.

I did want to mention that when I talk about the implementation of ICD-11, I am really talking about the implementation of what is called the ICD-11-MMS or ICD-11 Mortality and Morbidity Statistics. We are not going to be implementing the foundation of ICD-11. We will only be implementing what WHO calls the ICD-11-MMS –

Jamie mentioned that WHO is saying that – the last revision of – they said that with ICD-10 as well – clear by the mid-2000s that structural changes – ICD-10 – ICD-11 was created.

While the ICD-11 foundation component might be sufficient – going forward in perpetuity, the linearization perhaps may not be sufficient. It may be that – mortality and morbidity statistics might be required if structural changes are needed to that – I just wanted to mention that.

I did want to talk a little bit about what is at the moment, how we about handling mortality. Cathy will be familiar with this graphic here, working in vital – for so long. Essentially, we have a collaborative relationship with the state vital record agencies that provide us with information from the death certificate and then we compile that information at the national level and then use it to create national statistics from the information that we receive.

With regard to coding, we are pulling information from the death certification from Part 1, which is causal sequence leading to death, any contributing conditions that are mentioned. There are several check boxes that can affect the coding for certain causes of death and an extra box for injury description to give us sufficient information about – code the external – all of this information that is used to assign codes, code each entity, and any entity that could be coded in ICD-10 currently. And then we select an underlying cause of death for statistical tabulation.

Richard Landen: Is that done by whoever is filling out the certificate at the state?

Robert Anderson: It is not.

Richard Landen: No ICD coding on –

Robert Anderson: No ICD codes appears on the death certificates. It is all free text that gets reported. That is what we are asking. NCHS, as of 2011, does all of the cause-of-death coding. We take that text that is reported on the death certificate and we assign the ICD codes. Prior to 2011, some states did their own coding. But because of state budget issues, there were a lot of states that were asking us to take on the coding. There was a point at which we were not sure how much we needed to budget each year to do the codes. We centralized all of the coding starting in 2011. We – cause-of-death coding.

The coding is largely automated. We currently use the software called MedCoder. This is a successor to a system called Mortality Medical Data System. Some of you may be familiar with software terms like SuperMICAR and MICAR. ACME and TRANSAX – those were the programs in that suite of software for MMDS.

We implemented MedCoder and I will talk a little bit more in more detail about this in just a minute of how MedCoder works. We did that mainly – we made this transition mainly because with volume of deaths that we have to code, we really needed to increase the throughput of the system. MMDS was capable of coding 70 to 75 percent of records automatically. MedCoder is able to code about 85 percent – that is a really big deal with current volume of deaths that we have. We have roughly 3 million deaths so 15 percent of 3 million is still about 450,000 records that require manual review and some manual coding. At 75 percent, you are talking about 750,000. It was significant savings in terms of resources.

PARTICIPANT: (inaudible) the fact that it can –

Robert Anderson: Everything that goes through MedCoder right now is being coded accurately. It cannot code everything accurately. Some records it rejects because it does not recognize what is on the certificate. It does not know what to do with it. But some records are rejected because we know that it does not do it right. We – reject those records.

PARTICIPANT: Is it a natural language process --

Robert Anderson: Yes. I will talk about that in just a minute.

PARTICIPANT: It is a little hard to hear –

Robert Anderson: I will speak up a little bit more.

As I said before, all information on the death certificate that can be coded is coded and we store it. In addition, we store the text literals as well for quality control purposes and in case we need to look at something that perhaps does not have a code. We have done this with a lot of the drug mortality because the drug information in ICD-10 is not that detailed. We store all that information. And then of course, we return the codes that we produced to the states and retain a copy for national statistics.

The turn-around time right now for coding and for the automated coding is a few hours at most. But for the manually coded records, it is right now taking us about 12 days on average to return information back to the states. The more records we can code automatically of course the better.

Then with regard to MedCoder, MedCoder is based on some machine learning and natural language processing but also there are some rules-based programming that are retained from the old MMDS system.

ACME and TRANSAX, which was the module that did the underlying cause selection has been retained in the MedCoder system. That is a rule-based – based on a set of decision tables that re used to select the underlying cause.

The natural language processing and machine learning are used to interpret the medical terms that are reported on the death certificate to assign what we call the multiple cause codes that are then used for input to ACME to select the underlying cause of death.

We implemented this fully in 2022. The whole process of developing this system when we started it in, sort of started it in 2017. It did not get really rolling until 2018. It took us a few years to get this working correctly. It works quite well. The machine learning is done on ten years of mortality data. I do not know how many millions of records that is. It is something like 15 million records or something like that. 13 million records.

Going back to the ICD-9 to ICD-10 transition, while the clinical modification lagged quite a bit, we did implement ICD-10 for mortality in 1999. That was even then quite late. Most countries were implementing – 1994 and 1996. We had quite a few issues in the implementation. Of course, most of the time and expense had to do with the revision of the automated coding software and the decision tables – a transition like that. These decision tables are massive because the decision tables include information about the relationships between all conditions within the ICD because we are trying to decide whether the causal sequence that the physician is reporting is correct or not in order to assign an

appropriate underlying cause of death. They are really massive. And revision is really a substantial effort. With the ICD-9 to ICD-19 transition, we had to do that ourselves. We were, at the time, really the only country that had a functioning auto-coding system.

It took us about seven years from the time the ICD-10 tabular list was published, which was in 1992. The index for ICD-10 was published in '94 – a lot of work that then had to be done.

Unfortunately, part of that transition was a move of our automated coding system from mainframe to PC. The initial work started with DOS. And during that time of course, Windows was developed and released. Then we had to transition away from – basically, start all over to redo the transition from our mainframe system to Windows. It was Windows 95 at the time. Ultimately, it ended up taking us about seven years to do and costing I think somewhere in the order of $7 million or $8 million to make that transition.

From ICD-10 to ICD-11, it is going to take us some time as well. I am going to save the timeline to last. I am going to talk a little bit about what we have to do – in order to implement this for mortality. It seems like it would be a fairly simple process but it is really not.

This is a list of the main implementation tasks that we have to accomplish in order to implement ICD-11. There is the revision of the automated coding system and decision tables. I will talk about each of these in a little bit more detail.

We have to revise coding instructions and training materials. We have to retrain all of our coding staff because we still will be having to manually code nearly half a million records.

We have to revise our database and computer specifications, revise tabulation lists and report specifications. We have to do a comparability study to assess the comparability between the two revisions. And then of course, we have to create a communication plan to communicate both to our state partners and to our data users what the impact of the transition is.

With regard to the automated coding system, I talked a little bit about the translation of the decision tables and what a big effort it is. We have to do this translation. It is complicated because there is not a one-to-one relationship between every ICD-10 and ICD-11 code. Where there is a one-to-one relationship, it makes it a little easy because you can use a crosswalk to do that. but we also have to review those causal and modification relationships to make sure that they are still valid – medical knowledge has changed since we first did this back in the mid-90s. We need to make sure that those relationships are still valid.

We have to modify the coding software, which is a bit complicated. The conversion of MedCoder to ICD-11 – we hope that this will be possible. But we will not have 10 to 15 million records on which to train the system on ICD-11. We will not have that many records – we had millions of records for ICD-10 but we will not have that for ICD-11. For trying to figure out exactly how we might still use our MedCoder system but then convert it to ICD-11 rather than ICD-10.

Fortunately, we developed this collaboration with the Iris Institute. For those of you who are not familiar with Iris, it is an automated coding system that grew out of an international collaborative effort that we worked on for many years with a group of countries. The Iris Institute is a collaborative initiative between seven countries and that all use automated coding systems that are using Iris. Even though in the United States we do not use Iris, we use different systems, we have a set of shared decision tables.

Iris uses the same decision tables as we do. We have maintained our collaboration with them even though we do not that Iris software.

We are working with them on the development of an ICD-11 version of Iris. Most of the work on the decision tables has actually already been done in this collaboration. We have not had to go it alone this time. We have been able to collaborate with these other countries and share resources to do the decision table revision.

There is some work on an ICD-11 dictionary as well. Many English-speaking countries have been working with them on dictionary work. Iris uses the dictionary as opposed to what we use, which is the machine learning – natural language processes. It is more similar to what we had in MMDS.

R. Lenel James: I am not advocating but I am just asking – AI – but has this collaborative been looking at AI as the main part of the solution to speed up the effort?

Robert Anderson: Yes. The initial work was on the decision tables. We still want a rule-based system for selecting the underlying cause of death for transparency sake. But we have been talking with this group about using artificial intelligence to do the initial multiple-cause coding. Those discussions are being had at this point.

Jamie Ferguson: You may have mentioned this and I missed it. But as you identify differences between 10 and 11 that are important for mortality reporting, are you using the WHO – to request in some cases new classifications or new codes or are you just using the – as it is?

Robert Anderson: We work very closely with the mortality reference group, which is part of the – it is a group that advises WHO on the mortality implications for ICD-11 and ICD-10. I was co-chair of that group for several years. Any changes to ICD-11 for mortality have to go through this group before they can be approved. We are working very closely with them.

Jamie Ferguson: -- do make requests –

Robert Anderson: Yes. We have made requests through the mortality reference group to change ICD-11 for mortality where it did not look like it was fit for purpose.

R. Lenel James: -- machine learning is a subset of AI – were you talking about --

Robert Anderson: I do not know the answer to that. That is not really my area. We do have on our staff some folks with expertise in that. We have been working with a group with the Office of National Statistics in the UK that is very familiar with the AI process. But I sort of defer all that stuff to them because I do not really know that much --

R. Lenel James: Please do not take this the wrong way. I am just curious to hear your thoughts on that it seems that – seem to implement --

Robert Anderson: And I am not taking it the wrong way because there is good reason why. The reason is volume. Most of the European countries and even the largest European countries have roughly 500,000 deaths a year. They do not need to code the volume – automatically code the volume – we are looking at prior to the pandemic, 2.8 million records. Now, it is something over 3 million records. We have to have a system that can auto-code a much higher proportion than they do.

R. Lenel James: They --

Robert Anderson: Yes. Some of the European countries code exclusively manually. But those that use Iris – Iris is capable for ICD-10. For most countries, codes around 50 percent, 60 percent of records. It is just not adequate for us; otherwise, we would have implemented Iris years ago.

For us, we have to go through this extra work to get a system that can code a substantial proportion of the records. And you know, with the ICD-9 to ICD-10 transition, most of the European countries weren't using auto-coding. I think it was Sweden and France, and that was it, and they implemented both countries implemented right around the same time we did. I think 98. The other countries that implemented sooner were all manual coding.

R. Lenel James: It's more difficult to really follow trends in mortality, when you make transitions like 9 to 10, from 10 to 11, since they don't match. Different countries wind up coding things differently I would think and it affects the trends in mortality.

Robert Anderson: Right. This is one of the reasons why automated coding is so important, because it sort of standardizes the process, and if we're all using shared decision tables and at least a similar system, then the coding will be consistent from country to country.

Obviously, the staggered implementation across countries causes a problem, and it causes sort of differential discontinuities from country to country and makes comparisons difficult during the transition. But unfortunately, since we all have different resources, some countries are going to be able to implement sooner than other countries.

Let's see.

Angela Alton: Can I ask a follow-up question? Is it also taking the United States longer because of maybe quality or accuracy as opposed to the other countries as well? Do you notice that at all?

Robert Anderson: I don't think so. I don't think it has to do with quality or accuracy. The system that we had in place prior to MedCoder did a pretty good job and we knew where it didn't and we would force reject those records for manual coding. There's always difficulties with manual coding, because you have the issue of intercoder reliability and it's harder to standardize human beings. So the more records that are manually coded, of course, the more room for error.

Angela Alton: Do you know the percentages of the other countries that do, what percent they do manually and what percent they do --

Robert Anderson: Most of the countries that use Iris, it's around 50 to 60 percent auto-coded. The UK claims to be able to code automatically with using their dictionary and Iris about 90 percent. But they're not counting deaths due to external causes. Anything that touches the coroner is manually coded. And that's actually a fairly substantial portion of the records. So ultimately it comes out to be -- I think they're right around 70 percent (inaudible) records.

Rebecca Hines: Bob, we've got a question here. Are you evaluating the use of WHO's DORIS, Digital Open Rule Integrated Cause of Death Selection Tool?

Robert Anderson: Yes. Yes, but DORIS is unlikely to be useful to us and to those of us who have large volumes of records and do full ICD coding. DORIS at the moment is most suitable I think for those sort of barebones ICD code, very simple codes at the three or four digit level. That may change over time,

but we have been working with folks who are working on DORIS to make sure that at the very least we are consistent with what they're doing.

So just to -- I don't want to take too much time, but I just wanted to sort of show you in a little bit more detail what's involved with the transition. Here with regard to coding instructions and training materials, we have provision of our instruction manuals, which are quite extensive. These are the manuals that the coders use. We have to redo all of our training materials and all of our coders are going to have to requalify for ICD-11.

Then we have the database computer specifications. We have to be able to accommodate slightly longer codes.

Valerie Watzlaf: I was going to say this is a lot of work that needs to be done. If we don't have to do a clinical modification, and I'm assuming we won't have to for mortality, is this a WHO effort to create these materials, is it a combined effort, or is this something we have to take on with the United States?

Robert Anderson: Just to be clear, we do not use the clinical modification for mortality. It's the international version. We do work with WHO to do these materials, but we still have to train people.

As I said, the codes are a little bit different in ICD-11 and so we have to revise our database to be able to accommodate those. We have to figure out if and how we would deal with extension codes. We won't do cluster coding for mortality, but we will probably use extension codes at least to some extent, and we have to figure how we're going to incorporate those into our data storage and into our edits and QA specifications and things like that.

Then we have to revise our standard tabulations lists for ICD-11, and some of you may know that standard tabulation, the main list that we use, this list of 113 selected causes of death, is actually the list on which ranking causes of death is based. So we are going to have to do something there for ICD-11 to make sure we have something that is reasonably comparable that reflects the new reality but gives us some comparability between revisions. We have to redo our table programming. We have to change our report formats as well.

We have to do a comparability study, and this is quite a huge effort. This was actually one of the first projects that I took on when I arrived at NCHS in 1996, at the transition from ICD-9 to ICD-10. It was a lot of work.

Essentially we have to code a single year of data using both ICD-10 and ICD-11. Now, what we will do is we'll take a year that's already been ICD-10 coded and then we'll recode it to ICD-11. Most likely this will work in parallel to our testing efforts for our automated coding system. So we'll pick a year, we'll recode it, we'll check it, we'll recode it, we'll check it, recode it, check it. We'll do that several times, and then ultimately what we end up with will be used in this bridge coding comparability study.

We do have to have a working auto-coding system in order to do this. So we can't -- while we're coding and production, we can't be manually coding 3 million records. It just won't work. That is going to be a bit of a challenge, because we will be working on this at the same time we're doing production coding for whatever data year we're working on.

So then we have to do an analysis of the coding. The change, the bridge-coding study from ICD-9 to ICD-10 was very useful, because it helped us understand the discontinuities caused by the revision. We don't expect quite the extent of discontinuities with the transition to ICD-11, the underlying cause

selection rules are generally -- it's changes in this underlying cause selection rules that tend to cause the biggest discontinuities and from ICD-9 to ICD-10, there were quite a few changes in those rules, whereas from ICD-10 to ICD-11, there really aren't.

There still will be discontinuities just because of the different structure for some cause categories, but we don't expect a huge, huge discontinuity between the two revisions.

Rebecca Hines: Bob, I don't know if this is too much in the weeds, but how would you use extension codes without doing cluster coding?

Robert Anderson: Well, the extension codes are sort of a subset of cluster coding. So, yes, it's a cluster. When I talked about cluster coding specifically, I'm really talking about the combination of stem codes as opposed to stem code and extension code. We don't see any reason to cluster stem codes, because entities are reported on the death certificate together. We would code them separately, and then for analysis, if somebody wanted to cluster those for that purpose, they could do it. But we don't see any reason to cluster stem codes in the coding process for mortality.

For extension codes, that's a little different, because the extension codes aren't used by themselves. They only provide additional information about a stem code. So it might be lefthand side or it might be acute or chronic or it might be something along those lines, something that you wouldn't code by itself but just would modify a stem code.

And then we will need some stem codes I think in the auto-coding process. In the past we've used what are called created codes. We would probably use extension codes in place of that. We're still working on that part.

The question then would be whether those extension codes get passed through the auto-coding system to be used for tabulation purposes later on. We're not sure exactly how that will work. So I hope that answered the question.

Let's see what else. And then of course we need a communication plan. We have to target communication both to technical and nontechnical audiences, to our data providers, which are the vital registration jurisdictions mainly, and then of course to data users, those who do research or who are doing statistical work at the state and local level or at the federal level, and then we also have to target legislators and the media so that they understand what it is that we're doing, what the impact of the change is, and how to use the data going forward.

Last but not least, timeframe. Now, some of you I think have been on this committee for a while and may have heard me speak about this in the past, and I think last time I said that I didn't think we could implement prior to 2026. And then of course, the pandemic happened and we kind of got sidetracked. So this is sort of our rough guess at this point, assuming all goes well; we expect to have a working prototype of ICD-11 for Iris with revised decision tables by October of this year. We'll start development work on a revision of MedCoder probably early next year, and then we expect that to take a couple of years. In the meantime, we'll be working on revising our instruction manuals and training materials and such, whatever we can do without the auto-coding system in place.

Then we figure another year for the database revision and all of the QA and documentation and testing, and then our comparability study, coder training, communication plan probably 2026 to 2027. So if everything goes well, we probably can't implement before January 2028, which is a little past where WHO would like us to be, but it's I think not too bad, under the circumstances. So it's possible that we

could do it sooner if things go really well with MedCoder. But I don't know. MedCoder initially took us four years to produce. Revision may be, I'm thinking, maybe two years, but it could take us longer.

Jamie Ferguson: I was going to ask a slightly different question about this. Once you get MedCoder done, if you had the resources, could you do some of the additional steps in parallel to accelerated couple of years.

Robert Anderson: Maybe. Maybe. It's just it's unclear at this point, I mean, how much we could do while we're working on MedCoder. So some of these things, we can't really do the quality assurance stuff. We can't really do the quality assurance and some of the database work until we have some output to test with. Some of the initial work might be able to be done, I mean, it is possible that we could do it sooner than 2028, but I don't want to promise anything. So at this point, we're thinking probably not before 2028.

Tammy Banks: Not being familiar with the two different code sets, mortality and morbidity, is there anything that can be leveraged from this work to ease the implementation of morbidity or is there any pros to doing it in conjunction so the communications plan rolls out the same way? I mean, is there enough similarities between those code sets? You're doing some amazing work here. Do you see anything to leverage?

Robert Anderson: The code sets are similar. So ICD -- the international version of ICD-10 that we use is very similar to the ICD-10-CM. The CM version is just more detailed. There are some, a few structural differences, but for the most part, the international version is sort of a subset of the CM version for the most part.

The problem is not really with the code set. It's with the use case. So for mortality, we're really looking at cause of death information and we're working towards an underlying cause of death, whereas the use case for morbidity is quite different. So while I think perhaps there could be lessons learned from each, I'm not sure that it would make sense to try to do any of the work in conjunction. I don't know. Others might have different opinions about that.

Based on my experience with the ICD-10 transition, I don't think implementation for morbidity learned much from implementation for mortality.

And that's it for me. So feel free if you have questions that you think of tonight while you're -- you wake up in the middle of the night with questions, feel free to email me. Don't call me.

(Laughter.)

I won't respond in the middle of the night.

Vickie Mays: I'll do it now. I saw something on the slide that I just was not aware of, that you do all -- the slide says cause of death coding. You do the coding for the territories.

Robert Anderson: Yes. When they send us data.

Vickie Mays: Okay, now you've explained everything. Because we wrote a letter before about some of the problems we had, that's what I was trying to figure out.

Robert Anderson: We do all of the coding for five territories. Guam, American Samoa, Northern Marianas, Puerto Rico, and U.S. Virgin Islands. So we do the coding for them when they send us data.

Most of the territories in Puerto Rico, Northern Marianas, Guam, are really good about sending us data. American Samoa and Virgin Islands not so much. So there are some years where we don't have any data for those territories. But when they send us data, we code it.

Vickie Mays: One of the things that was talked about from the data modernization is that NCHS sent resources to the territories in order to help them to be in a better position. So given that people go back and forth for these territories to the United States, I think that this is something important for us, particularly given the communities that they often are landing in when they go.

Can you talk at all about, you know, what did the data modernization money do, is it more improved, are we getting better data or more frequent data from them? If not, is this something we need to be worrying about in terms of --

Robert Anderson: Right, so some of those funds went to help with electronic registration, and Puerto Rico has implemented an electronic registration system. Virgin Islands has an electronic registration system that I don't think has been -- well, they say that it's been implemented, but it doesn't seem to be used at the moment. The whole idea being that by implementing electronic registration you wouldn't need to -- collecting data at the source in electronic format, you wouldn't need to do any data entry or you end up with better quality data and better quality data faster.

So some of the money has gone to do that. Some of the territories like American Samoa, Guam, Northern Marianas in particular are quite small. They haven't been really interested in electronic systems simply because the cost is even with assistance is more than what a few hundred deaths would warrant. So we have looked at the possibility of creating a system. There's been some research done to cover all of those territories, cover any of the territories, to use it. So they wouldn't have to build and maintain a system. We would do it for them. That doesn't seem to be a whole lot of interest still in that. So we do have director of the Division of Vital Statistics, Steve Schwartz, who used to be the state registrar for New York City -- city registrar. I shouldn't use the term state.

He has taken on a detail to focus on these issues specifically. So he hasn't stepped down from his position, but he's on a detail, special detail right now, to focus specifically on these issues. I expect a report will come out of that, something we can share.

Vickie Mays: Let me ask one more question. The death data and social determinants of health, there has been a push to try and link this stuff, and there's been push to utilize for example in terms of the violent death data, particularly in terms of homicides and suicides, and the narrative for investigators to get a better take on this and we're in an epidemic when it comes to violent deaths and we're in an epidemic when it comes to suicide.

So I'm just trying to get a sense of, given that you all are using AI much more, whether or not there's any focus on attempting in the death certificate or the death record to pull out social determinants of health, to pull out the demographic characteristics, particularly the SOGI data for the suicide.

Robert Anderson: The National Center for Injury Prevention and Control has a program called the National Violent Death Reporting System, which does the sorts of linkages that you describe where it's linking death certificate information to the police reports and coroner medical examiner reports, toxicology reports, and so there's a whole lot more information about the circumstances surrounding the violent deaths in that system.

We do have also a fairly robust link to the program, National Death Index, that can facilitate linkages between mortality data and other. It is very expensive. It is expensive, although we've been working on ways to try to bring that cost down, and we have been successful to some extent for NIH grantees, but it's still for any, someone coming in that's not an NIH grantee, it's still quite expensive. But those linkages can be done.

We're trying to do as much of that as we can in house with our own surveys at NCHS, and so there is information where we've linked our Health Interview Survey and our Health and Nutrition Examination Survey and some of the healthcare surveys to mortality data.

Vickie Mays: You actually don't have SOGI data for example in the violent death. SOGI data is only presented if it had to do with the cause of the death. So it doesn't exist as a demographic factor, but yet that's one of the high suicide categories. So there's really been a request to attempt, just like you do in terms of the quantitative data, to put that in the quantitative data, as well.

Robert Anderson: That is something I think that they're looking at with regard to some of the other surveys at NCHS where we could potentially link through those surveys.

Other questions?

Valerie Watzlaf: I just wanted to make a comment. I just think what you put together here is really, really good as far as us being able to possibly use some of your slides, what you put in, as we transition with the ICD-11 and CM. Because you just brought in so many good aspects that I think we need to keep talking about with the training, all of it. So I really liked your, how you just outlined everything, and I think we could use that. I don't know if that's what you meant, but I think we could use some of that. I don't know that we'll ever get aligned in doing it in the same timeframe, but hopefully that can happen. Thank you.

Robert Anderson: Well, good. I hope it will be useful.

Rebecca Hines: My sense is this is the beginning of a new relationship.

(Laughter.)

You just walked into, just given that the transition from Donna Pickett to you, because she was very --

Robert Anderson: That is actually what I was going to say. Donna is much more familiar with the morbidity side of things than me. All of my work with WHO has been on the mortality side. I used to always say I only care if you die from it. But I'm going to have to be more familiar with --

(Laughter.)

I'm going to have to become more familiar with the morbidity side of things as I move forward.

Jacki Monson: Thank you so much for the conversation here. We are way ahead of schedule. So what Rebecca and I have discussed is we're going to take a long lunch and reconvene at, let's see, 1:15.

Rebecca Hines: So for folks on Zoom, we'll be back at 1:15.

(Lunch Break)

Subcommittee on Privacy, Confidentiality, and Security: Briefing on Reproductive Health Information - Panel 1

Jacki Monson: Good afternoon and welcome back, everyone. This is an exciting afternoon. So I will turn it over to Val and Melissa to kick off a couple of panel discussions that we have on reproductive health and health policy.

I think, Melissa, you're going to start us off.

Melissa Goldstein: We are ready. Thanks, everyone. I've turned off my video in case there's an internet issue, which of course there could be. I'm Melissa Goldstein again. Thank you all for coming this afternoon. We are so honored and pleased and grateful that we have a such a stellar panel this afternoon. We have two members of the panel online: Professor Sara Rosenbaum and Professor Elizabeth Mosley, and two people with you there in the room: Lisa Satterfield and Monica Edwards.

Because Professor Rosenbaum may need to leave a little bit early, I'm going to ask for her to speak first, and then we can take questions for Professor Rosenbaum, and then we'll move on to the rest of the panel, just in case she has to leave before we're able to finish everyone's remarks. Okay?

So Professor Rosenbaum, please, whenever you are ready, go ahead.

Sara Rosenbaum: Thank you so much and I'm really sorry not to be there in person today. I am going to be brief, and my remarks are really framing remarks for the rest of the panel, sort of a way of thinking about the aftermath of Dobbs and what the issues are that the committee might want to consider.

So in my view, there are sort of three lenses through which to view Dobbs. The first lens, which I'm sure I don't need to dwell on, is the elimination of a constitutional right, a fundamental constitutional right, which of course has never happened in the United States, but that it has particular resonance for your committee, because the right in question is a right that is grounded in constitutional principles of substantive due process which in this case are what is understood to be a right to privacy, and so because the right was grounded in privacy and the right no longer exists, the effect of that is to, and I'm sure other panelists will spend a lot of time on the privacy issue, the effect of this is to subject people to the full force of state laws that regulate the conduct and behavior of individuals and their information.

The effect of Roe was to act as a buffer against that kind of intrusive state regulation, which under basic principles of constitutional law can be very extensive, especially in the field of healthcare, unless there is a law prohibiting it or a constitutional right that's implicated. So that's number one, and it really brings this committee right into the bullseye of Dobbs.

The second lens through which to view Dobbs, of course, is the public health lens, and to understand the impact of Dobbs from a public health perspective is going to involve years and years of data collection across a huge number of events, some of which we can figure out today, and some of which we're only beginning to understand, because the impact of taking away the right to abortion is just so enormous.

But just the things that public health community is concerned about and of course Professor Goldstein can add to this, are maternal mortality, maternal morbidity, infant mortality, infant low birth rate, infant morbidity, early childhood development measures, family violence measures, certainly poverty measures, measures having to do with the health and wellbeing of families. The reverberations are huge, and the sufficiency and reliability and accessibility of data to researchers is going to be a huge issue in all of this.

But the third lens I would flag for you all is the lens of medical care itself. Dobbs directly and completely, as we're seeing in the EMTALA cases and the cases reported in the news regarding the impact of Dobbs on the integrity of obstetrics and obstetrical care, the effect of Dobbs -- and I should note, it doesn't stop at obstetrics, because there are situations where other kinds of medical professionals may feel impaired by Dobbs and what Dobbs curtails in the prescribing of medication, prescribing of treatments -- but the effect of Dobbs is to impair medical judgment directly and completely, to the point at which even completely nonviable pregnancies are being forced to continue with enormous risks to the health and lives of the people carrying those pregnancies.

So I think that data around the impact of medical interference this profound becomes also an issue for the committee. And I would just end by saying you have a lot of consequences. This committee is incredibly positioned to deal in a real important fashion with access to the data that we're going to need to understand what Dobbs did.

Melissa Goldstein: Thank you so much, Sara, and thanks so much for taking the time to be with us today. First I would start with the other panelists, if you have any direct questions for Sara before we move on. Anyone? And what about the members of the committee? Any direct questions? And then as long as you can stay, Sara, we'd love for you to stay with us, but we'll move onto the other panelists if there are no questions now.

Okay. It looks like everyone's eager to hear what the others have to say. That was amazing framing. Thanks so much. I sat here thinking how can I frame things as well as Sara does?

Denise Chrysler: I had a question. I am assuming -- Sara, thank you for talking about the importance of data and how we're not going to know the consequences unless we gather very important data, and yet we've got this whole (inaudible) public health, you gather the data, and then you need to protect the data. But I'm assuming our later speakers will be addressing that issue, Melissa? I didn't know whether to address this to Sara.

Sara Rosenbaum: I assume myself that the committee's crucial responsibility is to balance the two, and I assume your other speakers will address the issue of data privacy and I should -- I can only say that the issues are so compelling on both sides. The absolute need to understand what is happening, but the absolute need to protect people from the full force of the state that is making incursions into areas of privacy that until 2022 were unthinkable. So it's quite a charge.

Melissa Goldstein: Thanks, Denise.

Anyone else in the room? Okay, Lisa, I think your name is next on the list that's on the website. For those of you who are on the webinar, the website has a list of the panelists for this panel, for all of the panels, and their affiliations for some more background information.

Go ahead Lisa, thank you.

Lisa Satterfield: Hi, everyone. Thanks for having me. This is a really important discussion and I hope I don't throw a wet blanket on everything, because I know you probably want really joyful news, right? I'm representing the American College of Obstetricians and Gynecologists. I'm the senior director for health policy there and I also staff CPT (inaudible) and ICD-10 coding.

I have a lot to say, and thank you, Dr. Rosenbaum, for framing that. I was taking notes, like, yes, yes, all these are large problems that are being seen by our members. We actually have an anonymous site

where members can contact us and share their stories, so I pulled some of those for today, just to give you the reality of what we are hearing from ACOG.

I'm just going to read for a bit. I have a story here about a transfer for out of state. A local community obstetrician contacted us; she had a patient with an ectopic pregnancy in the fallopian tube for treatment. The pharmacist did not feel comfortable releasing appropriate drugs because of their personal interpretation of the law, so the patient had to be transferred out of state to receive care for their ectopic pregnancy, in a state where this would have been covered otherwise. But it was stopped because of the fear of the pharmacy in the state (inaudible) prescription. This physician is still fearful that this case will be discovered, that the pharmacist may turn her in, and that she will be prosecuted. So that's one story.

I have one really compelling story I want to make sure I hit, on documentation, which is really going to affect your ability to even collect the data that you're hoping to collect, and I'm not going to sugarcoat it, it's going to be really difficult for you. It's going to be really difficult for everybody to get the right data, because of this documentation issue.

I am a physician in a state that criminalizes abortion, but I am able to send my patients to a colleague in a nearby state. However, I don't know how to document these cases. Obviously I cannot put abortion in the medical record, or even the pregnancy exists, or gestation. What if the records are subpoenaed? What if another healthcare provider sees this record and finds a way to report it to the family or the state? Even if the records are protected, what if in the transfer of the patient someone sees the care I recommended. My colleague across state lines is in a similar situation. If the records coming back are found, how does it implicate us. Instead we have decided not to document, and this is not unusual. Instead we have decided not to document, which is against every fiber in my being, but it will keep my patients safe and our medical licenses in the clear. I don't know how else to handle this. Help.

It's hard. Because all is confusion. Even if we come back to her and say you're protected, you have these protections, it's too scary and too real for them at the grassroots level, and they don't want to take any chances. So the confusion that's coming out of everywhere, it's not the fault of HHS. Right? I want to make that clear.

But the confusion is perpetrating more fear, and as you all know, when HHS did put out something early on, after Dobbs, they were immediately sued for the information that they put out. So there is going to be a lot of documentation problems.

This is another one at the hospital. Our hospital policy now requires that we obtain signed statements from another physician that a pregnancy is threatening the life of the mother. And an additional signature from neonatology on the patient's chart that indicates their pregnancy cannot be resuscitated, before we undertake any abortion procedure, including surgical treatment of an ectopic pregnancy. These requirements are designed to protect us from criminal liability, however, they are slowing the treatment of potentially life-threatening conditions. It takes neonatology away from the care of somebody else's live newborn, critically ill, to write a note that my patient's six-week ectopic pregnancy cannot be resuscitated. It also demeans and erodes the profession of obstetrics and gynecology by implying that other specialties can be trusted to assess these issues, and not me.

So I have many, many more stories. I'm happy to share more with you. But as you move forward in your work, it's something to think about on how you can potentially get the data when it's probably not being documented, or documented the way it would have been prior to Dobbs.

Additionally, we've had discussions at ACOG over just the just the codes themselves. The CPT codes for abortion, including care for miscarriage and ectopic pregnancy, all use the word abortion in them. So we have physicians who are treating miscarriages not even wanting to bill with the CPT code because it uses the word abortion. Let alone the ICD-10 codes for the reason that, again, it's very complex. Physicians are so fearful in so many states about the implications of using the codes and putting it in the medical record.

Happy to answer any questions about this.

Valerie Watzlaf: I just wanted to ask you a clarification question. You were saying that physicians are even fearful to document in a state where it is lawful, correct? Because of just the transfer of that information into another state.

Lisa Satterfield: Yes, because of the transfer of a medical record with the patient to another state.

Valerie Watzlaf: Do hear anything from (inaudible) -- do they talk about that at all, and is it another issue when they're even dealing with medications and so forth?

Lisa Satterfield: The medication issue is quite a mess right now with all the injunctions and everything. Nobody's actually wanting to do the medication at this point. We can't get pharmacists in states where it's protected, even. I have another story of a person who traveled postpartum and started bleeding, called her physician in her state -- both states were protective for abortion care -- but because of all the confusion of the medications right now, the pharmacist wouldn't fill the prescriptions to have a postpartum woman with her bleeding issues. So this is beyond abortion. This is miscarriage, ectopic pregnancy, postpartum, general women's health, is being affected by this.

Valerie Watzlaf: It's beyond documentation, too, you're saying it's stopping treatment.

Lisa Satterfield: Right.

Valerie Watzlaf: Do you have any idea as to how to -- I think that was one of your questions to us, how do we get the right data, and you say it's very difficult. Any ideas around it as you talk to other --

Lisa Satterfield: What we have told the administration in different comment letters is that we need to figure out how to separate the data, and that's something we've been saying for years, for the medical records. We've been told that it's very difficult to separate the medical record data out. I'm not an IT professional, I'm a health policy one, so I don't know the logistics behind all that, but even when we were talking before post-Dobbs, about intimate partner violence and privacy for teenage pregnancies, we've had trouble getting the data separated and it's just too enmeshed into the medical record.

So that needs to happen, but honestly even if it happened right now, I'm not sure what we would find anyway, right? And I don't know how we can reassure physicians that their data will always be protected. We're working on different things at ACOG like putting a legal resources action fund together, but what one of us anywhere would want to utilize the legal resources action fund? That means that legally something has happened to us.

I'm sorry I don't have any really great answers.

Melissa Goldstein: No, Lisa, your perspective is incredibly helpful for us, and I wanted to ask you, if you can, really spell out for the committee and the people that are watching online, what exactly

practitioners are fearful about? Is it criminal prosecution, loss of licensure, is it all of the above? For doctors, what are the expressions of fear?

Lisa Satterfield: It is all the above. It is loss of licensure and the inability to practice. That's probably the primary one. The person, the case that recently occurred in Indiana of the Indiana provider that provided care for the child from Ohio -- she got a slap on the wrist and a fine, but she was put in front of her board for 18 hours to testify, 18 hours, continuously. Not like over three days, all day long. And while her punishment may be seen as minimal to some, it was quite a process and quite devastating for her emotionally. And then to have her medical board of fellow physicians say that she broke the law.

So that's what they're fearful of.

Rebecca Hines: We have Michael and then Vickie have their hands up.

Michael Hodgkins: I have a question in response to the thought of figuring out a way to separate this from the medical record. It's just not an answer. There is never going to be an efficient way to isolate reproductive health in the electronic record. You factor in things like patient (inaudible). That's not the route to go. So I just think that pursuing that is futile.

Vickie Mays: I guess I'm concerned about how we can document the issues, so sometimes when we can't get data from individuals, we think about bumping it up and doing surveys, so that we get some sense of, let's say, prevalence and things like that.

So I'm wondering if there is any way that ACOG might be comfortable with surveying its members? Like once a year or something like that, that would actually at least give us some anonymous, but at least give us some information. Is that at all a possibility?

Lisa Satterfield: I can certainly look into that. I know even setting up this portal was quite a feat, because of wanting to maintain privacy. And ACOG, in our position, we don't want to be in a position also where we get subpoenaed to share information.

Vickie Mays: I think it would be great if you could have your lawyers come to you and figure out if collecting anonymous data which would give a sense of what the care incidence or some bigger geographic field like the north-south, east-west, rather than specific -- but I think it could really help.

Tammy Banks: I know you're representing your membership, but this is a bigger issue. It used to be documenting to protect from lawsuits. Now it's protecting from retribution, whether it be legal, whether it be interested individuals with different viewpoints. We have consultants now that won't do databases with gender preferences because they're afraid they're creating a list that will be used in ways that is not intended.

So I think as we talk about this issue, we have to realize it's much bigger across healthcare, and the issues are not going to be just specific to the issues that we're talking about right now. It's across, and I hate to use the word minority, but I don't have a better word to use, and how to we protect patients from those that are going to use that data inappropriately, for whatever police system, whatever legal system. I just want to raise that, as you think about issues, this is a bigger issue that are going to need the same types of solution.

Lisa Satterfield: Absolutely. We had a conversation actually where -- I haven't heard of this happening yet, but if an explanation of benefits has a miscarriage or abortion CPT code on it, and a neighbor finds it

in the trash, what are the implications for the patient of that? There's a lot, we can go down the road and think about what could happen, what is happening.

Tammy Banks: Like the false claims, right? You need to report that and you get your reward. This is even to a higher level, to a detriment of individual patients. It's just really sad we're at this place.

Melissa Goldstein: It is, what you just said, Lisa, was very interesting to me, because whether or not there's a real, what we might call a real legal risk there, it's this perception that there might be a legal risk, and the reality that that might affect medical care because of a fear of a legal risk, whether or not it's real, that we have to take into account as well. And it's the trust in the system, both on the patient's and the provider's side, that we have lost overall. It is, as you said at the very beginning, when you started speaking, it's very difficult to speak about this topic without sounding bleak. And you've pointed out some of the reasons, and we appreciate that.

I want to let everybody know that we have plenty of time. We have at least until 2:45, but possibly some time after that. I know that Professor Rosenbaum will have to leave us at some point, but I don't want you to feel pressed for time with people's questions, either.

Should we move on to Monica now? Is there anyone else with a question or comment in the room?

Maya Bernstein: I had a question, but I'm anxious to hear our other speakers first and to have everybody join in the conversation afterwards, so with deference to my co-chairs, if that's okay?

Melissa Goldstein: We can move on then. Thanks. Sounds great.

Monica Edwards: Thank you all. That's just a perfect segue, because I'm also going to talk a lot about the impact specifically on the constituency that my organization serves, which is Black girls, women, and gender-expansive people. And I will preface all of this by saying I also don't have answers, at all. And I know this is something that we're trying to figure out in this rapidly changing legal landscape. But I do think it's important to provide the perspective of communities that are most impacted by the fall of Roe in the Dobbs decision, as well as talking about it from a reproductive justice lens.

So, hi, my name is Monica Edwards. I use she/her pronouns. I am the director of policy and advocacy at In Our Own Voice, National Black Women's Reproductive Justice Agenda. We are a national/state partnership, and our state-based partners include organizations such as Spark: Reproductive Justice Now, the Afiya Center, Women With a Vision, SisterLove, Inc., Black Women for Wellness, SisterReach, Black Women's Health Imperative, and New Voices for Reproductive Justice.

Our core mission is to amplify the voices of Black women, girls, and gender-expansive people at the national and state levels in our ongoing fight to secure reproductive justice for all people.

I realize I'm throwing around the term reproductive justice. So if that term is new to you, it can be defined as a human rights framework and movement, which was started by 12 black women in the 1990s. At its core, the tenets of reproductive justice is the right to have a child, the right to not have a child, and the right to parent our children and to live in safe and sustainable communities.

Since the Supreme Court's decision in Dobbs v. Jackson Women's Health Organization and the fall of Roe v. Wade, we've all seen a chaotic situation unfold impacting many people, including providers, healthcare facilities, practical support organizations, abortion funds, and people seeking abortion themselves. But I must be frank and say that even before Dobbs, even before the fall of Roe, the most

impacted communities could already not access their constitutional right to abortion. Millions across the country were force to navigate, before Dobbs, an uneven obstacle course and a patchwork of abortion access across the country. Restrictions like the Hyde Amendment, mandatory ultrasounds, mandatory waiting periods, and parental involvement laws impacting young people, the most impacted communities have never truly had a right and access to abortion. It's only been in theory only.

After Dobbs, the inability to access reproductive health across the country have been exacerbated, which is of course why we're all here. Though this is the reality, what is also the reality is that the community of which I am a part of, and the community which In Our Own Voice serves, Black women, girls, and gender-expansive people, want to be clear and say nothing about this chaotic situation is new or surprising for us.

Black women, Black (inaudible) people, have always had to exist in a country where our health decisions and our lives and our futures were not our own. This can be seen as far back as enslavement, medical experimentation on Black women, and as recent as the current moment of continuous antiabortion restrictions, even after Dobbs, attacks on our history from the classroom, and anti-trans legislation currently moving right now at the state level.

It's no wonder that as stated in the department's NPRM in April, marginalized communities already have medical mistrust. We already have medical mistrust of providers and the healthcare system at large, due to the historical and current violence and oppression.

If these already marginalized communities believe that their private health information is not their own and will not be used in its intended purposes, they are less likely to seek needed healthcare. That is why it's important to strengthen privacy protections for all people and for all forms of healthcare.

In a time where religious freedom in some instances is being weaponized to deny care to consumers, and I preface all that by saying I'm a Christian, southern-raised in the Bible Belt -- where miseducation about what is and what is not being taught in our schools continues to persist, and where attacks on abortion care persists, additionally there are also attacks on people wanting to achieve menstrual equity, simply wanting to have period products in schools, have been blocked by numerous state legislatures across the country.

In addition, there is also continuous attacks on gender-affirming care. With that, it is going to take strengthened protections and a whole-government approach before we can work toward a world where reproductive justice is a reality.

As I said earlier, In Our Own Voice has eight strategic partners, and I want to take a little bit more about what they're seeing and the impact on the ground. In addition to our strategic partners, we have state enhancement partners, where we provide technical support and grants to those organizations to do their work in those states. That includes Birth in Color, Oshun Family Center, Black Women Physicians Association, and the Wisdom Institute.

So collectively all of our partners reside in Washington D.C., Pennsylvania, New Jersey, Michigan, Virginia, Louisiana, California, Georgia, Texas, and Tennessee. So that means that the majority of our partners reside in the south and the Midwest, and the majority of them are in states where abortion is either completely banned or there are severe restrictions.

Further, some of these same states, which I'm sure you all know, are the states where the maternal health outcomes are the worst and the gravest, where Medicaid coverage has not been expanded, and where many face obstacles trying to achieve any type of healthcare at all.

To also be frank, the majority of our partners in the south and the Midwest are in those regions, and those regions are where there are statistically the largest population of Black Americans. I say all that and attest to that as a Black woman sitting here today and who was also born and raised in Alabama, who moved to northern Virginia almost five years ago, and comes from a state where right now abortion is currently illegal and also healthcare is inaccessible. Quite honestly, Alabama government has completely failed its constituents. I say that not in theory, but via my experiences and facts.

Growing up in Alabama, I continued to witness the government make decisions that were not in the best interests of its constituents, but in the best interest of the people with power. Alabama has one of the largest incarceration rates in the world. I'm going to say that again. Alabama has one of the largest incarceration rates in the world -- not the country, the world. In 2020, in the midst of a global pandemic, my state chose to spend over a billion dollars in revenue to build a new prison system in Montgomery, and they have current aims to continue building more prisons and spending millions of dollars over the next three years.

Alabama is currently one of the many states where abortion is currently illegal, and as recent as this year the Alabama attorney general Steve Marshall said, although he later walked back the comments, that he would pursue utilizing the state's chemical endangerment law to criminalize people who use mifepristone, one of the safe and effective medications to use for medication abortion. And though this threat was later walked back, the fear and negative implications of these sentiments and the sentiment of simply criminalizing birthing people for seeking abortion is not far-fetched.

In fact, in 2019, Alabama made national news after Marshae Jones, a Black woman in Alabama, was arrested and charged after being shot, resulting in the loss of her pregnancy. The previous year, Jessica Lindsey was sentenced to prison after pleading guilty under the chemical endangerment law in Alabama for using a substance while pregnant.

I don't tell these stories or say all this in a one-off way, and I don't say this to paint my home state in this negative light. However, I do say this to paint the picture that people are scared and that it is the people in the south and Midwest and those most impacted who are having to deal with the repercussions of the Dobbs decision.

For Black women, girls, and gender-expansive people, the situation will only get worse. Last month my organization, we released our second iteration of our policy agenda, titled Reimagining Policy in Pursuit of Black Reproductive Justice. This over 30-page document serve as a guide to federal lawmakers and agencies to think critically about the issues that are most pressing for Black women, in hopes that they can and will work to utilize every tool in the toolbox to implement policies that meets our needs. From gender-based violence, voting rights, police violence, pregnancy and maternal care and abortion access, we discuss the issues that heavily impact Black women, girls, and gender-expansive people.

So I'll close by saying in this increasingly changing legal landscape, it is important that privacy protections be strengthened. I don't know how that works or how that would work, and I don't think we all know, I think that's why we're here today to have these conversations. But it's important that with any avenues that you explore, any decisions that you make, that you do so from a reproductive justice lens, and you do so from a lens that centers the people who are most impacted.

Melissa Goldstein: Thanks so much, Monica. We really appreciate your coming today.

Are there any questions from the other panelists, comments? Anyone from the room directly for Monica, before we move on?

Vickie Mays: Thank you for pulling many things together to give us a sense of a bigger impact. We often talk about data, but what I've appreciated from both is the stories talk about the criticalness of needing the data in order to be able to make policy changes. So I want to thank both of you and in particular the way you highlighted some of the state issues.

I'm going to ask a question that I know is a difficult question, but it's the same question I posed before. I know some of your organizations, they have some of the most courageous women that will stand up to a lot of things, and I guess I'm wondering, in this instance, where the federal government's hands are being tied, is it possible that you all could think about, particularly because you have organizations that are in the states where the clock has been broken -- I won't even say turned back, but broken -- that you could mount an effort particularly if it falls under research, and you have the certificates of confidentiality, whether or not you all could think about doing that so that we have some data that we could utilize?

Monica Edwards: I will give the same answer Lisa gave. As a person that's not going to make that decision, but I definitely can take that back. I do think it's important to weigh in with that important data, specifically from our constituencies in those states, so that is definitely something I can take back. I personally think that could be very useful, (inaudible), but I will take that back.

Vickie Mays: You have the trustworthiness, so I the depth of either doing the story narratives or the -- finding the questions, and I would say pick questions sometimes that the federal government has on its surveys so that you can even do comparisons. I'm going to leave that as a challenge for you all, which I know some of your directors are up to.

Rebecca Hines: We can move on to the next speaker.

Melissa Goldstein: Professor Mosley, thank you. Are you ready?

Elizabeth Mosley: I am just so honored to be here. Good afternoon to everyone, and thank you so much for having me on this panel about such an important topic and with these really incredible co-panelists.

My name is Elizabeth Mosley. I use she/her pronouns, and I'm an assistant professor at the University of Pittsburgh School of Medicine, with Converge, the Center for Innovative Research on Gender Health Equity. But I live and work in Atlanta, Georgia. I was also raised in the Bible Belt down here in actually South Georgia. But I live in Atlanta now, and I'm also an affiliate faculty member with Emory Rollins School of Public Health. We have a center there called RISE, the Center for Reproductive Health Research in the Southeast.

I'm also a full-spectrum doula and volunteer in the community serving mostly women of color who can't afford doula care, and I'm honored and privileged to do community-engaged research with community-based organizations, including reproductive justice partners.

Today I want to set the stage for the research conversation by highlighting some insights about the kind of abortion research that's needed, how we do abortion research, and sharing some of the stories about IRB and regulatory challenges that we've been facing as researchers since Dobbs. I also want to

illuminate how our gold standard, the NIH certificate of confidentiality, might be tested in this new policy landscape, and how abortion stigma and illegality leads to uncertainty and potential legal risk for researchers like myself.

And then finally I want to end with how we as researchers, how this committee, and other reproductive health stakeholders, can all problem-solve and move forward together.

I want to quickly set the stage for abortion research and data security. First, abortion research has and always will be needed to ensure high-quality and patient-centered healthcare, as well as to optimize reproductive health outcomes and to reduce maternal mortality, to some of the points of my co-panelists. However, abortion research is most critical in moments like this, following monumental, unprecedented shifts in reproductive health policy, where the legality of abortion is now restricted in over half of U.S. states, where 25 million people of pregnancy capacity currently live.

Restrictive abortion policies are just one manifestation of abortion stigma, the social process of assigning negative attributes to and then discriminating against anyone associated with abortion. Second, abortion research also includes patients who reach abortion care, patients who face barriers and might never reach abortion care, and even people who are self-managing their abortions outside of the health sector.

Abortion research also involves longitudinal study designs that allow us to follow participants during pregnancy and then after the pregnancy ends, and for that reason abortion research employs not only secondary analysis of health records data or medical claims data, but also primary data collection through things like self-report surveys and even qualitative methods like in-depth interviews.

So this landscape that's characterized by stigma and by the need for these sensitive, identifiable data, introduces a lot of challenges and some risks related to data privacy, confidentiality, and security.

Researchers work really closely with our institutional review boards, IRBs, for ethical and regulatory oversight of our human subjects research. However, the Dobbs Supreme Court decision has injected a lot of confusion and concern into the IRB review process.

For example, at the University of Pittsburgh, we're conducting a study on pregnancy acceptability that involves in-depth interviews and longitudinal surveys with people who recently found out they were pregnant. Two of our study sites are Texas and Tennessee, where abortion is completely outlawed. When seeking IRB approval to conduct our in-depth interviews with pregnant people from Tennessee and Texas who were seeking abortion care out of state, our IRB raised these questions: what are the risk mitigation strategies for interviews in restricted states, and how is your team articulating those protections to research subjects? Will the audio files from your interviews remain identifiable, and will there be a risk to subjects who are not even involved in your research? For example, if an abortion is completed out of state for someone who resides in Tennessee, then could the practitioner or others involved in assisting that individual while seeking the abortion be at risk for civil or criminal penalties? Please give additional information to the IRB on how you will minimize these risks.

In other scenarios, though, some institutional review boards, even those in more restricted states than Pennsylvania, don't seem as concerned about real risks to our human subjects in abortion survey research. For example, at Emory University, I co-lead a community-engaged full-spectrum doula study in Georgia, where abortion is now outlawed starting at six weeks since the first day of your last menstrual period. And the study involves in-depth interviews and surveys with doula who provide abortion information and support, including helping patients seek abortion care out of the state after

the six-week limit. Yet the IRB deemed that our study was exempt from IRB oversight, even after I made repeated requests for review and oversight, because it was evaluated as low risk to the doulas involved.

All of the IRB and regulatory challenges are amplified when we're doing research with adolescents, who do experience pregnancy and who face disproportionate barriers to abortion care, and while pregnant minors are able to consent to research without their parental involvement, they can face additional risks if there's a breach in confidentiality of their data.

To date, the NIH certificate of confidentiality has been our gold standard in data security for research. The certificate is a form of protection that permits researchers in our institutions who are under subpoena not to disclose any research participant data. However, there are limits to certificates of confidentiality, including child abuse and the threat of harm to self or others. Meaning if a researcher like myself learns from a participant who's a minor that they are experiencing child abuse, I might need to report that incident to the proper authorities.

The certificate of confidentiality has been challenged in court a few times and so far has been upheld. Just to give you an example, one case involved a defendant who was being tried for statutory rape, and one of the prosecution witnesses was a member of a longitudinal drug use study at Duke University. The defense requested all of the study data related to that research participant be handed over to the defense and the prosecution. This was ultimately denied, though, because that study was protected by a certificate of confidentiality.

People often point to substance abuse research as another example of sensitive data about a criminalized and stigmatized health behavior, but we believe this is a false parallel, a false equivalency, without appreciation for the severe stigma against abortion that equates this health service with murder. Researchers and regulatory bodies alike are wondering what Dobbs could mean for the certificate of confidentiality and abortion research.

For example, could fetal personhood laws, like the one here in Georgia, be used to seize research data on abortion patients, providers, and their supporters, under the claim that abortion after six weeks is child abuse?

These unprecedented reproductive health policy changes have created a lot of uncertainty and potentially legal risk for abortion researchers. For example, it's standard practice for us to offer our research participants a resource sheet at the end of any survey or interview, and in reproductive health research that often means resources related to pregnancy support, free needle care, abortion services, and adoption. However, new state laws like SB8 in Texas, which outlaws aiding and abetting abortion, could be interpreted to outlaw the provision of educational resources.

This law in Texas penalizes anyone who knowingly engages in conduct that aids and abets the performance or inducement of an abortion with a fine of $10,000. As the University of Pittsburgh IRB asked our team, is an interviewer who gives a pregnant woman in Texas the phone number of an abortion fund out of state violating state laws or putting the participant data or the researcher at risk?

Similarly in Georgia, I co-lead a medication abortion study with reproductive justice organization SisterLove, Inc. We were funded by the Society of Family Planning to create an educational video about medication abortion. That happened before Dobbs. But then after Dobbs, we needed to update our video based on the new state laws, and so we secured funding from a local university to do that. However, the university's legal department raised concerns about our video, and they asked whether it violated Georgia's six-week abortion limit. Luckily in Georgia, only the provision of abortion care is

currently outlawed, not the sharing of information about abortion, and we had an incredible reproductive justice attorney on our team who helped us navigate all of that.

However, because of stigma and lack of legal clarity, we nearly lost that supplemental funding to produce a video that is urgently needed by Black and Latinx communities here in Georgia.

As we move through this precarity and towards solutions, our abortion research community has been meeting regularly to discuss these common challenges that we're facing and novel approaches to dealing with them. We've also been working really closely and consulting with reproductive rights and justice attorneys, including at the women's health law project at If/When/How and at the Digital Defense Fund.

We're implementing new standards of research practice, including anonymizing our data completely whenever possible. For example, collecting contact information on surveys completely unlinked from the survey data, or using standard participant ID code questions rather than creating a file that links participant IDs to that compact information.

However, we are researchers. My PhD is in public health, and we need help especially from sectors outside of abortion research. For example, we need partnerships with IT, with legal, regulatory, and the health sectors. Perhaps most importantly for this committee, we as researchers need guidance and standardized requirements that are set forth by the federal government to steer researchers and IRBs on the ground.

For example, we have clear HIPAA policies around the protection of health data, but those policies and protections don't extend to research data. So I hope this is the start of a continuing partnership to build and implement some of these safeguards that we need to ensure urgent and important abortion data can continue to be collected with integrity and with adequate protections for our human subjects and for researchers.

Just thanks again for this opportunity and your attention. We really look forward to strategizing together and working with members of this panel and members of this committee. Please feel free to contact me or our center at University of Pittsburgh, or at Emory, for questions, for more examples, or continuing partnership.

Thanks so much.

Melissa Goldstein: Thanks so much, Professor Mosley. We really appreciate you coming and giving us this information.

Lisa or Monica, do you have any questions first for Elizabeth? I would let the public know that Professor Rosenbaum did need to leave, and she apologizes for not being able to stay for the whole panel. Especially to the panelists, and then the rest of us as well.

Professor Mosley, I will start with a question for you about -- it's very interesting to me, the non-linking of data, the trying to use completely non-linked, 100 percent anonymous, and when I say non-linked, there is nowhere, nothing, that links a response from one of the participants to contact information. And I'm assuming not even an informed consent form, a written form. So there's nothing anywhere in your data where not even you could figure out who -- exactly.

Voice recordings would be -- video -- so my question for you is as a researcher, is there any detriment to you and the study and the results and the public, and generalizable knowledge, from not having identifiable information? Longitudinal, I know that researchers often prefer data that can be identified, for instance, for future questioning, that sort of thing. But I'm not a researcher myself, so I wanted to check with you on that.

Elizabeth Mosley: No, I think you have good intuition, then, about research. You raised some questions that we're struggling with. I think there are definitely downsides to not being able to collect identifiable information in general. So the first, maybe most obvious, are things like contact information. Especially for things like longitudinal studies, if we want to be able to contact someone over time, we usually would house a linking file where we have their contact information that tells us this person, participant ID number, is actually this person, and it gives their name and email address.

And that used to be standard practice. That was saved on secure servers, encrypted through all of the protections that our institutions can offer from IT, and it allowed us, as you said, to keep contacting people, including for future research. Maybe not for the current study, even, but for future studies.

Honestly what we're realizing now is that the tradeoffs just aren't worth the benefits anymore, and the risks are so high that it's not worth being able to contact someone again. Or we need to find better or more creative ways of figuring out how to contact them, that never allows me as a researcher to connect their identifiable information to their survey answers or their health data.

There are some ways that we can still do longitudinal studies, like the coded participant ID I was mentioning, where people answer a series of questions at the beginning of every survey, that are standard, like what's the first letter of the street that you lived on when you started this study. And they would answer that the same way each time they do a survey, and so we're able to link them over time. But we're not able to link that survey back to an individual.

So I've been thinking through some of the downsides. I would say, we're already seeing on surveys, for example, we are trying to survey people who are seeking abortion care from restricted states, trying to measure whether or not they actually access abortion care that they need, if they are able to access or not able to access abortion care, what are their outcomes in terms of maternal and child wellbeing, long-term? And normally, we would like to collect things like people's zip code, like where are they living, and that would tell us physically how far they are from the nearest abortion clinic. But it became clear to us that collecting zip code is another form of identifiable data, and it wasn't worth it to us to ask that level of private information, just to answer a particular research question.

So I would say that we are having to give up some important research questions and are balancing that with the potential risk to our participants. And I think as a community, I would like to say that we have thought carefully about this for a long time, but the risks now are just so urgent and high, that I think a lot of us are just pivoting and working with groups like Digital Defense Fund to think through very carefully what are the points of risk for our subjects at each stage of the research, and how can we minimize it at every phase?

Melissa Goldstein: Thanks so much. From my perspective, the interaction between what you have just said and what Monica has said, from the perspective of reproductive justice, if we don't have the information, from a research perspective or a data collection perspective, from public health or writ large, how do we address the issues in reproductive justice that Monica's been talking about -- that we've known about -- that are almost or possibly, definitely, more critical now, because of this change. So that connection between the two is really startling to me.

I'll pass it off now so, panelists, members of the committee, please let us know if you have questions.

Maya Bernstein: I am hearing from email, from people who are online, that it's the questions that are hardest to hear. We can hear the panelists. So use your outside voice.

Vickie Mays: I want to thank you, Dr. Mosley, for your comments. I'm trying to really understand what, from a federal standpoint, can be done in terms of research and what is a local issue. So for IRBs, one of the things is at the federal level there are usually principals, and then there's a kind of standard of practice that has a local jurisdiction issue that takes place.

So one of the things I'm going to ask about is the certificate of confidentiality is usually protection of a person. Are we in need of some kind of certificate of -- I don't know -- protection or confidentiality that has to do with location data or populations. I'm trying to think about what feds can give you, because a lot of stuff is very local. The group that you probably also could be talking to is PRIMR, which does all the training for the IRBs, in terms of best practices. So I'm trying to think, at the federal level, what would be your request?

Elizabeth Mosley: Thank you so much for your question, I appreciate this. I agree that the IRB is one of those global kind of approaches and principles, and then highly localized application. What we're seeing though at Emory, at Pittsburgh, and other institutions across the country, is that the IRBs are doing that guessing game of what-if, what-if, and they're taking it down each legal fear pathway that you could imagine. Without a legal background it can be hard for me to answer some of those questions from them. And what they're asking for, I think, is some sort of standardized guidance.

Maybe at the federal level that is more high level standards of practice around reproductive health data, or to the woman's point, also around trans data, as we know that that's another data sensitivity that's being targeted right now. But thinking about what are the principles that the IRB can help balance? Because what's happening on the ground is that abortion research is being stopped in its track, because the IRB has so many questions that can't seem to be answered easily.

I'm working with the Society of Family Planning. We're also working with ACOG. We're speaking with NICHD, to get any sort of leaders in our field also to issue some guidance, anything that we could hand to our IRBs and say this is standard practice, and this is some of the stuff, like the delinking of data, the destroying audio files. If we could just set up some best practices, really, and all adhere to that, I think it would help some of us get on the same page and it would definitely help those of us working in restricted states, when we have IRBs that are especially fearful of legal ramification, to be able to say these are best practices that reproductive justice attorneys have looked at, that IT folks have looked at and agreed with us that this is the best we can do to protect our subjects right now.

So maybe it's starting with that, kind of general guidance. But my colleagues and I have been talking a bit about HIPAA as sort of this federal precedent that changed the game for data privacy. And are we at a point where we need a HIPAA for research, because those kind of policies would be really helpful right now.

Our feeling on the ground is that the certificates are not strong enough. Every lawyer that I speak to is telling us we don't know if these certificates of confidentiality will hold up. So I fear that another certificate would give us the same feeling of it just isn't strong enough. What can we do, through data solutions, IT solutions, research practices, so that we never even have those data that someone might subpoena us for?

Michael Hodgkins: This is a question and a comment. I was thinking that a lot of the research that you provide may be funded through federal dollars, and if that were the case, then certainly involvement of the federal government here, even though as Vickie has pointed out, there are things that are very much function locally in practice. But is a lot of this research being funded with federal dollars, or is it really mostly coming from (inaudible)?

Elizabeth Mosley: It is a mix, I would say. It can be challenging to get federal funding for any abortion research, but I would be remiss if I said the federal government does not fund abortion research. It certainly does, because it's within the scope of institutes like NICHD, Child Health and Human Development, reproductive health, demography, abortion certainly falls under that. And access to abortion care has ramifications for maternal and child health outcomes. So we do get some federal funding, as well as from NICHD, but also maybe NIMHD, and other NIH institutes, but a lot of the research funding is being funded by private foundations that are interested in reproductive health rights and justice.

So to your -- I apologize but I couldn't quite hear the full comment, but I imagine it was something about federal funding for data that then need to be open to the public and potentially available; was that part of your comment?

Michael Hodgkins: I guess I was just saying to the extent that it is federally funded, then there certainly is a role for the federal government in trying to address the issues that you've identified (inaudible). Federal monies flow to institutions like the ones that (inaudible), and that gives the federal government some leverage or potential leverage in acting in support of efforts.

The last thought I had is, I sit here thinking back on the response that was crafted to the NPRM, and this is like a huge gap exposed in what we could have responded, even though it wasn't being asked by the federal government in the Notice of Public Rulemaking, this whole aspect.

Rebecca Hines: So, think about that when we get to the workplan discussion. Is there a sense that that's something you want to work on? It's fair game.

Melissa Goldstein: Rebecca or Val, could you repeat a little bit of what Michael was saying? Elizabeth and I had trouble hearing him.

Valerie Watzlaf: I think what Michael was saying was that this whole research area, we really did not include in our comment letter to the NPRM. SO this may be an area we may want to focus on, because we are -- we're really gathering all your expertise, this has been fantastic, so that we can think about other recommendations we may want to make in this area.

Michael Hodgkins: I think you summarized it quite well. I think to Vickie's point, Vickie, you're saying we've got to get more data. Well, an important source of data is the fact the research that Elizabeth and others conduct, and if we can't protect that research, that just further exacerbates the problem, of lack of data with which the (inaudible).

Vickie Mays: Part of what I think we're struggling with is the difference -- what's different about this is that it's these legal issues, and it's not just putting the person you got the data from at risk; you're talking about putting a provider at risk, you're talking about putting a healthcare system at risk. That is a little different, because the notion of what you're talking about, and I'm trying to minimize it, but almost at the beginning of many different epidemics the IRB would run us in the ground with questions. When HIV started, we didn't know what to do, then when heart started and there were substance abusers, we

didn't know what to do. One of the things IRBs are -- I think it's federal -- are required to do is for prison research, they are to have an expert at the table. And I don't know if having an expert at the table that is -- it's almost like -- I think this is what's different. IRBs are to deal with harm and risk to the participant in the study. We're looking at harm and risk to beyond that. This is a new territory to some extent, but I do think it's one that SACHRP and the federal government have significant roles to play, because of the research enterprise is so important to the federal government, to maintain and protect.

PARTICIPANT: Can you remind people what SACHRP is?

Vickie Mays: SACHRP is the federal government's committee on human subject protection. I forgot what all the things stand for. But they are the policymaking group for HHS on IRB issues.

PARTICIPANT: That's right. The Secretary's Advisory Committee on Human Research Protections.

Vickie Mays: Somebody, I saw them look across at PRIMR. PRIMR is the Public Responsibility in Medicine and Research, and they are a nonprofit that's charged -- and I should say, I'm on the board -- that's charged with helping the IRBs to know best practices and they provide education and training.

Elizabeth Mosley: That could be very useful.

Michael Hodgkins: I was also going to say that although here are potentially technical solutions that we haven't explored yet, but to me it's sort of like what I said about trying to fix in the EHR, this isn't something that you should be looking to solve through technical means. Adding more technical solutions creates more overhead, consumes resources, which diminishes the volume of research that can be conducted. So it just seems -- it just begs for policy related decisions that can be enforced at the national level.

Melissa Goldstein: Just one quick question. Elizabeth, have you heard of anyone -- there are different regulations that apply to certain populations within the common rule. One of those populations is pregnant women. Have you heard of anyone talking about particular regulations with regard to -- and the goal of the pregnant women is a separate population that IRB members need to think about with particular specificity when we -- and I'm on the IRB -- approve research?

So the way this used to be handled before we approved research online was that we had a different color sheet that we had to fill out the checkboxes, and perhaps the pregnant women sheet was pink. I don't remember exactly. There was a pink sheet and a yellow sheet and a blue sheet. Have you heard of anyone specifying particular regulations indicated to protect people, vulnerable groups, such as reproductive health, gender care, things like that, in research? Doulas, providers who provide gender care, things like that? And a different color sheet, for instance.

Elizabeth Mosley: It is a really good question. In our abortion-related research, we're constantly interacting with pregnant people, so when we're filling out human subjects protections for IRB review, we do have to do those modules, about how are guaranteeing the safety and protection of pregnant people in your study. Luckily, for me at least, I'm not doing clinical trials. I'm mostly doing survey research, sometimes a randomized control trial with things like decision aids to help people make decisions about contraception.

But it's usually minimal risk research that doesn't actually affect the physical body of the person who's pregnant, so I actually haven't gotten into a lot of deep discussion with the IRB about that protected group, and is there a way potentially to offer additional protections to people in survey research who

are pregnant and giving us some of these sensitive data. That's I think an interesting angle, and one that I can definitely think through.

We have a series of meetings coming up with our own institutional IRBs and are trying to get some conversations going nationally so that IRBs can also talk to one another a bit and figure out some of these best practices. And maybe that is one avenue that we could go through.

I'll say the other place that I run into this is with minors. I do research with adolescents, and including qualitative interviews about their pregnancies, and that is an area where, speaking of reproductive justice, young folks are absolutely disproportionately affected by abortion bans and equity and benevolence and all would tell us we need to do research with these adolescents right now to understand how they can access care safely that they need to terminate pregnancies when they want to terminate them.

And right now, because IRBs are particularly concerned around the abortion issue, and you add minors to that, as you can imagine the regulatory concerns are exponential. Our IRB has asked so many questions we actually have halted our adolescent recruitment, which deeply pains me, because I know that not including adolescents in research does more harm than us doing surveys. It's hard to move forward, again, without some of this clear guidance and best practices.

Something that would help our local IRBs feel like, okay, this is the best that people can do, and it is important to still continue moving forward with research, including with vulnerable populations like pregnant people and adolescents, but I would say, if anything, Melissa, I'm seeing people throwing up more red flags when we're dealing with those vulnerable groups, rather than thinking about what additional protections could we maybe offer, because we need to have a special eye for these groups.

Melissa Goldstein: Thank you.

Wu Xu: My question is not related to the panelists. It's for Sharon. I really like Vickie's question, suggest associations to conduct survey with (inaudible). I wonder if it's possible HHS or CDC have a national on survey on this issue? Just a question.

Rebecca Hines: So, the National Survey of Family Growth, NSFG, at the National Center for Health Statistics, gets at some of it. But I don't think it gets at all of it. And I'm not sure what the impact of Dobbs is on that survey and people's willingness to participate, because it is a nationally representative survey -- there may be people who are no longer willing to answer questions, and I'm not current on the status of that, but if you are interested, we could certainly have them, if we have questions or would like a presentation, we can arrange that.

Maya Bernstein: I wanted to ask Ms. Satterfield and Ms. Edwards, I've been thinking, we've been talking a lot about the effect on care and on patients and so forth, but I wonder what you're hearing from your constituency about the pipeline of professionals. I know that in areas that are underserved, the places that you described, where you come from, Ms. Edwards, people have already historically had a difficult time getting access to care, but if this Supreme Court's decision is likely going to affect who wants go into research. Who wants to be an OB/GYN. Where they're going to practice.

Are you hearing from your constituencies, or what are you hearing about that pipeline, about medical students, about the Black girls who are going to turn into the Black OB/GYNs, and are going to serve that community, who are the place where we're going to be able to create trust, are you hearing from your

membership about that? Are we seeing changes in that? I know that we're seeing some changes to that, but tell me what you're hearing from your constituency.

Monica Edwards: I think it's been mixed. I think there's been a lot of people, specifically in the places where a lot of our organizations are in the south and Midwest, where there's an energy from younger people, from people who were already in medical school, people who are switching practices and potential areas of focus because of the Dobbs decision, and I think there is an energy around wanting to add to the healthcare field, whether or not to be fighters, researchers, et cetera. Specifically, like we all know less than 2 percent of providers are Black women, so I do think there is energy around that.

However, I think there is also that fear as well as we know, Black women, Latinx women, people of color, are more likely to be criminalized, and so we already have seen specifically in places like Texas where you have felony laws, places like Alabama where, like I said, the AG has already made comments about not only using laws to prosecute people seeking abortion, but also abortion funds, practical support organizations, providers, people helping them seek care. So I think there is a balance of energy, but also that fear of I don't know if I can go into a specialty, for example, to provide the care that I would want to provide to my constituencies in my community. So I do think it's a mix of both.

Lisa Satterfield: I was just looking up, there was an article in the Times recently that said that OB/GYN residents are not going into states that have restrictions. So there's that. I do know anecdotally that we have a couple states, actually I want to say Idaho, but I don't want to promise it's Idaho, but we do have some folks that are losing physicians because of the policies, and that some of those restrictive states are, like people are moving. They're leaving.

We haven't collected any data on that. I think we'll have to continue to monitor this and continue to collect data on it. But we know anecdotally there are decisions being made by residents and by fellows.

Maya Bernstein: Are there federal sources of data about that, or are there something that the department can think about or do or recommend?

Lisa Satterfield: I am sure this residency data -- it might be federal. When people are matched into registry. So I don't know that we have any other sources of federal data, because it's a lot of state-by-state data, that's where we get our data is the number of licensed OB/GYNs in the state. Besides our membership.

Maya Bernstein: Which doesn't cover everything. I mean, you have a particular membership, but I'm thinking other primary care or emergency physicians or other people who are going to treat people who are pregnant or might become pregnant. There's a whole sort of panoply care there that's not just maybe ACOG members. I don't know how much you can see into that, or whether you can see more into that.

Monica Edwards: I'm also on the board of (inaudible), as well as this Alabama Women's clinic. (Inaudible) in the state of Alabama, and West Alabama Women's Clinic used to provide abortion care; of course since the Dobbs decision the trigger ban that went into effect in Alabama were forced to not provide their care. But they're also not necessarily moving providers per se, but because of the changing landscape, having to lay healthcare support staff off, having to go through this maze of what falls under my First Amendment right, what type of information can I provide to the people that come into my door, not for abortion care, obviously, because it's illegal, but also because, oh, I need to go and get my annual pap smear, and if I get a question from someone about accessing abortion care, what is going to be a violation under Alabama law?

So I just think it's not necessarily a situation where we're per se losing people -- this is specifically Alabama -- but I will say we have gone through this maze where people are losing jobs and having find other ways to engage in the reproductive health space. Not necessarily to provide (inaudible) care.

Lisa Satterfield: I will say, too, I just know people who are physicians who are from the south, they want to stay in their communities that they grew up in, they want to serve their communities, and they're struggling. I do know a couple of folks, I personally know, have retired early. That's another option.

PARTICIPANT: Follow up to a little different area, but are you seeing fears around even birth control options, and that documentation as well? Or could you talk a little bit about that?

Lisa Satterfield: Sure. The short answer is yes, because of so much of the misinformation and disinformation out there on certain types of birth control, that are classified inappropriately by policymakers in states, that there are -- (inaudible) are misunderstood by many, and even having a conversation about that is -- put some people at unease (inaudible).

Monica Edwards: I do think there are people (inaudible) like you said, I think there's a lot of (inaudible). And I think a lot of that, unfortunately, is intentional by the people in power in states where abortion (inaudible), and I think a lot of people are looking to, specifically talking about the Dobbs decision, the Dobbs case, and a lot of the concurrences, speaking of Justice Thomas, like a lot of the threats that were made with the actual Dobbs decision, the text of that decision I think has provided some fear for a lot of people about it's not just abortion that's going to be taken away, but the right to marry who you want to, access to birth control, et cetera. So I think that it's also kind of aided some fear about what people can access.

Michael Hodgkins: I'm really stuck on this, but having earlier said that it's a losing game to come up with more sophisticated methods of encryption. (Inaudible.) I'm by no means an expert in this area, but speaking of Elizabeth's situation in particular, you might want to go to your computer science department and start to have a conversation around synthetic cohorts and virtual trends. It's an emerging area in computer science that's starting to creep into clinical research. It's not a complete answer to the problems you're encountering, but the nice part about it is that there's no way to undo it, because you're generating patients from the computer, using real-world data, but there's nobody there.

Elizabeth Mosley: Thank you so much. Could you say the name of that technology one more time?

Michael Hodgkins: There's two related things. Synthetic cohorts is one of the things I mentioned, and the other one is virtual trends. They're both derived from real-world data, but the computer is really generating who the participants in the study are after that, so there's no there there. There's no person to go after.

Elizabeth Mosley: I am going to look those up and definitely meet with our computer science department. We've been working with IT a bit, but I love some of these ideas. I know with qualitative data we've done something similar where we can jumble up the different stories so that any particular story we share is more an amalgam of the data, not an actual individual. So I'm going to look into this for quantitative data. I appreciate that suggestion.

Melissa Goldstein: Thank you. I think we have time for one more question.

Lisa Satterfield: I just have one comment I wanted to add about the workforce shortage. HRSA is starting to collect that data for OB/GYN providers. Somebody asked about a national resource.

Maya Bernstein: Just one more. We are fortunate to be joined in the room today by Dr. Alison Cernich, who's the deputy director of NICHD, and she may have a question or a comment, and I thought I'd call on her since the committee had no further comments.

DR. CERNICH: Thank you, Maya, and thank you all for the discussion and Melissa, thank you for your presentation. I think just two clarifying comments, and you raised, federal funding is the issue. I think many of you who may have received federal funding know that even though you have federal funding, it doesn't overcome state or local law. Once it goes to the state level, we no longer have the direction to say disregard that because you have federal funds. So that is the struggle that researchers are having on the ground. So that's number one, just to clarify for those of you who haven't seen those notices of award.

I think the second thing that was raised, and I just want to caution you all, and it's been a longstanding policy discussion, and I know ACOG has been very involved in this, and this is the question of vulnerable populations. We've worked really hard to have pregnant persons not classified as vulnerable populations.

So there's two sides of that coin. If you are a vulnerable population, there are additional consent conditions, and I'm going to say this, having been pregnant. When I was pregnant I didn't lose my decision-making capacity, and I was not in a power differential situation where I could no longer make a decision for myself. This has implications for therapeutics development, it has implications for research with pregnant people, it has implications for people participating in clinical trials, and as you saw in the pandemic, when we didn't have information about vaccines for pregnant persons, one of the concerns that was raised was around vulnerable populations.

So as you think about your workplan, I will just say from the perspective of those of us who are trying to ensure that people are allowed to participate in clinical trials when they are pregnant, that you need to weigh both sides of that particular coin. Because we've worked a very long time, if you're interested we're also going to be looking at the implementation plan for the taskforce on pregnant and lactating people. There are a number of recommendations, we've been working with FDA on this with respect to clinical trials. This has been a long time. So as you think about that, just make sure that you take into consideration both the potential protective effects and then the risks for other types of research. So just as a cautionary policy note.

You're welcome. Thank you for hearing those two small concerns.

Melissa Goldstein: Thank you. That is great. Do we have time for a break now? I wanted to thank our panelists again. Thank you so much. So critical, this discussion, and we really have benefited from your expertise. Thank you.

Maya Bernstein: Can I just add, if our panelists have anything they want to add, either a summary or slides, or anything that you may want to add for the committee on the record, if you get it to us in the next two weeks-ish, we'll be happy to add whatever further information you want, so that it's available to everybody.

(Break)

Subcommittee on Privacy, Confidentiality, and Security: Briefing on Reproductive Health Information - Panel 2

Rebecca Hines: Thank you, Deven and Richard. We are getting started, if you would be able to video yourself, we will spotlight you here in the room. And at the table you have your colleague, Jake Laperruque, hello, Jake.

I think we're ready to go.

Valerie Watzlaf: Thank you for being here, we appreciate it. I am Val Watzlaf. I am the other co-chair of the Privacy, Confidentiality, and Security Subcommittee, along with Melissa Goldstein. We very much appreciate you being here.

This second panel is on reproductive information and technology policy. We have Jake Laperruque, who is the JD and deputy director for the Security and Surveillance Project at the Center for Democracy and Technology. And we also have Richard Salgado. He is JD and former director of law enforcement and information security with Google. He's also a lecturer at Stanford University Law School. And we also have Deven McGaw, who is JD, MPH, and lead data stewardship and data sharing.

So I think we'll start off with Jake. We'll just go in that order, and some people might have questions for you in between, but we'll try to get through all the speakers and ask the questions later. But if you do have questions, feel free to ask.

Jake Laperruque: Hi, everyone. Thank you so much for having me. I appreciate being able to attend this important event. I'll give a brief intro of the Center for Democracy and Technology, (inaudible) space and then talk a little bit about (inaudible) some important areas for HHS and the government to potentially engage on the issue of reproductive health privacy, especially in the context of (inaudible).

So the Center for Democracy and Technology is a nonprofit (inaudible) created in the 90s (inaudible) was really just coming into its own. Our mission is to ensure that in the face of rapid technological development and use of the (inaudible) both promoting new technology, but also making sure that new technology supports democratic principles and individuals' civil rights and civil liberties. So that goes from commercial data privacy to free speech to competition issues and net neutrality to my area, which is our security and surveillance project, which deals with the interaction of new technologies and --

Maya Bernstein: Can you speak up? I literally got an email that says please ask you to bellow.

(Laughter.)

The room has been having issues all day. So it's not your fault. Thank you for trying.

Rebecca Hines: If you move over to your right, there's a mic over there. Or to the left.

Melissa Goldstein: Rebecca and Val, we can hear Rebecca, Val, and Jacki best. So that may be the best area in the room. I don't know.

Jake Laperruque: So, as I was saying, we work in kind of a variety of fields in the technology policy space. My focus is on security and surveillance, which deals with just how are new technologies going to be harnessed by the government and how can we protect individuals' rights and liberties, especially the Fourth Amendment and the right to privacy, in the wake of technological innovation.

Now, after the Dobbs decision last year, or organization knew that the ramifications of this on tech policy were going to be seismic and long-lasting. In the realm of surveillance, a huge variety of states now are going to have a basis to monitor a highly sensitive topic, our health and medical activities and

choices. And obviously, that is most focused on reproductive health choices, which is in itself highly important, but we worry that also broadly a justification to look into reproductive health decisions is going to put a microscope and a larger surveillance on a whole variety of medical choices and activities.

So we began to work a number of areas on this. Again, our fields of surveillance, consumer privacy, speech, created a taskforce to help coordinate with companies that were facing new types of legal demands, as well as reproductive health advocates and experts. We have also been working since the creation of the taskforce on discussion of data privacy concerns and reproductive health privacy concerns with lawmakers, both at the state level and Congress, the administration and with providers.

Last month we submitted a comment on the updated privacy rule to HHS, and I'll discuss now a few areas where we believe recommendations that we want greater protection for health data and privacy and ways to do that.

First area of action we looked into is how to limit law enforcement access to health data, and we believe that there are two key components to this. First, we believe a warrant rule should be required to access health information generally with very narrow tailoring required for requests (inaudible). Recently, members of Congress which was led by a group of 17 senators and over two dozen members of the House of Representatives sent a letter to the administration making a similar request. I think that letter really hits the nail on the head when they said that Americans expect their health information to be at least as private as their email and text messages, their phone calls, and their location data.

Currently all that information that I just listed requires a warrant for the government to collect. Health information is not at that standard (inaudible).

Also one item to note in this respect is that we think that there should be a broad rule applying to private health information generally, there probably should be exceptions for non-sensitive high level information such as basic subscriber information. But the contents of (inaudible) information by and large really should be subject to a warrant requirement for any law enforcement access.

Second, we believe that law enforcement access to private health information should face limits from HHS that it may only be used for the specific investigation and purpose for which it is requested for and should not be used for purposes beyond that or shared and disseminated for any purposes outside of that.

This would stop health records from being repurposed in ways that are not foreseen when the information is turned over and which hopefully there will be scrutiny of as information is turned over. It would also remove incentive for broader collection and stockpiling of private health records that we may continue to see more and more, given the criminalization of reproductive healthcare and other choices and medical decisions.

Enforcement for this we believe, the second point, should be a certification rule backed by penalty of perjury, essentially forcing any law enforcement entity receiving health information to make an agreement in a certification that they will not use it beyond the investigation and the specific methods that they've described in the warrant.

We also believe it's very important that the burden on enforcing that rule not fall on providers themselves who do not either have the resources or are not simply structured (inaudible) to enforce those rules and to investigate what law enforcement is doing. We believe that that's something that the government should strive to enforce and also that ideally the certification could be designed in a

manner that would in itself provide teeth, such as I mentioned a penalty of perjury. Ideally, (inaudible) certification would trigger an exclusionary rule under the fruit of the poisonous tree doctrine whereby using that information in that manner would be a criminal act and therefore it would be subject to exclusion in court.

Additionally, providing (inaudible) models (inaudible) comply with this idea of having again a certification with teeth we believe would be highly helpful to providers that are going to face demands for data from law enforcement in the future.

These measures are important for reproductive health privacy but also in general for ensuring medical care. We don't want to disincentivize people from seeking medical care because they're worried about how their data might be used in the future, again, not just for a specific procedure or activity that they're focused on at the time, but how that might lead to sort of a puzzle piece in the greater expanse of what someone's medical activities, practices, and choices are.

Another important area that we've looked into is revising definitions to protect (inaudible) health activities more broadly. It can be highly difficult to find the bounds of reproductive health information and what indicates reproductive health activities. This was something that we encountered to a significant degree after the Dobbs decision, when a lot of lawmakers and just general experts and folks in the news began focusing on things like period tracker apps that, on the one hand obviously, can be a strong indicator of reproductive health activities. We wanted to make sure that while focus on those items was good, that it wasn't done at the exclusion of other types of data, because obviously a huge array of data can, given just modern technological developments, indicate a variety of choices, including medical choices and activities.

So we want to make sure it's very important that private health information and health activities is defined broadly so that any type of information that can be used to define and basically parse out individuals' public health activities is covered.

For this we believe that reproductive health information should be defined in a broad manner that captures all data could be used to (inaudible) health activities. We also believe that protection should be defined to include gender-affirming care. The reason for this is because both these health services are facing similar threats and criminalization in a variety of states, and these types of care often come from these same type of facilities and clinics. Wherever possible, we believe that expansion of protection to all protected health information should be done instead of just providing protection to reproductive health information. But regardless of that, that reproductive health information should be defined in a broad manner to sweep in not just data that is in itself explicitly indicative of reproductive health choices, but any other types of data that could be used in combination or through deduction with a greater pool of data to show reproductive health activities and choices.

Finally, we believe it's important to place new safeguards on ensuring electronic health records, there are three different areas I will talk about as far as how to (inaudible) greater protections in this space. This is an area where I'm also (inaudible) from our discussions with providers, there seem to be various (inaudible) concerns and active (inaudible) of information in electronic medical records being shared in a manner that has endangered patients and providers.

First, we believe that by default, electronic medical records and health information records, that no sensitive health information should cross state lines and be shared with entities that are not covered by HIPAA. This is a means of protecting broader sharing of information that (inaudible).

Second, we'd like to require details (inaudible) being requested with an option for the sharing entity to block or refuse to do so if it's against the patient's interests or needs and with a limit on sharing information to be only used by and disseminated for the purpose listed when information is requested.

So again if, much like with law enforcement, information is being requested by another provider, another entity, nonstate actor, it should come with a specification of what is the purpose of this and a certification that it will only be used for that purpose. It will not be used or further disseminated beyond that purpose. And again, for that to be effective, I think there needs to be an attestation and one with strong teeth such as a penalty of perjury to ensure truthful compliance.

Finally, we believe that requiring health information exchanges, like Epic, to give patients the ability to opt out of sharing their information, could be an effective means of preventing oversharing and potentially endangering patients through sharing of electronic medical records and other private health information from going to hands that then ends up in law enforcement.

Some concerns here that we've heard from the initial discussion of this idea is how will patients know when to opt out, how can we make sure that's effective if they have the wherewithal to do that, how exactly (inaudible) structures, whether it would be select information, procedures, on what basis? I think these are very good questions and we don't have the answers to all of them. But they are some we're eager to work with a broad set of stakeholders on further defining answers.

So those are the main areas in terms of sharing of medical records that we have been focused on.

One final thought, I don't know, I want to flag as this is something Rick might talk about, is that a variety of states have enacted what we're calling shield laws. Information that in a variety of ways stops entities, sometimes private companies, sometimes medical providers and data repositories, sometimes state actors like law enforcement or judges, from complying with or supporting data demands or subpoenas, requests for law enforcement cooperation, for anything related to criminalization of reproductive health services.

One potential benefit of these shield laws is that they could allow sources of medical, electronic medical records, to effectively find a safe haven data hub if they store all their records in one of these states with a shield law, because states that have said that judges cannot domesticate a subpoena or warrant or other demand effectively are putting those entities within their state out of the reach of (inaudible) law enforcement.

If a Texas law enforcement agency sends a warrant for data to an electronic medical records provider that's based solely in California, California judges are prohibited from domesticating and basically allowing that warrant to be served in California. And the entity that is trying to be served upon will never get it.

So I think it's important, although we don't have specific policies that we have to consider how would we encourage entities that maintain electronic medical records and incentivize them to move to these safe haven states where shield laws are in effect where their records might be safe from demands for data meant to criminalize reproductive health or also, as I said, gender-affirming care activities, medical procedures, et cetera.

So that's the main areas I want to talk about, but I'm very happy to take questions and look forward to the discussion.

R. Lenel James: Thank you. So one of the things I'm involved with is health equity and national level association and also the standards bodies of (inaudible), one of the things that we discuss a lot is about restricting through HIPAA. Because of health equity, a lot of (inaudible) based organizations are part of active pilots for which the (inaudible) even in the records information and the information that payers and providers have to provide care. So I'm just reminding you that's a broad sword you're using for HIPAA, and in the reality in health equity, there's a whole bunch of non-HIPAA entities that are now critical in the community, whether it's underserved individuals, Native Americans, it's a challenge that is actually already happened; several payers' lawyers have said, I'm sorry, you can't do health equity because you can't communicate to a HIPAA-covered entity. Realize you've just impacted some of care related to underserved individuals for health equity with that broad approach.

So I'm not saying there's a solution. I'm just saying that's one of the operational impacts being experienced in the field trying to deal with healthcare disparities.

Jake Laperruque: I think that's a great point and that reflects that some of these sort of items that are discussed might work effectively in combination. (Inaudible) examples were (inaudible). You know, maybe there's a space for that. I worry about a (inaudible), but if we have (inaudible) well, only sharing types of information, having certain rules of sharing has to be based on it providing benefits to the patient and it could only be used for select purposes that those entities might need it can shared out or repurposed beyond that. That seems like a way maybe you could potentially have exceptions to kind of that broad rule for the concerns you're expressing, while still accomplishing goals of trying to make sure that you don't sort of have a general sharing regime that can end up having to data go to places where it's not in patients' best interests.

Valerie Watzlaf: Any other questions at all? Could I follow up just to ask you another question about the shield laws. Do you feel that those are effective? Are they very inconsistent across states and if you can just give us a little more information on that.

Jake Laperruque: So there's a huge variety of shield laws that exist right now. I kind of went through the list of some apply to electronic communication providers, state police and government officials, judges, and state medical laws, because different states have all kinds of different combinations of which of those entities are linked in by (inaudible).

And also, yeah, I think based on the attacks, it seems like some of the states are going to be more effective than others in actually guarding off demands. We're actually working right now (inaudible) to a sort of full rundown of all the different state shield laws and what is included in those, and so yeah, I think number one, it's very early to say how effective they will be in practice, and we'll certainly expecting that they will face litigation challenges. But yeah, I do think it is kind of a bit of a hodgepodge system where the extent of the protections and the effectiveness of protections varies by state to state.

Valerie Watzlaf: Do you know how many so far are out there? Is there a number of them?

Jake Laperruque: I believe there is over a dozen that limit some entity, and the most common entity, it's an executive action or law saying that state government employees or state police or other entities like that can't share or can't assist with the investigation into reproductive healthcare. So a doctor in Massachusetts, Idaho, says that they violated a cross-state border abortion ban, they're asking for (inaudible) doctor in Massachusetts. Massachusetts police not allowed to comply with the order.

More requests come in, (inaudible) three states is a shield law saying if a company like Google receives a warrant saying hand over this person's email, we're investigating this unlawful abortion, California law,

because their shield law now says, Google, you're not allowed to comply with this. So that I think it (inaudible) much more broadly, and that type of shield law is much narrower. There are only three states, California, Washington, and New York, that have enacted some sort of variation of blocking that type of activity via communications providers.

Valerie Watzlaf: Thank you. Any other questions, anybody online, any of the -- I don't know if Deven or Richard, do you have a response?

We'll just move on. You can speak next if you would like to, Richard.

Rebecca Hines: We're not able to hear you, Richard. Give us a second.

We can skip to Deven.

Deven McGaw: Thank you all very much for the opportunity to speak with you today. It's been quite a bit of time since I have stood before NCVHS for its privacy security committee so it's really nice to be here. I am the lead for stewardship and data sharing, not over everything in the world, I'm realizing my title truncated, but the name of the company I work for, which is Invitae.

Invitae is a clinical genetic testing company that produces genetic testing when the tests are ordered by medical professionals. We do not do any direct-to-consumer testing. We produce genetic tests when ordered by a medical professional, and we produce a broad range of them consistent with the American Council of Medical Geneticists' approved list of tests.

I came to Invitae when it acquired a company that I helped to co-found called Citizen, which is on the patient-facing side. It helps patients to gather all of their health information from all of the places that they've been seen so that they are then empowered to use that information and to share it with other providers or even to contribute it to research. Before I founded Citizen, I was the lead for -- the deputy director for health information privacy at the HHS Office for Civil Rights and the acting chief privacy officer at ONC.

So I've had lots of opportunity to think about HIPAA in various iterations. I also did a few stints in private law practice counseling clients in how to comply with HIPAA, and formerly worked with Jake at CDT for some small period of overlap. So lots of ways of touching this issue.

I was extraordinarily impressed by NCVHS's comments to OCR's proposed HIPAA regulations. We obviously have quite the conundrum with the Dobbs. It's not the first time that information has been used against a patient or a medical provider, but certainly the Dobbs decision and then some of the political shifts around gender-affirming care are certainly creating enormous challenges and may be shining a much greater spotlight on HIPAA's, I don't like to call them loopholes, but HIPAA's permitted sharing.

Again, HIPAA has always established a pretty comprehensive set of rules, but they were designed to allow for traditional workflows that a healthcare organization, like a medical doctor or a hospital or a health plan, have to deal with on a daily basis. So you've got all of these expressed permissions around to whom you can share data and for what purpose, based on, again, those traditional workflows, and the privacy layer is, well, if it's not expressly permitted, then it's subject to the consent of the individual or there are some conditions on some of those purposes for which data can be shared.

They all sort of make sense when you initially think about it. Well, maybe let's put the law enforcement one to the side for a second, but sharing for public health, sharing to report child abuse and neglect, sharing for healthcare oversight, all of those seemed to make a lot of sense, probably, at the time, but in the light of where we are today, look extraordinarily weak because they're being essentially manipulated or have the potential to be taken advantage of in order for information to then be utilized in either a civil administrative or criminal proceeding against a pregnant person or a once pregnant person and/or that person's medical provider.

So this is obviously a pretty serious situation. I am in agreement with NCVHS's letter about why do we have these law enforcement exceptions anyway? That was one of the first things that came to my mind when I was drafting our comments to the proposed HIPAA rules, and I thought, why? Why do we do that anyway?

And then I was reminded, actually fairly recently in a conversation with Donna Shalala that regulations are subject to some pretty intense negotiations, not just in terms of the comments that are filed, but in terms of everything has got to get past the Justice Department. Everything's got to get past a number of agencies who see their own interests in these rules. So consequently, lots and lots of compromises were struck, but not necessarily struck in a way that's as helpful today as might have been sustainable.

Again, HIPAA's got some conditions, like if I think about the healthcare oversight exception, for example, you can get protected health information, identifiable data, in order to investigate an institution or an organization to see if they are compliant with rules. There was a recent article in The Tennessean about Vanderbilt University having to release a bunch of data around gender-affirming care, purportedly because they were looking to see whether that care was appropriately billed for.

The health oversight exception does not allow for that data to necessarily be released for the purpose of weaponizing it against the patient. It's potentially to weaponize it against the institution if they were wrongly billing, but once that data falls outside of HIPAA and goes into the hands of a state institution that itself isn't covered by HIPAA, what they subsequently do with it, there are no controls that exist in HIPAA to prevent that.

So we've got these permissive sharing provisions that are on their face looked pretty benign about five years ago that don't look so benign today because of the mischief that can happen even when information is originally pursued for a valid, lawful purpose. It can be turned around and then be utilized against someone, is I think what the Dobbs rule is attempting to get at and -- largely supportive, completely agree with NCVHS's comment, which I know this group spearheaded, were pretty spot on, I think, in terms of strengthening that.

I want to say a couple more things. I have a personal interest in this issue, but also, Invitae, one of the types of tests that it performs are tests that are called noninvasive prenatal screening tests. These are blood tests performed on pregnant persons and pregnant persons only in order to provide an early indication of certain of types of potential fetal abnormalities, and the blood tests are then, if they are uncertain or show up with a positive result, are designed to then be followed up with more extensive prenatal testing such as amniocentesis or chorionic villi sampling in order to get fetal tissue or blood in order to determine with a little bit more particularity.

But ever since the Dobbs decision, we have been incredibly nervous about the data that we hold on pregnant persons who have received NIPS testing and received either uncertain or negative results in terms of utilization in further investigations of what happened in that pregnancy. What happened in the case of what was the behavior of the treating providers subsequently for that pregnant person who was

tested and found poor results since there are so few of these laws that provide an exception for fetal health and disability.

The other thing that I am seeing is I'm pretty heavily involved in lots of conversations around facilitating the adoption of widespread information sharing consistent with the information blocking rules and the trusted exchange framework and common agreement and trying to get more data moving. The privacy issues are pretty serious, but so are issues of non-sharing of health information. When health information doesn't go to the right place when it needs to to treat a patient, that can have very devastating consequences.

So we have to strike a very careful balance here that some of what we propose as a solution to this doesn't end up requiring patients to trade off their right to get the best possible care, to have the data flow to the places where it needs to, while making sure that that data then can't be used against them or their medical provider for a healthcare service that they might have received in the past.

When you think about what's happening with this network creation, we literally are trying to connect all the states, all the places, all the counties, so that information can be more liberally, for lack of a better word, shared across state lines. Now, only for purposes for which it can flow lawfully. We're not suggesting that the laws go out the window. If it's lawful to share it, you need to share it, because we have a history, actually, of data not being shared, largely for anti-competitive reasons, and sometimes because the technology doesn't talk to one another.

So I have another concern that some of the solutions that we craft to addressing this problem are aimed at bottling up the data a bit more and making it harder to share or having patients make choices that they don't share the data with anybody, because I'm afraid downstream what will happen as opposed to a more overarching approach frankly like the one OCR has proposed that gets right at the root of the problem. Let's not let this data be used to hurt people, just merely for delivering the service that was lawful at the place where it was delivered.

The last thing that I'll add since this is a technology panel is, notwithstanding that I applaud NCVHS, actually, for not going down the consent route as a way to address this problem; I think consent doesn't stand up very well against the long arm of the law or state requirements to disclose. Having said that, we have long talked about allowing people to have some more granular choice about how their data is shared and to allow for a bit more data segmentation, and yet those efforts to develop and have technologies that can segment data, that can just share discrete data elements versus entire documents, have been very slow and there are probably a lot of reasons why this is the case.

Some of it is the technology, but after years and years of watching this, I can't help but think that so much of it more is culture. Understandably, clinicians don't like it if they don't have all of the information about a patient, and part of the point of these interoperability activities that are going on at the federal level and in some states is to take that off the table. You no longer are not going to have the data that you need to treat a patient. So the idea that we're now coming up and saying, well, actually, we want to give patients choices to keep you from seeing data is not something that sits very well with the primary users of the technology that we are building.

So there is a big cultural barrier, as well as some patient education around what the consequences are when you decide if you have the right not to share or you're given an opportunity not to share and you decide not to, what are some of the consequences of that? Again, I appreciate the opportunity to speak to you and I am happy to address any questions.

Valerie Watzlaf: Thank you. Any questions from the committee?

Rebecca Hines: Richard, let's try your sound again.

Richard Salgado: Thank you for having me here. I'm sorry I wasn't able to be there in person. My name is Richard Salgado. As you heard, I have a history of working with some of the bigger communication service providers on lawful access to their data which is another way of saying the different types of legal process that these big companies get to compel them to disclose information about their users that is otherwise not public.

So I've done that for a couple decades now and I am now primarily teaching at Stanford. I'll be at Harvard in the fall. I do a bit of consulting on the side and work with great talent out there like Jake and his colleagues at CDT and some other organizations.

I thought what might be useful today, I don't really have an expertise in healthcare, that's certainly not been where I have had much of a professional focus, but it certainly has had an intersection with the rules around access to user data at big companies, as you've already heard.

I thought it might be useful, and feel free to interrupt me and ask questions and ask for clarification or go into other areas that might be of more interest, but I thought it might be useful to give you an idea of the world that these communication service providers live in when it comes to government requests for information about the users.

Jake's already talked a little bit about this, but I can give you a different perspective, I think, than you might have when you're really focused on healthcare data specifically.

So I'll start at a high level. These companies that are out there, there are a number of different types of them, some of them are apps providers, some of them provide communication services. My focus has been on the larger providers, the Googles, the Yahoos, the Amazons, the Microsofts, the Metas, those kinds of companies, Reddits, all sort of these giant companies that hold so much of the world's data and provide so much of the not only communication services but data processing services, docs and calendars and photos.

Increasingly, all that stuff is of interest to governments, and governments around the world. These companies do business around the world. They've got users from every country there is and some areas that aren't even countries. This dataset sometimes becomes of interest to law enforcement. Most of the companies now will publish transparency reports about the data disclosure requests they receive so we have some idea of what the volume is of these things.

They come in from all over the world. Some of the bigger companies can get in a year over maybe 800,000 requests for user data, individual requests. Some get lower than that, but you can see a pretty high volume of these requests coming in.

These requests for user data aren't necessarily just for one user, either. So one request could have an attachment that has a whole list of users that are subject to that one piece of legal process. So in some cases, you have a company in a year that may actually be addressing demands that cover over a million of their users, even if the number of legal processes is underneath that.

Typically, the way these things work is you get a piece of legal process and it will have some identifier of the users, so a Gmail account, it would be the Gmail address of the user. If it's Facebook, it might be a

Facebook URL, that sort of thing, a phone number for WhatsApp. There will be different kinds of identifiers that come into the company.

The companies will have to deal with all of those requests. Those are high numbers for an operational task that is somewhat bespoke, which is the case with law enforcement requests. It's a drop in the bucket when you consider how many users these companies have. It's a really small percentage of users.

But it is a heavy task for companies and it's something of a high risk task when you think about it. It's like, the high volume of these requests coming in, I'm calling them requests but they're legal demands and often times there is some statutory or other support behind them being compulsory pieces of legal process. They're coming in at high volume and they're seeking some sensitive data about the users. So the companies are in a position of you've got to honor these things or at least you have to respond to them. They're compulsory.

But at the same time, if you over-disclose, you're doing no favors for your users and that's also a terrible position to be in. So there is a narrow area there where companies operate when it comes to these things. They're at such a high volume, you've got to deal with them in a timely manner.

So it becomes a pretty tricky area of compliance for these companies. Most of the bigger companies, and quite an increasing number of medium-sized and smaller companies, have dedicated teams to deal with these requests as they come in.

And they need to have that. They need to have a whole operational and legal policy organization to deal with this burdensome but important workflow that comes in. You can think about the variety of things. If you take a step back, they're coming from all over the world, so these are going to be legal requests that are based on different legal systems. They might be in different languages. They'll be based on different criminal statutes and different cultural issues in different countries, and of course they will be asking for different types of data.

So there's really no way companies can deal with this in a totally scaled way where you just set up a system and the requests come in and the data comes out or rejections come out. It is a fairly manual process. That might be good in some ways, because it means that every piece of legal process these companies get, they're looking at.

And it means that there is some opportunity there to really scrutinize it and see if it's valid, make sure it's in the proper scope, that it's based on the right law, that it's asking for the type of data that can actually be disclosed, and the companies will do that.

But one thing that is very difficult is that even though there is a wide variety of these pieces of legal process that comes in, most of the time the legal process is very bland in describing what is the investigation, what are the facts and circumstances behind the demand, what is the criminal charge that's being investigated?

If you look at a subpoena from a sheriff's department in Kentucky and you compare it to the police in Taos, New Mexico, the subpoenas are going to look a little bit different. They're going to ask for the same kind of information, but neither one of them is going to tell you very much about the case under investigation. And the providers don't really have an option to withhold compliance with that legal process pending the police explaining to the companies what the investigation is about.

Really, probably the companies shouldn't be in that role anyway. There are some actual privacy issues with the police telling everybody they're seeking evidence from the facts and circumstances behind the investigation which could very well lead to nothing. So there are some good reasons why the legal process is fairly bland when it comes to describing the facts and circumstances and the crime under investigation.

The companies also are not going to be conducting their own investigation into the account to try to speculate as to what the demand is about. So if Meta gets a demand for an Instagram user, and they can't tell what the legal process what the case is about, they're not going to start looking through Instagram or their other data about the user to try to figure out what could this investigation be about. Even if they thought they knew, they'd be speculating anyway.

Plus, and this may even be the bigger point, they would be intrusive steps that would violate the user's privacy anyway. So there is really no desire to be doing that in any event.

So all of that by way of saying that these companies are dealing with this stuff coming in pretty fast and furious. They've got to deal with the language and the legal differences between it. They don't have a lot of insight into what the investigation is about.

They do have some room to push back when it looks like it's outside the scope of the legal process or it's too broad, it's too vague, there are lots of ways you could object to the legal process that are sort of on the face of the legal process issues, but it is typically pretty difficult for a company to know that it's an investigation that's invalid or has some other deficiency because of the nature of the investigation and that that would deserve a pushback.

One thing that has changed a little bit in the last few years has been a change in the behavior of the companies around how they take legal process from law enforcement. A lot of the big companies have now built interfaces where law enforcement can create an account, like you could be a police officer with the right to issue subpoenas, you could create an account with one of these providers through their law enforcement interface, verify that you're a police officer, and then use that account to submit your subpoenas whenever you've got a case and you need to submit a subpoena. The interface requires that you put in your name and maybe your badge number and it may ask you some other questions and some of the questions might include a bit of inquiry as to what the case is about.

Is this case about reproductive rights? Is this case about fraud? You can use the interface to get a little bit more information from the officer as a condition of the officer attaching the legal process and submitting it to the company. The interfaces were really developed because fax machines are just awful and email is awful. It was one of the happiest days in my career when we got to unplug the fax machine and move over to the interface.

(Laughter.)

But it proved to be a pretty good tool to get a little bit more information about what the case is about in general.

This kind of touches on what Jake was talking about, what he was referring to as shield laws, and the three shield laws that talk about the states California, Washington, and New York basically saying companies, if you're here, you can't be honoring legal process from a jurisdiction who has reproductive rights that are different from ours, and they are investigating the violation of those laws. Companies in

our jurisdiction, you are not allowed to comply with that type of legal process. Nomenclature I would use to describe that isn't a shield law, it's a blocking statute, but it's largely the same thing.

So the companies are put in a little bit of a difficult spot there, as you can probably tell from my comments already, because they don't necessarily know what the legal process is about and they're getting a lot of legal process. But the interfaces do provide a moment for these companies to have a law enforcement official provide an attestation that the request is or is not going into a matter that would be about reproductive rights and would be illegal in the jurisdiction to which it's being submitted. So there is a moment there where companies can get that attestation and that's become the practice in response to these blocking statutes.

Not every company has an interface and they're having to come up with their own ways of how do they get an attestation, and of course the vast majority of legal processes they get have nothing to do with reproductive rights. It's going to be the narcotics cases or fraud cases or all sorts of other things, but they still need to go through this step with everything that comes in the door so they make sure that they're not violating the law of California, Washington, or New York, wherever they may be subject to.

One of the limitations of this is that that attestation is really only good for that moment in time that the request is made. There are certainly going to be situations where a law enforcement official is investigating a crime on day one and they get information and they realize on day two or day three, oh, there is a different crime being committed here.

It started off with a petty vandalism charge and it has now turned into serial murder. At the moment of asking for the data, it was a misdemeanor charge, but down the road, it becomes a capital offense. So those things do happen.

So the attestation does have a limited shelf life potentially, but at least at the moment and this is the way that the laws seem to be reading, at the moment the investigation was not about the prohibited legal violation and so the disclosure by the companies could be made.

I think that's how right now the companies are behaving around the potential violation of the blocking statutes in these three states. As Jake said, I don't think there has really been enough time, to the extent there are any of these requests coming in and they're being rejected and there's a battle brewing, I don't think there has been enough time for any of those to become ripe or mature. So we don't really have a track record of whether they are effective or not.

Frankly, even if we never see one of those, that doesn't mean they weren't effective, because there is the possibility of like, well, don't even bother to get these records because we're going to run into one of these laws and we're going to get into a big fight, we don't need them that much anyway. So it's going to be very hard to tell what the effectiveness of these laws are, I think, although we'll see. We'll see where we are in a year or so from now.

I guess the other things I'll say really quickly, most of the companies have adopted principles that they've published or they've adopted by joining NGOs that have announced these principles like the Global Network Initiative. There are several of them, but things like we won't disclose user data unless we are compelled to by law. There might be some exceptions to that. We will give you notice as a user when we're allowed to give you notice and we will try to give notice to you in advance of the disclosure so that if you've got an objection to it, you may have a privilege argument or some other objection, you'll have the opportunity to assert that objection before the disclosure is made.

If we can't give you notice before the disclosure, it'll be sometime after the disclosure. Your remedies may be somewhat limited at that point, but maybe there is something you can do to limit the use of the information or claw it back. Most of the companies have also said that they are going to push back on legal process that's overbroad that may be out of proportion to the cases that they understand, that sort of thing, and certainly push back when the legal process is invalid.

I guess the bigger picture here, though, is that these companies are just getting flooded with legal process and this is an important set of laws they need to be dealing with, the laws around the blocking statutes that we referred to. So they've had to build into this much larger operational legal policy system some way to try to catch those so that they can honor the law and let the system operate as it can, but it is in a much bigger context with an awful lot of other pressures that are going on there.

And I think really my experience has been that most of the legal process, the vast majority of the legal process, is completely valid. These are cases that ought to be investigated. You want the system to be rule-driven and proportionate and lots of good due process, but at least in the United States, we actually do see these legal authorities being used responsibly by the law enforcement. I'll stop there.

Valerie Watzlaf: Could I ask you one question I think that I was -- and maybe I'm confused on this, because you said that most companies will not know -- they may not even know what the investigation is about. But they can give notice, I believe, they could give notice, so that someone could have actually assert an objection. So would they -- they don't know what it's about. How would they know to do that or not do that?

Richard Salgado: Let's say, we were running a communication service together and we got a search warrant and the search warrant -- let's say, we were running Gmail, and the search warrant was for dobbyboy1982@gmail.com. We would read the search warrant, and we'd say, boy, we really don't what this case is about. Maybe it comes from the narcotics unit at some police agency, and like, okay, it probably has something to do with drugs. That's about all we can know.

So we can't really go beyond that. What we would want to do, however, is let the user know that this request has come in, and so we would have developed a policy that says, okay, as long as we aren't gagged, we don't have an order by the court that's prohibiting disclosure, we're going to notify our user that we have received this piece of legal process. Maybe we'll be allowed to actually attach the piece of legal process. Maybe we won't. There's a lot of nitty-gritty pain that goes into giving user notice.

But then the user is able to go, maybe go get their own counsel, maybe they already know what's going on and they aren't fussed by it, who knows. But it sort of brings the user into the fold and maybe the user has some defenses. Maybe this is a patient-physician privileged material that's being asked for, and certainly you and I as the owner of this communication service wouldn't know that and we're not going to read it to find out. But the user might be able to know.

So the user might be able to assert an objection in the court where the search warrant issued to block law enforcement from getting the information.

Valerie Watzlaf: Thank you. That helps. Any other questions from anyone? Go ahead, Melissa.

Melissa Goldstein: Hi. Thanks so much to both of you. You have given us perspectives that are much needed. Richard, my question for you is -- well, first of all, if a law enforcement individual or law enforcement agency came to in our case a healthcare provider, for instance, right? Asking for information and that person is identified as a law enforcement individual or agency, then there's going

to be some sense that that's where they need to go under HIPAA to see if it's a permitted disclosure or not, right? I just wanted to check with you on that.

Of course, there's the idea that Deven brought up that if information is disclosed outside of a covered entity, it's no longer protected, and somehow at that point, it gets into the hands of law enforcement, right? So that I'm not sure -- that we cannot address under HIPAA, I don't think, unless there was some sort of redisclosure like there is currently under part 2, but that world may be changing a little bit too.

So back to Richard's question. There was this intermediary that you described that companies had set up that would take the requests and then make, then maybe a clearinghouse. I'm not sure what it looks like technologically. But to me, this seemed to be similar to or useable by the NPRM that has been put out by the agency that requests an attestation from the law enforcement individual saying that I am not requesting this information for use against the individual, either the provider or the patient, and this intermediary step could possibly be used to lessen the burden perhaps of setting up attestations like that from law enforcement for these types of disclosures.

Because one of the things that we spoke about in our letter was that this is going to be a huge burden that providers and healthcare systems are worried about, like how are they going to figure out what to do with these attestations? How are they going to dive through them and figure it out, and essentially they're going to have to do the data segmentation for each one on their own to figure it out, but I'm wondering about the possibilities for the technology intermediary that you mentioned.

Richard Salgado: Yeah, for these providers, and really we're talking about them as providers to consumers as opposed to -- when I'm saying provider, I'm talking about communications providers, not healthcare providers.

Melissa Goldstein: Right, and I am trying to translate it into this world, right.

Richard Salgado: Exactly. So most of what I was talking about was communication service providers to really patients who are going to likely have some information about their health stored in their personal accounts, and the government can get that by coming to the provider. As I understand it, my limited knowledge of HIPAA, that's largely outside of that regime. If the communication service -- now, maybe I'm wrong about that.

Melissa Goldstein: Depends on whether -- it could be an EHR, for instance, right, that the patient can access. So it could be the provider releasing information from the EHR.

Richard Salgado: This would be purely from your Google Docs where you've uploaded your healthcare information and it's now on Google servers controlled by the patient through their Gmail account. So that's mostly what I was talking about, where the communication service provider is providing the communications platform for a healthcare provider for a hospital. Then I think we're in a different world. Then I think we've got, as I understand it, limited knowledge, my understanding is that then you've got the HIPAA requirements, they're going to flow to the communications service provider in that situation.

To your question, as I understood it, what I can describe is what the providers have set up. They have set up interfaces for law enforcement to log into and where law enforcement, each law enforcement official has their own account. So Google has an interface for every FBI agent who wants to submit a piece of legal process, they can create the account with this Google through the special interface, and they can submit those and their search warrants, and sheriffs departments and police, all that, the U.S.

authorities have the opportunity to do this through Google. Meta's got their own. Microsoft's got their own. A bunch of companies do.

As part of the flow of submitting the legal process, there's going to be some checkboxes that the officer needs to check. One of them will be an attestation that either it is or it is not a request that goes to particular types of investigations, which could include reproductive right investigations. So it's pretty simple. It's just an interface. This is how your request is going to come to us as a company, law enforcement official, and to use this very smooth simple interface, you do need to give us a little information, which includes an attestation about the nature of the investigation. So it's nothing fancy.

Melissa Goldstein: Interesting. That is helpful. One other follow-up question. As you were speaking, it struck me, I was thinking about a cellphone provider, all right? Cellphone service provider. Where there are cell tracks, you know, and the provider has the cellphone number and can give law enforcement perhaps the calls, right? The phone numbers exchanged. And perhaps there might be a pregnant person exchanging phone calls, a lot of phone calls, with Planned Parenthood, for instance. And that that could possibly be a source for law enforcement. It's somewhat farfetched, but trying to find people who may be engaging the services of Planned Parenthood in a way that may not be legal in a particular state.

And I was -- separate from HIPAA, I'm wondering if you know if any of those organizations -- I know that some of them have said, and I'm not sure which ones, that they're not going to share data for these purposes in these states, and I don't know whether you've heard about that from cellphone providers or that sort of provider.

Richard Salgado: My understanding is that they are covered by these laws. I would look to Jake for confirmation of that. I think Jake has done a deeper dive into them than I have. But I do, I actually have the same questions about that, of how they are going to do that. Now, an awful lot of these phone companies, the larger providers also have interfaces. So it could be that they've simply borrowed the same technique for the submission of legal process and had an attestation, but I'm not familiar enough with the telco practices to be sure.

Melissa Goldstein: Thank you. I'm done, Val. Thank you.

Jake Laperruque: So, I'll go to (inaudible) from the telcos to the (inaudible) general attestation. As far as I know, these laws the way they are written would cover phone companies, but none of the major telcos are in states as of now that are, that would bind them by these types of shield laws or blocking statutes. In Texas, I don't think they're passing a shield law any time soon.

So that's kind of where we stand on the telcos. As far as attestation in general, I think Richard has it right, like the point of this attestation is it should be very simple and straightforward to follow, and from the ones I've seen from companies that are now bound by these laws, it is usually a one or two sentence question, does this investigation relate to reproductive health services or choices, gender-affirming care activities, et cetera. One, two sentence question, yes or no answer. You have to click one of those boxes. If you don't, then they're not going to process your warrant of subpoena.

I think that's exactly what we want this scenario where it's very clear, simple, straightforward short question, yes or no answer, along the same line as some of the other ideas we discussed, you know, very simple, just one or two sentence, will you commit that this information will not be shared beyond the specific use case that you have outlined for (inaudible), yes/no answer, and I think there needs to be an

enforcement mechanism that -- I mean, to your point -- does not put the burden on providers to try to enforce. It's not their role, it's not something they're resourced to do.

So I think something like a penalty of perjury rule would be very effective, because if it's going to law enforcement, law enforcement lies in the attestation, if I'm a defense counsel, now I have a very good reason to say, well, this information you got, you obtained it by violating the law. That is a very good grounds to try to get that evidence thrown out in court, and hopefully that would discourage the bad actors from lying in that attestation.

Additionally, I think we want to consider other mechanisms like potentially having HHS audit attestations. I mean, not going to look through all of them, but again, if you wanted a portion of them, that's another way to deter bad actors from lying in the attestations or going against the (inaudible). But yeah, I think in general, there are ways to make sure that these attestation rules are through a set of very simple straightforward questions that are ideally yes/no answers. Ideally, that's something that an entity like HHS could provide a sort of model attestation for entities to use. I know for the companies under these shield laws, they've typically sort of gone for some very simple question, looked at each other's of like, okay, this is a good model, we can probably build off of that very similarly ourselves.

So ideally, it could have a sort of model attestation that providers wouldn't necessarily be required to use, but hey, here's a way to put this out in a very clear manner and you want it to be as simple as possible and you want the enforcement mechanisms to be through government entities playing watchdog or through aspects that are built into the rule like the penalty of perjury, so providers don't suddenly have to go around policing when it's just not the role that they were designed to do.

Michael Hodgkins: This has been very interesting. I want to thank the panelists. But you know, it occurs to me, a couple of things. It's nice to know on the one hand that these larger social media companies, you know, were implementing mechanisms where you could start to have boxes to check. But I wouldn't assume that any of them are at all sophisticated with respect to matters related to healthcare.

And so at the very least, you know, it seems like there would be a need to educate them about what might be the appropriate questions to ask through the mechanisms they're putting in place. You know, what boxes need to be checked, for instance.

Because the NPRM was really dealing primarily with the EHR. It wasn't really addressing the issue of somebody's wanting to protect their health information. It was what could be (inaudible) health information from a social media company.

The other gap for me, the thing that I worry about, is there's this proliferation of mom and pop solutions that are not covered entities. You mentioned period trackers. But there's all kinds of stuff going on that are, there's mental health applications and other things, there's all kinds of stuff that can pop up that are related to reproductive health or gender-affirming care or what-have-you, and haven't even touched those.

Maya Bernstein: I have many questions. Richard, when we talked on the phone, you and I talked a little bit about the reach of the shield laws, and I just thought, could you say a few words about how far the reach of, say, the California or the Washington law is? If I'm in Texas and the sheriff comes to, I don't know, the local Google office or what happens in that circumstance?

Richard Salgado: It is a good question. The laws themselves are not addressed to the law enforcement official. The laws are not addressed to the user. The laws are addressed to the company, and more

specifically, it's addressed to any company that is headquartered in the state or is incorporated in the state, and again, Jake is really the expert on the text of the statute, so you can correct me if I'm missing some nuance here.

But once those conditions are satisfied, then the law kicks in. There's a company in the state of California for the purposes of the statute and is now governed by that law. So if a Texas official issued legal process and it was directed to Google and tried to find some Google personnel in Texas to serve it on, I think California would say, no, our law still applies. The fact that you're a Google rep who doesn't happen to be in sunny California doesn't make any difference. Our law is applied at the entity, you're a representative of the entity, the entity cannot comply without legal process or at least, you know, we have to go through the attestation flow before you do.

So the law is about the entity being located or headquartered, incorporated, in the state of California and its behavior. As a practical matter, what happens there is the law enforcement official would be told by the Google personnel, I can't take any -- I am not authorized to take this. You need to go through the legal department and use the interface, blah blah blah. But the more important there, all this other conduct could be happening outside the state of California, but because the entity that's doing the disclosure is subject to the law, it needs to act consistent with California's legislation.

Jake Laperruque: I think that's right. I would just emphasize that this, it really does just come down to the company's location. So it can not only necessarily be law enforcement in Texas asking Google in Texas, it could be because I'm investigating a person in Texas who received an unlawful abortion in Texas. But if it's information held by Google on a Google server in California, then Google I think would be compelled to say, well, California law says we can't hand over those emails or those other records to you. And that would then create a pretty unprecedented situation where they probably end up going to court and the Texas will say, hey, our law says they have to turn this over and California will say our law says they have to not turn it over, and a judge would end up deciding who prevails in that conflict of laws dispute where the laws essentially say contradictory things.

One thing I would add to this that's worth thinking about. We've mostly thought about this in the context of these really large entities that have, that serve nationwide actors, you know, Google, Apple, Amazon, Microsoft, that are bound by these shield laws. I think we haven't seen this yet, but eventually someone's going to get served in the state that's making these demands, like Richard said.

It's not how the process typically goes, but their way of getting to court will be to say, well, if you ignore this request, we are going to hold you in contempt and we're going to take your Texas employees and throw them in jail for contempt if you don't respond, and that's how we'll trigger the lawsuit.

If you have a company that's, let's say, entirely based in California that hypothetically let's say provides virtual medical advice and information and Texas law enforcement wants that. They don't have employees in Texas. They don't have an office in Texas. The only way that they can get that warrant (inaudible) is to forward it through California, have California courts domesticate it, and then basically have someone in California serve that there in-state. Texas can't send their police to go arrest or serve a warrant in California. They don't have jurisdiction there.

The shield laws that say, well, not just these companies, but California courts, you can't domesticate that warrant, and, California law enforcement officials, you can't serve that on a company. So I think that's really worth thinking about, especially in the context of medical data and electronic medical records. That could be -- I don't know where that conflict of law dispute goes for a company like Google. But if the company is only based in California, Washington, and effectively the warrant can never get to

their front door, I think conflict of laws disputes aside, it would, these days, trying to make these demands would be in a very tough place.

That is potentially a very strong incentive as far as, well, this is a way to keep our patients' data safe is if we can put it in an entity that only exists in states with these shield laws where the warrant is never going to get domesticated or served on us.

Maya Bernstein: I was about to ask Deven, like I don't know where Invitae is now based, but whether -- you sort of said you were, you feared such a request coming or that you anticipated that one might one day. It sounds like one has not come yet.

Deven McGaw: No, not to my knowledge, and we are located in the state of California, but we do have some laboratory facilities in North Carolina and in Seattle. I think it's -- I'm not sure, given healthcare facilities and licensure laws, that we necessarily have the ability to basically hold our data offsite from our operations, but it's an interesting idea.

Richard Salgado: I would add on Jake's point, I am not sure the data location matters here. I understand the reading of the statute, but I don't actually -- I'm not actually convinced that the data has to be in California for the California law to apply, as long as the entity is there and has possession, custody, and control of the data, wherever it exists, I'd say it applies.

Jake Laperruque: Specifically the California law says either the data, the records, or assistance has to occur in California. If any of those happen in California, it's covered under the law. So I think setting aside the complicated questions of what if you have data that's moving in three different servers, if the company or their lawyers and their people who respond to law enforcement are in California, then they would assist by sending, all right, I'm going to forward along all the data, if you're sitting in an office in California, that law still triggers.

I think kind of going to the sort of data hub, I think we're -- because what we're interested in is not just if the data is stored there, but if the entire corporate entity is there, then I think the shield law would be pretty effective in stopping a warrant from getting to that company. Google, Apple, whoever else, if we ever get into a dispute, eventually they're going to find a way to serve it on someone, even if it's not the person who would handle the data in California or Washington, they'll do it. But if your only office is in California, if all the data is in California, I think it would be very hard for a state with a ban to find a way to push a warrant to try to (inaudible).

Maya Bernstein: So given that discussion, I wanted to ask you, Deven, you've been a very strong advocate as you mentioned for patients getting access to their own data. A lot of that time means it's out, it comes to be outside of HIPAA once they get it, maybe held by some other, not a Google or a Facebook, but a smaller company, and I wonder, given your past advocacy, has your approach to that idea changed? Has your posture sort of changed post-Dobbs about how you think about patients getting access to their own data and what considerations they may want to think about when they're getting that access and what could happen to their data in a post-Dobbs world?

Deven McGaw: Well, my advice to people generally about how to treat their own data and what kinds of protections that they should take on and whether it makes a lot of sense to track your periods in a period tracking app versus just this little book like we all used to do when we were younger. You know, but in terms of whether I have changed my tune and said, oh, it's too dangerous out there and patients shouldn't have access to their own data because they're going to be more likely to have it abused now or at least certain types of data, definitely have not changed my tune only because the types of patients

that we serve with our citizen platform really need their health data. Like, they need it in order to help power research to find treatments for kids with rare diseases for which there are no known treatments, and very little understanding of disease, and the research undertaken by the data holders is often too slow and the data is too siloed because these populations are stretched across lots and lots of different institutions all over the world, frankly, and to get critical mass, the patients have found that it is much -- it's much more, they can push research better if they've got their data and they can contribute into places where they can get something out of it.

Similarly, and that's just one example. People trying to find clinical trials, that their medical provider doesn't know anything about. You can't do any of that without your medical data. There's too much that's lost when you say it's too dangerous out there and we shouldn't let people do this, because there are some significant consequences on that end as well. So I think to me it just ratchets up the need for federal privacy protections that extend, that are not bound by who has the data under HIPAA and that are not necessarily vested on whether that data meets some concept of whether it's been breached or not or fit within the jurisdiction of FTC's current jurisdiction of the health -- the breach notification act for personal health records.

Like we're just sort of stretching, stretching, stretching against the types of authorities that we have to regulate privacy, and there's all sorts of data flying out all over, because it's based on who has it and it's not comprehensively regulated in the way that they do in other jurisdictions. So it just to me creates increased pressure on Congress to act. Will they do so? I don't know.

So instead, of course, we're seeing all these states come up and pass comprehensive laws and the patchwork isn't great either, but it's in some ways at least from a privacy standpoint better than nothing and continues to ratchet up the pressure on policymakers to do something beyond the current regime we have where we just leave lots and lots of data vulnerable.

To say to people don't use tools that could really be useful to you and that you really need because they're underregulated is a really poor response, I think. I mean, it would be unfortunate if we had to do that.

Maya Bernstein: I surely was not suggesting that. Just on the latter part of your response, was sort of like what can we do given this environment.

Deven McGaw: Have a sit-in on the Capitol floor. Not leaving until you pass comprehensive privacy legislation.

(Laughter.)

R. Lenel James: I have a quick hypothetical for Jake. Richard, you may back up on it. Which is from the large payer or large provider, based in California or based in Texas, if they have multistate operations but their headquarters, their corporate headquarters, is in Texas or California, is there a difference in how they'll be able to respond to these requests?

Jake Laperruque: So two points. First, when you say providers --

R. Lenel James: Large health systems.

Jake Laperruque: So actually, they wouldn't be covered under the California law in the first place, because that only applies to electronic communication providers and remote computing services, so people who run your emails, your texts, store your stuff in the cloud.

One thing we have talked about in our advocacy of these shield laws is states, they might want to consider extending it to some other entities such as entities that maintain health records, because those can be just as sensitive as your emails. I think that would be a really good idea for how those shield laws might expand to directly include those types of things.

Now, the way the shield laws typically work is they say, they maintain jurisdiction over companies that are either incorporated in that state or headquartered in that state. So if you're -- I think Apple is incorporated in California, if I'm not mistaken. That would cover them for that.

Meta, they're not incorporated in California; they're incorporated in Delaware, like most companies, but they are headquartered in California. So they're covered, too.

I believe the specific language is like their principal place of business operations or principal headquarters of operations, but, yeah, it's essentially it's either incorporated there or headquartered there. That's what sort of gives the hook of the state saying, hey, actually, company, you live in our sandbox, we get to make the rules of how you operate, how you handle your data. So you can share under these circumstances, you can't share under these circumstances. Of course, all those companies, they have offices in places like Texas, but the place of incorporation or headquarters, that determines whether the law applies to them.

R. Lenel James: A quick follow-up for Jake. What if I the payer or I the health system, my contract is with Apple to store my data or with Meta, does that give me a shield?

Jake Laperruque: It would give a shield from Apple turning over that data. If law enforcement went to you directly and you were -- either you were based in California or you were one of those entities like electronics communications provider that the law applies to, it doesn't cover you. But if they went to Apple and said we want that data, they would have to say no.

R. Lenel James: Thanks.

Valerie Watzlaf: Any other questions? I want to thank all of you so much. This was wonderful. It really helps us to move ahead and consider other areas we may want to explore in the area of reproductive health and privacy, and thank you so much for being here. We appreciate it.

Melissa Goldstein: Thanks so much.

(Break)

Updates/NCVHS Workplan Development

Rebecca Hines: We're getting near the end of the day, and we have some time to talk about the PCS workplan. Because we have five new members, we thought, Jacki and I, it might be a good idea to point you to something that could be very helpful when thinking about how do we decide what to focus on, what projects are we going to take on.

Vickie, you actually had a role in development of this document. We have a very lean strategic plan -- and this is on the website, and I think we provided it to you, but that was when we gave you sort of a

firehose of documents. So basically, very simply, there's these simply stated, they're quite broad strategic goals. Improve data usability and analytic capabilities to sustain continuous improvement in health and wellbeing for all, and then some very specific activities there. Accelerate the adoption of standards. That should be familiar to the standards folks. To achieve the purposes of safety, effectiveness, efficiency, privacy, security, and interoperability of health data and systems through very specific objectives. Expand appropriate access and use of data while ensuring relevant safeguards. Today's discussion. And the fourth one is improve health information and data policy by taking the long view.

What I wanted to point you to is not only to get more familiar with these, the project selection criteria. So as you're thinking about what are we going to focus our precious time on, because we don't have -- you all have day jobs -- just wanted to quickly remind us of these criteria, which I think are still just as relevant today. If you do want to revisit these, it's your document that keeps -- it's a living document, but it hasn't changed in about six years.

So the first is clearly be consistent with the committee's mission and at the appropriate scale. Be complimentary and aligned with one another to advance the goals and objectives in this strategic plan. So that's important. So we don't want to have projects that are kind of at cross-purposes.

Result in information or recommendations that are actionable by the HHS Secretary in partnership with state and local organizations and agencies when appropriate, or actionable by the private sector.

Obviously, it needs to fulfill any mandated requirements. And then, last but not least, take into account urgency and then the resources available to the committee to ensure that if we start something we can finish it.

So I thought it would be helpful just to have that in mind, know where this is on the website, which is under the about tab. So I just wanted to take a minute to put that in your consciousness as you this afternoon talk about the PCS workplan and tomorrow talk about the standards workplan, and any other projects you want to work on. There's the ICD, which we're pretty clear on what we're doing with that for the next short term. This is located under the about.

Melissa Goldstein: Rebecca, how long do we have for this discussion, since we're a little bit behind. Just wanted to check.

Rebecca Hines: About 20-25 minutes.

Valerie Watzlaf: I can go fairly quickly. We're just going to give you an update on the PCS subcommittee, and before I start into that, I just wanted to thank everyone who's been on the Privacy, Confidentiality, and Security subcommittee. Of course, Melissa, who is online there, our co-chair, and then we also have our veteran members Denise Chrysler and Vickie Mays and Jamie, who has just joined, so thank you for that, and then we have recruited new members; Angela, did you know you were on our committee?

And I guess we do have someone that will be coming on, we haven't met, Mariza Hardin. So thank you for joining us.

And then special, special thanks to our staff. Maya, my goodness, what would we do without you? And Rebecca, the same thing. So you keep us so on task. Thank you so much for all of your hard work and for everybody's work this past year and as we move ahead.

So on the next slide, we wanted to talk about some of our -- how we've been building on some of our recent work, and we do have these little QR codes on the righthand side, so if you haven't looked at some of these documents, you can pull that up and look at them.

Melissa Goldstein: It is a great idea, but it takes Val to implement.

Valerie Watzlaf: And they do work. So the first one there of course is our comment letter to the NPRM on HIPAA's privacy rule to support reproductive health privacy. This took several months I think of work that we did there, and all of you really, thank you, for participating and providing feedback. We couldn't have gotten that letter in without all of your help. I think we got it in right at the deadline.

And then the other area that we have had, if you haven't taken a look at it, it's a wonderful reference, and that's it just was completed in December of 2022, and that was the environmental scan on emerging issues and privacy and security post-COVID. This was done special thanks to Cason Schmit, who is a JD and assistant professor at Texas A&M University, and we have asked him to come in and do an environmental scan on all of the different state laws that have been enacted and considered, federal laws that are being considered around privacy, (inaudible), and AI. He goes into law enforcement, all of the issues, reproductive rights, and so forth, a ton of different issues that he puts into that environmental scan.

R. Lenel James: Can I ask a procedural question? For something like that, the reason I am asking is the Sequoia Project, one of the workgroups that is looking to start up deals with privacy and security. So an environmental scan like that would be (inaudible) as they think about how to focus that activity. But is that shareable?

Valerie Watzlaf: It is on our website. All of it is publicly available.

Rebecca Hines: Make sure you spend the time with the products tab. It's everything that we have. It's all of our output over the last --

(Cross-talk.)

Maya Bernstein: This is a public meeting. Everything here is public. Everyone can see it.

Valerie Watzlaf: Okay, good question, thank you. And then on the next slide, we also had -- this was a letter that, recommendation letter, that was completed in 2022, two of them, one dealing with privacy, confidentiality, and security and data collection and use during a public health emergency. We had hearings around these issues that were held the last few years and other resources about data collection and use during PHE, as well as the gaps and quality issues in collection of race and ethnicity data. So that one took us a good while, but we did complete that letter.

And then also recommendations to strengthen cybersecurity in healthcare. Couldn't have done that without you. I think basically you did just about all of it. So thank you for that.

We also had panels that provided us with information about cybersecurity and all of the issues around that and so you were able to complete those two letters in 2022.

So that really kind of summarizes our most recent work. Again, I want to thank you all for your input. I know many of you were very instrumental in getting these recommendation letters completed.

On the next slide, then, we don't want to forget about some of this wonderful past work that happened in 2019, too. This is also on our website, and that is the Beyond HIPAA privacy work. Excellent, and there's still so many things in there that have not been addressed really. So please, I would recommend go and take a look at that and review it. It's really good.

And then there's also another letter that's very similar to the Beyond HIPAA work, but it's a little less lengthy. So if you want to take a look at the other letter on the recommendations for HHS, this second one.

Michael Hodgkins: The second one you just talked about, might that have impact on the discussion we just had about what do we do for better privacy for --

Valerie Watzlaf: Oh, yeah, both of them. I would think both of them. Definitely. So take a look at those if you haven't already.

Rebecca Hines: So when you read them on the plane ride home, you can connect them to something.

Valerie Watzlaf: And then there's one more here, and this is one on the deidentification. This is, it includes 12 excellent recommendations on what needs to be done with all the deidentification standard guidance, can really be applied, and these still have not been addressed, and this recommendation letter was completed in 2017. I don't think we have even gotten a response back on (inaudible). Very important. So we don't want to forget about these. They're out there and they're older, I think quite important (inaudible).

R. Lenel James: This particular past work is to me an example of how we might tie it together with the deidentification and protection. Is there a protocol when we issue some (inaudible) NCVHS and now with new tech, new needs, we can see (inaudible) using it. It seems like we don't have to go do new work. Is there a protocol to bring something back to say, hey, this ties to health equity, data protection, maternal health. Can we revisit it without having to do more work? Because we already did it.

Valerie Watzlaf: So we just did that with ICD, Lenel, where the committee did a whole lot of work out of the 2019 expert roundtable meeting and then the pandemic, as Jamie said, and then the pandemic happened. So we basically revisited that entire letter and all of the work and reissued a letter to a different Secretary, sort of post-pandemic, to get it back front burner.

So you absolutely, you would need, I can assure you, that you'll get more attention if you write another letter, but you can certainly reference it, attach it, draw from past work. You don't need to redo work, especially if the recommendation hasn't been followed, hasn't been carried out.

PARTICIPANT: I think we did reference the deidentification letter in the PHE letter. I think we try to do that as much as we can, so to say don't forget this. It's a great question, thank you.

Valerie Watzlaf: And then, Melissa, are you taking this one, or do you want me to take this slide?

Melissa Goldstein: Whatever you prefer. I'm ready, but whatever's easiest. So essentially, moving on from recent work and past work, this year, 2023, and the rest of the year, these are the areas that we've been focusing on and are thinking about continuing to focus on this year.

So the first is continuing in the cybersecurity work, and thanks again to Jacki for helping us, a lot, with this area. We had panels earlier in the year on legislative developments in data privacy and on current issues in cybersecurity, to really update the letter that we had done I think over a year ago now.

And then we had Cason actually speak, Cason Schmit, who we contracted with to help write the environmental scan. He spoke at an earlier meeting on the environmental scan, essentially highlights on the privacy and security emerging issues, and if you're interested, I recommend watching that section of -- well, I recommend watching the meeting in general if you want to catch up on the recent work, but Cason's section in particular goes into, and we had some lively discussions about different pieces that he had talked about in the report and that we are considering pursuing.

Of course, this also happened before the NPRM came out. And then everything ground to a halt while we worked on the NPRM. So it was a very good thick discussion I think that would be useful.

We've also, thanks to Maya, been reaching out to OCR for periodic check-in discussions, including one that we're going to have tomorrow, to see what's going on in the OCR world. We heard from Tim Noonan I believe earlier this year, but it might have been at the end of last year, and of course we took on, we made comments to the NPRM on reproductive health privacy, but we're continuing to think about what we might do in addition to that. Perhaps a different letter, that's what we're thinking, different recommendations.

Val, anything you want to add on that? Any questions, anyone? Comments from anyone on the subcommittee, current, present, future?

Okay, next slide would be great. These are the things that we've been thinking about working on for some time, and oftentimes they cross over each other. So we might mention in one letter, like Maya said a few minutes ago, the past work we've done on deidentification, and we also note that there has been no change from a policy perspective at this point. We've talked about AI and machine learning tools, inferences from existing data, privacy risk assessments.

We also note that the administration as a whole has been focused on this particularly this year and put out earlier this year new actions to promote responsible AI innovation that protects Americans' rights and safety, including an executive order. So we wanted to note that as well in these discussions.

We talked about in the panel we just had law enforcement access to and use of private information, reproductive health information, but other health information in general. How HIPAA interacts with broader privacy laws under consideration, which our last discussion I think was very helpful for that, and the availability for data for public health purposes, which we really spoke about during the first panel this afternoon.

So these are really recurrent issues that we have been thinking about, what should we do, what might we do, what do we take on first, what do we take on second, how much can we do? We are very happy to have new members, because we think that will help us with the person resources. So we're excited about that.

Finally, additional scoping issues in the security realm. First, impact of cyberattacks on healthcare systems and healthcare institutions. As a follow-up to the previous work we've done on cybersecurity, also recognizing here the larger administration's executive order on improving the nation's cybersecurity from 2021 and other actions by the larger administration.

Security principles and safety for patients and consumers regarding devices, apps, health information exchange, interoperability, wearables, telehealth, some of which might be covered by HIPAA, much of which is not.

Education and training of workforce on cybersecurity. We spoke a little bit earlier today about education and training of people on what happens to their information and if they share it or don't share it, what the consequences might be. This is education and training of workforce about cybersecurity issues and cybersecurity flaws that lead to unavailability of data, devices, and systems when we need it.

So then finally, this is a slide that shows a little bit about where we've been recently, now, and the anticipated future. So expert panels in the latter half of 2022, expert panels, discussion for project selection, and then the response to the NPRM in the first half of this year, and now here we are, facing the third quarter soon, developing project scoping documents, which is the first round; documents that are essentially the first stab at what we're going to do next. Shorter documents, scoping perhaps a project, and then we narrow that down, we circulate it. The scoping documents eventually, we hope, are approved by the full committee before we actually start on new projects.

So the subcommittee comes up with the scoping documents and then we discuss them with the full committee and come to agreement about next projects and then we start conducting the projects, forming draft recommendations, possibly we're hoping at the end of this year going into next year.

Val, anything else there? Jacki? Timing? And I think that is the last slide. Questions and discussion.

Wu Xu: (Inaudible) public health data in there. So my question, I assume the tribe health agency belongs to this category, right? We have the tribe data access letter. Have we heard anything back on that, how the --

Maya Bernstein: In general, the kind of response we get immediately in order to acknowledge our letter is merely an acknowledgment. Imagine what the department would have to go to to actually respond in a substantive policy way to our letter. They would have to consider our recommendations and go through a major policy change to do some of the kinds of things that we were suggesting.

So we almost never get a response like that. That kind of response comes later in the policy process when they think about what to do with our recommendations. But the kind of response we get is usually merely an acknowledgment, thank you for your letter, we're going to consider it. And it's hard for the department to do much else in a timely way, frustrating as that is.

Rebecca Hines: So to Maya's point, we just got one of those from the PHE letter, which is now up on the screen and which is on our website. Whenever we get one of these, we post it. So in response to your PHE letter a few months ago, this is what we got.

Valerie Watzlaf: I think with the tribal recommendation letter, what we were hoping -- I don't think it fell with either subcommittee. So I think what we also don't want to have happen is it to fall away and we won't revisit or we lose sight of it. So, because it really was just a group of us, right, that got together to do that.

Maya Bernstein: One thing you could do is to ask for an update, a public update, at the next meeting for example in November, I know that the department does have activities in that area in particular, and it

might be right at that time to have someone come who's working on the tribal public health information issues to talk to the committee with an update.

Wu Xu: Since you have one (inaudible), there, can we know that project under (inaudible) subcommittee so you can follow up?

Maya Bernstein: I can follow up anyway. You can follow up anyway.

Wu Xu: (inaudible) own it.

Maya Bernstein: Own it. I understand that. I don't have any objection to that. That's up to the co-chairs and chair to decide how they want to arrange, how you want to arrange your work, but I don't -- unless someone else on the committee objects to it, I don't see any reason we can't do that.

Valerie Watzlaf: I think that would be good and we can certainly bring it up and make sure we bring it up at our next meeting to be sure. I think that's a great idea, thank you.

Maya Bernstein: Can I add one little comment about just sort of thinking about how the letters are processed? I want to remind you that when we saw the rulemaking for the NPRM that came out, the committee's work was cited throughout the preamble to the rule, and that work was done between sort of 2006 to 2010, a long time later, and we're still talking about the kinds of recommendations that were made early on by this committee at that time about segregation of data, about particularly sensitive records, sensitive information in medical records, and so no, they didn't do something directly about it at the time, but that work still is in the fabric of the department and people are aware of it, and when there's something ripe or relevant, they're going to pull in the work that you do.

And so, part of the issue with, for example, deidentification, you know, without -- I don't think I'm talking out of school to say there are limited resources. You can talk maybe you want to ask the director of OCR when she's here tomorrow about this, but there are limited resources and they have priorities and they haven't got around to deidentification I don't think anybody has any question that it was the first crack, the first time anyone had created a regulation like this, and we did pretty good. But obviously there's room for improvement, and we made recommendations about that. I don't think that's particularly controversial in the department that those regulations could be improved and that then the committee has made useful and important recommendations, you know, but there's limited resources and there are other things that they have to do first. So they haven't gotten to it. But it's not that they forgot that it was there.

Jacki Monson: An example of that actually is in the NPRM, the most recent one, where actually they welcomed comments, and part of it is because it's addressing Beyond HIPAA. So there's connectivity back and forth, and I think right now I would assume they're preoccupied with all the comments they got on the NPRM. So it's part of the department's prioritization, but we should ask her tomorrow when she's here, along with what she does with civil monetary penalty money, we might be able to use (inaudible) NCVHS. Joking.

(Laughter.)

I think that the one thing for tomorrow is that we used to have connectivity directly in OCR with Rachel and we don't have that now. So I think if we're successful in our conversation tomorrow, if we could get somebody back to serve as staff to Privacy, Security, and Confidentiality, where you could have some of those conversations even more frequently on prioritization.

Jamie Ferguson: Thank you, Maya, for bringing up the deidentification issue and thank you, Val, for reminding us that we never got a response to the letter from six years ago, which predated my work on the subcommittee, because, in fact, that was what I was going to bring up.

I was very impressed recently reading a systematic review in the Lancet of reidentification where data from wearables in up to 100 percent of -- between low of 86 percent, mostly on 100 percent of cases, deidentified data could be reidentified. I think there's been very substantial change in the technology environment in the last six years, and I think it also could be a relatively small project to update that letter. So I would vote for that.

Public Comment

Rebecca Hines: So for those of you here, we've already got a hand up, but raise your hand to have your audio unmuted. You could also put your name in the Q&A. And if you're on the phone, press *9. When we unmute your line, just remember to state your name, your title and organization, and then you have three minutes.

Tejas Sathe: Hello, everyone. Thank you so much. My name is Tejas Sathe. I am a general surgery resident and currently a research fellow at the University of California in San Francisco. Part of my work involves for advocating for unique device identifiers, and we recently authored an opinion piece talking about including UDIs in billing claims to provide an incentive for health systems to start capturing this data that's on all the devices we implant into patients.

We recently had a meeting with CMS where they liked the idea of including the UDI in billing claims, but their reason for not being able to proceed was because of the July 14 letter from NCVHS which disagreed with including them in the claims. So my two questions are would it be possible to understand the main criticisms of inclusion; and number two, could you please provide me with some advice for how we can continue to advocate for doing this work while also respecting privacy and addressing any concerns, whether it's writing more papers, submitting a letter to your committee, or engaging in any other kind of advocacy. Thank you for the opportunity to ask my question.

Rebecca Hines: Thank you for your input. The committee hears you. I will say there's some different understanding than you have, on behalf of the committee, but we're not in a position right now to respond. But we are able to engage on this at a later time. Thank you for those comments. And you can send us a written question and comment to the email on the slide there, and we'd be happy to follow up with you.

Anyone else?

(No response.)

Wrap Up and Adjourn

All right, I think that's it for today. We do have another public comment session tomorrow, so with that, public comment has ended.

Back to our discussion. Thank you. Vickie, you had your card up.

Vickie Mays: The question I was going to ask, Jacki, you've actually started to comment on it, and that is the staff from some of these agencies. I feel like some of our letters are kind of going fallow, because

we don't have that. I'm wondering if there's a way to put -- as we think about what work we're going to take on, then we need to also think about what connections we need in order to make it stay alive.

So I think the OCR one is one. I think there's been less emphasis in HHS's disaster office. So the stuff we did, I think that kind of fell. I'm just trying to get a sense of how we can do that. Because, I mean, we worked really hard on some of this stuff, and it just, it sits there, and it was timely when we sent it, and I understand what you're saying about it has an impact, but can we either target particular staff to continue to work with us or something?

Rebecca Hines: I think that is a question for Sharon, who had to step out. So I think we should revisit this question tomorrow.

Anything else? We do have time on the agenda tomorrow to revisit the workplan. Jamie, you put in a plug. Think over the next 12, 20 hours -- oh, Richard's hand is up.

Richard Landen: Building on Lenel's comment before about we'd like to take things from the past and reuse them, we can as long as they're applicable, going back -- we talked about, Rebecca gave the example of the ICD-11 follow-up letter, and we talked about the evolution of things over decades. But also tomorrow, a subcommittee will hear about the (inaudible) project plan and the contemplated revisions to that.

So we'd like to build on what we've already done or recognize what's been enacted based on a recommendation to look at what's changed in the environment since we did that. But we don't want to lose sight of all the stuff we've done in the past. This committee has been very good at that, at being consistent in its approach and then not losing sight institutionally of what we've done in the past and the evolving steps as the situation changes.

I hope that helps the newer members appreciate that there's a lot of work that your predecessors have done going back over the years.

Jacki Monson: Anybody else have any last comments, thoughts?

Rebecca Hines: So we will be back here tomorrow morning at 8:45. So try to get here before that. And we have our wonderful colleagues, Marietta, Gwen, and Cody. Cody is going to be here in the morning as well.

(Whereupon the meeting was adjourned at 5:25 p.m.)