National Committee on Vital and Health Statistics

Transcript
November 30, 2023 10:00 a.m. – 4:15 p.m. ET
Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Angela Alton	City of Hope	Member
Catherine Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Tammy Feenstra Banks	Healthcare Consultant	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Healthcare Consultant	Member
Richard W. Landen	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
R. Lenel James	Blue Cross Blue Shield Association	Member
Steven Wagner	University of Pittsburgh	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Shirley Castillo	NCHS	Staff

Presenters		
Name	**Organization**	**Role**
Mary Stanfill	United Audit Systems, Inc.	Vice President
Patrick Romano	UC Davis	Professor
Vickie Mays	University of California at LA	Professor
Kin-Wah Fung	National Institutes of Health	Staff Scientist
Carmela Couderc	Health and Human Services/ONC	Branch Chief
Grail Stipes	Office of Science and Technology	JD
Travis Hoppe	NCHS, CDC, HHS	Associate Director

Call to Order/Roll Call

Rebecca Hines: Good morning everyone to Day 2 of the meeting of the National Committee on Vital and Health Statistics. Welcome back to those who were with us yesterday and a warm welcome to members of the public in attendance with us here today not here yesterday. This is our late fall/winter meeting of the committee. My name is Rebecca Hines, same as yesterday, and I serve as executive secretary and designated federal officer for NCVHS.

Yesterday the committee worked through six recommendations to HHS to strengthen the HIPAA Security Rule. The committee unanimously voted to approve the recommendations and the letter as a whole and once that is cleaned up and formatted for sending to the HHS Secretary, the letter will be posted on the NCVHS website along with all the other committee products.

I imagine this morning that some of you may be joining to hear the update from the NCVHS workgroup on timely and strategic action to inform ICD-11 policy. I never want to pass up an opportunity to spread the word on the open request for information, the RFI, that was published in the Federal Register on October 16. Thank you for putting the link in the chat. We very much welcome your input on this new version of ICD-11 and hope that you will take advantage of the opportunity to send input for the workgroup's consideration. It is very helpful and input is due January 12. We will remind you again during the update later this morning.

Let us take care of roll call now. Please state your name, your status as a special government employee, and any potential conflicts with today's work, starting off with our chair, Jacki.

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

Rebecca Hines: Thank you.

Angela.

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

Catherine Donald: Hi. Good morning. Cathy Donald. I work for the Alabama Department of Public Health. I am a member of the Full Committee and the ICD-11 Workgroup. I do have a conflict with any discussions regarding reproductive health so I will recuse myself from that discussion this afternoon. Thank you.

Rebecca Hines: Thank you, Cathy.

Debra.

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

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Good morning. Jamie Ferguson. I work for Kaiser Permanente. I am a member of the Full Committee, the PCS Subcommittee, the Standards Subcommittee, and I chair the ICD-

11 Workgroup. I have no conflicts today.

Rebecca Hines: Lenel.

Lenel James: Hi. My name is Lenel James with Blue Cross Blue Shield Association. I am a member of the Full Subcommittee, member of the Full Committee, and then a member of the Standards Subcommittee and have no conflicts.

Rebecca Hines: Michael.

Michael Hodgkins: Good morning. Michael Hodgkins, independent consultant, member of the Full Committee, member of the Subcommittee for Standards and ICD-11 and I have no conflicts.

Rebecca Hines: Rich.

Rich Landen: Good morning. Rich Landon for the next 14 hours or so, member of the Full Committee, member of the Standards Subcommittee. I have no conflicts.

Rebecca Hines: We will miss your sense of humor, Rich.

Steve.

Steve Wagner: Hi. I am Steve Wagner. I am a former health information architect. I am a member of the Full Committee, a member of the Standards Subcommittee and have no conflicts.

Rebecca Hines: Tammy.

Tammy Feenstra Banks: Tammy Banks. I am a consultant, member of the Full Committee, member of the Executive Committee, and chair of the Standards Subcommittee and no conflicts.

Rebecca Hines: Val.

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

Rebecca Hines: And finally, Wu Xu.

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

Rebecca Hines: Thank you. We do have a quorum. We also expect to have Denise Chrysler join us shortly here this morning and we will let you know when she is here. Let us turn it over to staff starting with our Executive Director, Sharon Arold.

Sharon Arnold: Hi. I am Sharon Arnold, executive director. I am the associate deputy assistant secretary for Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation.

Rebecca Hines: Thank you.

And Maya Bernstein.

Maya Bernstein: Good morning. I am Maya Bernstein. I work for Sharon in the Office of the Assistant Secretary for Planning and Evaluation as the senior advisor for privacy policy. I am also her lead staff in her role as executive director to this committee and also the lead staff to the Subcommittee on Privacy, Confidentiality, and Security. Good morning.

Rebecca Hines: Good morning.

Lorraine Doo.

Lorraine Doo: Good morning. Lorraine Doo, Office of Burden Reduction and Health Informatics and Interoperability Group and lead staff to the Standards Subcommittee.

Rebecca Hines: Thank you, Lorraine.

Shirley Castillo.

Shirley Castillo: Good morning. My name is Shirley Castillo. I am a Policy and Issues Management Analyst with CDC's National Center for Health Statistics and I provide support to NCVHS and Rebecca.

Rebecca Hines: Delighted you are with us. Thank you, Shirley.

A quick note for members of the public here with us this morning. You can sign up to receive email notices from the committee if you have not already. You just go to the home page of the NCVHS website and there is a button there to subscribe.

Finally, a note for this afternoon. The public comment period is scheduled for 4:45 eastern. We will have an open line for those of you attending from the public. It is possible that the agenda may shift forward and the public comment time could then shift earlier. If you would like to make a public comment, if you are planning to do so, suggest you be attentive starting around 4 p.m. Eastern or so. You can see it here on the screen. We will make these instructions available again for you then and you can also email us comments at NCVHSmail@cdc.gov. Thank you for the slide.

And the last point is that the agenda link is in the chat there on the website and available for you. With that, I will turn it over to our chair, Jacki Monson.

Welcome Remarks/Agenda Review

Jacki Monson: Great. Good morning, everyone. Let us pull up the agenda. We have another busy day today. The first thing we already achieved, which is roll call and open remarks. Next on the agenda is an update from Sharon Arnold from the Office of Assistant Secretary for Planning and Evaluation. We will then go into a discussion on the ICD-11 Workgroup, both an update, discussion of the workplan for 2024, and strategic action plans.

We will take a break and then we are going to go into a follow-up conversation from the July meeting on artificial intelligence and health care. At least one of the individuals is back from the last conversation. We will then break for lunch and then we will move into changes in state laws

on access and use of reproductive health data. Then we will move into the NCVHS workplan development Part 2 so the follow on to Tammy and Val's conversation yesterday. And then we will take a break and then we will go through any additional workplan development that is needed. And then we will move into public comment and then we will do next steps and wrap up and closing and adjourning by 5 p.m. Eastern time. That is our day to day.

I will turn it over to Sharon to kick us off.

Update: Office of the Assistant Secretary for Planning and Evaluation

Sharon Arnold: Thank you very much. I want to start off by apologizing for not being able to participate yesterday. Unfortunately, I had unavoidable conflicts. But I really enjoyed meeting many of you in person for the first time at our last meeting and hope to see you again in person in this new year. For now, it looks like our plan will be to meet approximately once a year in person with the other meetings virtually.

I want to start by reminding you of the department's strategic plan and our top goals. These goals are to protect and strengthen equitable access to high-quality and affordable health care, safeguard and improve national and global health and outcomes, strengthen social well-being, equity, and economic resilience, restore trust, and accelerate advancements in science and research for all, and advance strategic management to build trust, transparency, and accountability. These goals help us to stay focused on our priorities even when challenges arise.

As we continue with our work in this uncertain environment, I want to share with you some highlights of the last four months or so. There is a lot going on in the department. These are really just highlights that I think you would be particularly interested in.

Perhaps the most important thing is that on November 15, Congress passed a continuing resolution, which funds the majority of the department at current levels through February 2. We do not have an FY24 budget. We are operating on a continuing resolution, which means that there is a continuation of authority to make expenditures at the same level as last year.

In the last few months, Secretary Becerra has declared two new natural disasters related to public health emergencies, first in Hawaii in response to the Maui Wildfires and in August in Georgia and Florida in response to Hurricane Idalia in late August and early September.

On September 28, the department launched the Climate and Health Outlook Portal to identify counties at risk of climate-related hazards. The portal is an interactive tool that provides actionable, county-level data that can be used to prepare for climate-related hazard events. Policymakers, health care providers, and the general public can use that tool to better understand the health impacts of climate-related hazard forecasts in their communities and plan accordingly.

On October 30, President Biden signed a new executive order on artificial intelligence to protect Americans from the potential risk of AI systems. This order directs developers of the most powerful AI systems to share their safety net test results and other critical information with the US Government. Advances in AI will revolutionize the operation of critical infrastructure operations and impact the delivery of health care for many Americans.

HHS will be working in alignment with this directive to mitigate risk and identify opportunities to

help govern the safe, equitable, and responsible development and use of AI technologies. I know that we all look forward to the briefing later today on the executive order and associated guidance.

We are now in open enrollment season for health care coverage through the marketplace and that extends through January 15. This fall the Census Bureau released a report, which showed that the total number of people insured in 2022 increased compared to enrollment numbers we observed in 2021. This means the total of 304 million Americans had health insurance at some point during the year and people without health insurance coverage decreased in 27 states.

The COVID-19 hospitalization rate and weekly mortality count increased since the end of July 2023, peaked in September, and has since declined from the beginning of October.

Following the end of the authorities to collect certain public health data with the end of the public health emergency on May 11, hospital admission levels and mortality rates have become the primary surveillance indicators.

The end of Medicaid mandatory cost sharing occurred on September 30. However, persons with Medicare Part B and those with Medicaid have their flu and COVID vaccines covered without cost sharing.

Also, the Consolidated Appropriations Act of 2023 extended many telehealth flexibilities through the end of December 31, 2024. This means that people with Medicare can access telehealth services in any geographic area in the United States rather than only in rural areas.

I want to share a few additional highlights related to COVID-19 and vaccines. The FDA approved updated COVID-19 vaccines in mid-September. The updated vaccine is a monovalent version offered protection from Omicron XBB 1.5 subvariant. As of November, 13.9 percent of adults reported having received an updated vaccine since September.

CDC messaging to the public now states that individuals may get their flu, COVID-19, and RSV vaccine at the same visit. Each vaccine will help protect against severe illness caused by these major fall and winter respiratory viruses. CDC has awarded over 3 billion in funding for immunization programs within public health departments and expanded programs to include COVID vaccine.

To ensure health equity in the vaccine distribution, CDC now requires that 75 percent of total funding goes to programs to increase vaccine access, acceptance, and uptake among racial and ethnic minority communities and that 60 percent goes to local health departments, community-based organizations, and community health centers.

The end of the COVID-19 public health emergency did not impact the ability of FDA to authorize treatments for emergency use. Existing emergency use authorizations for products exist for a range of products, including an injectable drug for hospitalized patients receiving mechanical ventilation, two antiviral drugs for mild to moderate cases, free immune modulators for adults with pneumonia who are at risk of progression to respiratory failure and an oral antiviral pill.

The end of the public health emergency has meant changes in coverage for testing in vaccines. The requirement for private insurance to cover COVID-19 tests without cost sharing both for over the counter and laboratory tests ended with the expiration of the public health emergency.

However, individuals with private plan coverage through the marketplace are covered for vaccines recommended by the Advisory Committee on Immunization Practices without patient cost sharing, including those for COVID-19.

HHS continues to support direct mailing of COVID tests through COVIDtest.gov. Every home in the US is eligible to order an additional four free at-home tests beginning November 20. Fifty-six million tests have been delivered so far.

In September, HHS launched the HHS Bridge Access Program for COVID-19 vaccines and treatment. The program will create a unique $1.1 billion public-private partnership to maintain broad access to COVID-19 vaccines for millions of uninsured Americans. CDC has contracted with more than 20,000 retail pharmacy locations nationwide to provide free COVID vaccine to people without insurance or whose insurance requires a co-pay. CDC will also ship and fund administration of vaccines to public health providers, designated by the state and local health departments, which could include more than 1400 HRSA-supported health centers and 12,000 other vaccine providers.

Long COVID presents a significant challenge for public health. The Household Pulse Survey Data, the experimental survey that was designed to collect information quickly and efficiently on how people's lives have been impacted by the coronavirus pandemic has been instrumental in understanding long COVID prevalence. However, we now have an additional new data source in the National Health Interview Survey. In September of 2023, the NHIS reported that in 2022, 6.9 percent of adults ever had long COVID, and 3.4 percent of adults currently have long COVID, quite a large number.

In September, the Agency for Healthcare Research and Quality announced nine grant awards for about a million dollars each for up to five years to support existing, multi-disciplinary long COVID clinics across the country. These will expand access to comprehensive, coordinated, and person-centered care for people with long COVID.

The NIH RECOVER Initiative's efforts continue to produce some tremendous opportunities to better understand and treat long COVID. The program has launched several clinical trials of potential treatments in 2023 and more clinical trials are expected this year.

HHS is standing up a Federal Advisory Committee on long COVID and is seeking nominations through January 16. The committee will consist of up to 20 members and will reflect the experience of persons with long COVID as well as clinical, medical, public health, behavioral health, human services, employment, data science, and research expertise. Recommendations for qualified candidates from any of you would be welcome.

I am sure you know that COVID is not the only infectious disease that the department is working on. CDC has issued new and updated guidance and resources to support the judicious news of antibiotics and decrease antibiotic resistance. There are 2.8 million resistant infections every year in the United States, causing almost 36,000 deaths. A C. diff infection kills another 12,800 people per year. The CDC supports the implementation of antimicrobial and diagnostic stewardship across the spectrum of health care and evaluates progress towards equitable access to high-quality health care. This initiative is a crucial, national effort to ensure that antibiotics are appropriately used and is a core strategy to combat anti-microbial resistance.

Last year the United States faced an unprecedented outbreak of mpox. This summer thanks to

the combined efforts of the department and the LGBTQ plus community, we had an average daily case rate of one or fewer, down 99 percent, from the peak of August 2022.

For the first time in US history, people 16 and over can now receive a single dose vaccine against RSV. With the CDC recommendation, the administration is ensuring that Americans have access to stronger protection against now three circulating respiratory viruses. The Inflation Reduction Act requires that the new RSV vaccine was made available without cost sharing for those in Medicare Part D plans.

As of November 4, CDC reports the weekly cumulative dose in millions of influenza vaccines distributed for this flu season is 147.7 million. This is lower than last period, which was about a little over 150 million doses and even lower than the year before, which was 163 million doses. We have some growing to catch up. And vaccinations for all children are still 13.9 percentage points lower this season compared with the same time last season. Again, some ground to make up.

Turning to our work on opioids and the department's overdose prevention strategy, on September 29, the Secretary renewed the opioid public health emergency for another 90 days. And HRSA has implemented a number of programs, including the Rural Community Opioid Response Program and to date has invested over 500 million and serves more than 2 million people a year across 1800 rural counties located in 47 states and 2 territories. This program provides that community members and medical staff trained on issues related to opioid prescribing using the naloxone to reverse overdoses and on mental health first aid.

This past August the Substance Abuse and Mental Health Services Administration awarded 1.4 million to create improvements in access to overdose treatment. SAMHSA aims to expand access to naloxone and other FDA-approved overdose reversal medications for emergency treatment of known or suspected opioid overdose.

I now want to turn to some other important activities, starting with health coverage and access to care. The Centers for Medicare and Medicaid Services launched a five-million-dollar pilot to conduct rural-focused outreach and health insurance enrollment activities during this open enrollment period. These resources facilitate mobile and virtual outreach in rural communities and expand in-person appointments in more rural areas. HHS is also supporting rural hospitals by helping them avoid closure, offering a new provider type in 2023, the Rural Emergency Hospital Entity.

At the National Institutes of Health along with other HHS agencies supported the implementation of the first ever federal evidence agenda on lesbian, gay, bisexual, transgender, queer, and intersect equity to improve the lives of Americans, built federal capacity for data collection about sexual orientation, gender identity, and sex characteristics or SOGI data in advanced equity.

We also have some significant progress in access and treatment for mental health. SAMHSA supported 59.4 million in new funding to states and territories through the Community and Mental Health Services Block Grant program and SAMHSA has expanded the 988 Suicide and Crisis Lifeline by introducing American sign language services, enhancing accessibility for people who are deaf and hard of hearing.

Maternal health continues to be a priority for the Secretary and for HHS. Our country's maternal

mortality rate is the highest of any developed nation in the world and more than double that of peer countries. In alignment with the White House Blueprint for Addressing the Maternal Health Crisis, HHS has mobilized significant funds to address access to maternal health services across the country. In this last year, HRSA approved 90 million in grant awards to support the White House Blueprint for Addressing the Maternal Health Crisis to address maternal mortality and improve maternal and infant health, particularly in underserved communities. They awarded more than 65 million to 35 HRSA-funded health centers to address maternal mortality and the Federal Office of Rural Health Policy continues to fund Rural Maternity and Obstetrics Management Strategies program.

HHS has recently launched a health workforce initiative with the goal to support, strengthen, and grow the health workforce by leveraging programs across the department. This new initiative represents a 2.7-billion-dollar workforce investment proposed in the President's FY24 budget for HRSA. The initiative is focused on federal investments to support individuals across health workforce disciplines, including physicians, nurses, dentists, behavioral health care providers, community health workers, peer support specialists, and many others who dedicate their careers to improving the nation's health and well-being.

You may have noticed on Monday, President Biden convened the first meeting of his Supply Chain Resilience Council. HHS is a key member of the council and plays a vital role in the public health supply chain and industrial base. HHS accomplishes these responsibilities by supporting the advanced development and access of critical medical products and foods, promoting adoption and enforcement of regulatory standards, and by partnering and communicating with industry, patients, global partners, and other stakeholders to enhance supply chain visibility and to develop solutions to supply chain challenges.

A couple of the many actions HHS is taking to strengthen the US public health supply chain and address emerging supply chain challenges includes FDA, taking multiple steps to address areas of the health care supply chain, including by collecting and making available more data of product quality and compliance. FDA is in the process of developing a quality management maturity program intended to incentivize drug makers to invest in quality measures.

In September, the administration for Strategic Preparedness and Response announced a large investment of 600 million across 12 domestic COVID-19 test manufacturers to deliver tests across the country. In a July proposed rule, CMS commented on separate payments under the inpatient perspective payment system to establish and maintain access to a buffer stock for so-called strategic or safety stock of one or more of 86 essential medicines to foster a more reliable and resilient supply.

Based upon the comments, CMS did not pursue a payment policy in the final rule that was just published but they have agreed with commenters that a multi-faceted approach is necessary to address the underlying issues in the future and will continue to look for more comprehensive ways to address this.

And of course, I would be remiss not to mention the extensive research that ASPE has conducted to support advances in this space over the past few years, including work examining the supply chains for retail, pharmacy drugs. We have summarized the impact of drug shortages on consumer costs and described the relationship between drug shortages in the US and other countries. We continue to do important work in this area.

The Office of the Assistant Secretary for Health released a draft framework at the end of June to support and accelerate smoking cessation, building on supports that are already in place for people who want to quit. This framework will be a roadmap to enhance collaboration and coordination across HHS and with federal and non-federal stakeholders.

Complementing US playbook to address social determinants of health, the department issued a call to action, urging collaborative community-level efforts to address health-related social needs. It calls on cross-sector partnerships to create equitable, integrated, and health and social care systems.

There are a couple of CMS rulemaking I think that would be particularly of interest to this group. For calendar year 2024, CMS is proposing coding and payment changes to better account for resources involved in furnishing patient-centered care, involving a multi-disciplinary team of clinical staff and other auxiliary personnel. These proposed services are aligned with the HHS Social Determinants of Health Action Plan and help implement the Biden-Harris Moonshot goal of every American with cancer having access to covered patient navigation services.

For calendar year 2024, CMS is proposing to add health and well-being coaching services to the Medicare telehealth service list on a temporary basis and social determinants of health risk assessments on a permanent basis.

In addition, CMS has proposed a refined process to analyze requests received to addition of services to the Medicare telehealth services list.

CMS finalized a rulemaking for the Medicare physician fee schedule that will implement a separate add-on payment for health care common procedure coding system HCPCS code G22.11. This add-on code will better recognize the resource costs associated with E&M visits for primary care and longitudinal care of complex patients. It will be applicable for outpatient office visits as an additional payment. CMS is proposing to implement several telehealth-related provisions of the Consolidated Appropriations Act, including the temporary expansion of the scope of telehealth, originating sites for services furnished via telehealth to include any site in the US where the beneficiary is located at the time of service, including an individual's home.

I will talk a little bit about some ASPE activities. In late October, an interagency technical working group convened by OMB delivered final recommendations for revisions to the standards for maintaining, collecting, and presenting federal data on race and ethnicity or statistical policy directive 15 to the chief statistician of the US. Staff from NCHS, HHS' statistical agency, and our evaluation officer, who works for me, represented HHS on the working group. The recommendations related to content, included using a single question to gather information about race and ethnicity rather than the two-question format currently used, creating a separate minimum race category for Middle East and North Africa, which would remove reference to population from the white category, requiring detailed race or ethnicity data by default rather than the current requirement for the reporting on only the minimum race categories and a number of terminology changes to update the language, improve clarity, and remove outdated and offensive terms.

The workgroup included recommendations to support a smooth transition from the current standard to the proposed revised standard. The chief statistician will consider these recommendations and is expected to publish the decision in the summer of 2024.

The HHS Data Council, which is co-chaired between ASPE and NCHS, has a number of working groups, focused on I think relevant tasks. There is a data linkage working group, developing a document outlining the benefits of linking data, different strategies for linking data and common issues and considerations for protecting respondent privacy when linking records.

There is a group looking at modeling strategies for multiple response option questions, demographic categories and data harmonization and data modernization work group.

I will just highlight a handful of recent ASPE report releases. The first is health coverage under the Affordable Care Act, current enrollment trends, and state estimates, which provides current estimates of enrollment and health insurance coverage, obtained through the Affordable Care Act marketplaces, Medicare Expansion, and the CHIP program.

As of early 2023, more than 40 million Americans have coverage under the ACA, the highest total on record. A recent study on substance abuse and substance use disorders by race and ethnicity, an environmental scan laying out best practices for COVID vaccination and testing, and a study on trends in ownership structures of US nursing homes and the relationship with facility traits and quality of care. And then just on Monday, ASPE released the state and local estimates of the uninsured population that I talked about earlier.

At our last meeting, some of you asked about the new FDA Digital Health Advisory Committee and expressed the importance of coordinating with them. Indeed, FDA is seeking voting members with areas of expertise, some of which are similar to NCVHS, and these include transparency and labeling considerations for opaque box algorithms, artificial intelligence and machine learning, postmarket monitoring of digital health technologies, patient experience with DHTs, digital therapeutics and diagnostics and device software intended to treat, diagnose, cure, or mitigate a medical condition, patient-generated health data, wearables, remote patient monitoring, and connected care, real-world data and real-world evidence, decentralized clinical trials, personalized medicine and genetics, interoperability, cybersecurity best practices and software development, and medical extended reality, including augmented reality and virtual reality, technical and clinical questions.

Applications for voting members in those areas are due Monday December 11. Please spread the word if you know somebody who may be interested or apply yourself if you are interested. FDA anticipates the advisory committee will meet once a year or at most twice on specific policy topics. If you are interested, search online for FDA and the Digital Health Advisory Committee and you will find further information about the committee and a link to the application process.

Since our last meeting, Margaret Skurka and Melinda Goldstein have rolled off at the end of their terms last month. And I am sad to say that this will be Rich Landen's last meeting as a member of our committee after eight years of service. We really appreciate the tremendous contribution of all three.

Rich, I want you to know that we are incredibly grateful for your service and hope that you have found working with the Department and the Committee a challenging and rewarding professional experience.

In light of this, I want to remind folks that we are always looking for qualified new members with appropriate expertise that can serve on the committee. One important way we recruit members is through you, the people who best know what the committee works on. Keep in mind that we

are looking for a wide diversity of talent. Nominate people you think would be an asset to the committee and the department and that you would want to work together with going forward. There is now a section of the NCVHS website with the title about membership and you can direct any interested parties to information there about how to nominate themselves or a colleague.

This brings us to the end of my prepared remarks. There was a lot here I know. I would be happy to answer any questions you have. I want to give a shout out to Maya and others on our staff who helped prepare these remarks. Thank you very much.

Valerie Watzlaf: Hi Sharon. Thank you so much for that update. You actually reminded me to order my COVID test. Thank you.

I just had a question around everything that HHS is doing in conjunction with the White House, focus on AI and where you might see the committee's role I think specifically as it applies to health care, public health, and possibly research methods, working with surveillance data that might be biased. Do you have any feedback on that for us that we could focus on?

Sharon Arnold: I think the session this afternoon will be a really good opportunity to hear what is going on and maybe pose some questions about what might be helpful. I think we want to make sure that whatever the committee does is in collaboration with others across HHS. I hesitate to make any recommendations in advance of that presentation and discussion. But we should definitely look into that because I think it is a really critical area.

Jacki Monson: Two questions. How long do you think the COVID test will be free?

Sharon Arnold: I think as long as we have supply.

Jacki Monson: The second question is did HHS commit any funds to the SDH partnership in health care to build the platforms to reach out for referrals. I think the community orgs saw an increased need for resources to meet this need. Is there any plan to fund that?

Sharon Arnold: I do not know. I will need to check that out and get back to you. I do know that resources are scarce. In the Department, we have a CR fund. The budget situation is still somewhat uncertain in the future. I do not know at this point but we can check that and get back to you.

Lenel James: Sharon, you mentioned the Office of the Chief Statistician and the changes to the race and ethnicity coding. Can you clarify anything on the timing or resources for that, given obviously all the places and terminology that need to be touched? For example, at HL7, there is a CDC race and ethnicity code set that both the Blue Cross Blue Shield Association and NCQA have been looking at as part of some of the quality reporting related to race and ethnicity. There are definitely some substantive system changes so trying to make sure I have a better understanding of the timing and resources for moving forward for such a dramatic change.

Sharon Arnold: We expect the chief statistician of the US to come out with recommendations next summer. Those recommendations will include a schedule for transition. I think our recommendation or the committee, not ours, but the committee's recommendation was to recognize and appreciate all of the changes that need to be made and recommend a schedule that is commensurate with the significant number of changes that need to be made. We do not

know at this point what the instructions will be and obviously what kind of resources will be available to support those changes. But the committee members did recognize the tremendous changes that needed to be made as a result. We will hear more next summer. I think August.

Lenel James: Thank you very much.

Sharon Arnold: No other questions. Jacki, I will turn it back to you. Thank you so much.

Jacki Monson: Thank you. And Rebecca, is Denise back? Can we quick read her in?

Rebecca Hines: Yes. Good morning, Denise. Glad you are back with us. If you would like to read yourself into the record, that would be perfect in terms of timing.

Denise Chrysler: Denise Chrysler. I am with the Network for Public Health Law. I am on the Full Committee and on the Privacy, Confidentiality, and Security Subcommittee and I have no conflicts. I will be sitting in my office in a second.

Rebecca Hines: Great. Glad you could join us. Thank you.

Jacki Monson: Thanks, Denise. And again, Sharon, thanks so much for your very robust update.

Jamie, I am going to turn it over to you to talk about ICD-11 and lead the crew.

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

Jamie Ferguson: Perfect. Thank you so much. Let me first explain how this section of the meeting is going to run. First, I will give an overview of the first phase of work and I will fly through some slides on that.

Then we have several members of the workgroup who will talk about their experience and their outlook from their particular areas of expertise and perspectives. Then after that, I will come back and I will talk about the next phase of work, what is coming up in the future, and then we will have a good amount of time for committee discussion and a question-and-answer period.

Rebecca Hines: Jamie, let me just pop in just to say that there are also two federal representatives who are not members of the workgroup as part of that panel.

Jamie Ferguson: Yes. Thank you. I should have said workgroup members and participants. They certainly have been participating.

And then let me also point out that in the materials that were distributed to the committee is a draft report of findings from Phase 1 of the workgroup. This report when final will be published on the website. We just need to go through. It is actually out for final edits and formatting now. But you have the draft report in the meeting materials.

Probably everyone on the call knows this but ICD-11 was adopted by WHO in 2019. It became effective for implementation at the beginning of ’22. We typically talk about three primary uses of ICD-11. One is for mortality reporting, cause of death. This is done by NCHS. We had a report on that in a previous committee meeting.

Then there are a number of use cases of coding morbidity for health care, public health, quality, and safety reporting, medical records and many other purposes. And then of course there is the coding for reimbursement in fee-for-service medicine and for billing and payment. And this is where the adoption of ICD-11 would be important as a HIPAA-mandated medical code set.

The committee has, of course, a long history of activities around ICD-11 going back to an expert roundtable in 2019, followed by two letters of recommendation that we have reviewed and talked about many times. I just wanted to point out this history.

And the goals for US implementation. Overall, the committee wants to develop advice and recommendations to the department regarding adoption of ICD-11. We seek to avoid some of the issues that characterize the transition from ICD-9 to ICD-10. We want to ensure a smooth a transition as possible.

We want to identify the work that is needed to avoid the need for a clinical modification, and we will have a chance to talk about that in more detail. And then of course, we want to identify what it is that needs to be communicated to the industry and government I should say to foster stakeholder engagement and preparation for the transition.

Overall, in the first phase of work, we were able to recruit an onboard and orient our workgroup members. We gained shared understanding of ICD-11 context and status and what would be required in order to make it work. And we identified also divergent viewpoints from some different stakeholders.

We conducted an environmental scan of ICD-11 research that has been done to date and of course reviewed the prior NCVHS work. We had a first RFI that was published in the Federal Register on June 13th and we analyzed those responses and developed some proposed next steps for Full Committee review. We talked about that in our last – perhaps the meeting before last.

And then a very important event. We had an expert roundtable with about 50 people that gathered perspectives on key questions from experts in a wide variety of stakeholder interest areas and groups. We had several different breakout groups that developed and discussed new ideas for future work. And then we used all of that expert input and committee input and public input in developing a second RFI, which is the one that, as Rebecca mentioned a little while ago – this is currently out for comment. Comments are due January 12. It was published back on October 16 with a 90-day comment period. We also were able to draft this report of findings from the first phase of work that I discussed earlier.

I wanted to spend a minute and I am actually going to read this slide because it is important to understand what some of the themes were that came out of the expert roundtable discussions. We found that ICD-11 clearly presents opportunities and potential for supporting modernization, potential for burden reduction, potential for automation and transformation to a fully digital health care data infrastructure.

But we also found that there is a need for substantially improved or increased coordination in governance and funding. It is a very important thing that came up that we will hear about today is the maintenance processes that have to be very well understood and managed for the US. It is going to be different for ICD-11 than it has been for ICD-10 and 10-CM.

More content analysis clearly also is needed. The content analysis of how – we have different options for how to achieve the level of content coverage that we need. That has an impact on implementation approaches as to how we achieve that content coverage.

We found that stakeholders really do not understand and have a good feel for what the technical implementation will be like. It is very difficult to estimate costs at this point. Obviously, more research is needed there.

There was substantial discussion in the expert roundtable about clinical documentation use cases, the role of ICD-11 versus SNOMED, for example, and problem lists in the electronic medical record and other potential new use cases beyond the things that ICD-10-CM is used for. These different use cases are going to need to be analyzed more comprehensively.

And then finally, I will say that because this represents a shift, it is a big shift to a fully digital system based on a semantic network that is updated continuously. The education and workforce challenges cannot be underestimated. The changes could be profound from a workforce perspective. That also needs to be very well understood.

I wanted to just give those themes that came out of the expert roundtable as a starting point for the next part of this discussion. I think that is it for my slides for this section. And then what I would like to do is to turn it over to Dr. Kin-Wah Fung from the National Library of Medicine as the first of our six panelists. Thank you.

Kin-Wah Fung: Thank you, Jamie, for the introduction. The question that I am going to address in my presentation is whether we can avoid a full-fledged clinical modification if you use ICD-11 for morbidity coding. With the significant expansion of content coverage in ICD-11, particularly in the new foundation layer and also the availability of post-coordination coding method, it becomes pertinent to us the question of whether we should still do the same thing as we did for ICD-9 and ICD-10 to create our own US clinical modification for morbidity coding.

My presentation will be based on the collaborative study between the NLM and also NCHS. More details of the study can be found in that paper published in JAMA as referenced in the bottom of the slide.

We started with the sample of 1700 ICD-10-CM codes coming from two samples. The first sample is the most commonly used codes from all chapters, constituting about 900 ICD-10-CM codes. And the second sample is all codes from a specific chapter, which is the chapter of digestive diseases, which constitute about 800 codes.

The first sample can be likened to taking the top half of a cake, which we call the horizontal sample. And the second sample is taking a slice of a cake, which we call the vertical sample. For each of the ICD-10-CM codes in the sample, we will try to map that code to codes in ICD-11, using a waterfall approach. First, we will look for an exact match in the stem codes of the ICD-11 from the MMS, morbidity and mortality statistics linearization. And if we do not find an exact match in the stem code, we will search in the foundation. If we still cannot find an exact match, we will use the ICD-11 post-coordination method to expand the coverage. And if everything fails we will consider using a new ICD-11 code.

Here is the summary of our results. The first column lists all the different steps one through four. And note that in post-coordination in step 3, we further divided it into cases when the

existing extension codes are adequate and the cases in the next row were the cases, which we will need new extension codes on top of the existing extension codes. The central column gives the result of the coverage for each step. In the final column is the cumulative coverage before the waterfall.

What is obvious from this summary is that if we just restrict ourselves to stem codes alone, we can only achieve coverage for about a third of the ICD-10-CM codes. Adding entities in foundation, we expand the coverage by about 10 percent. But what is really game changing is the addition of post-coordination. Even if we only use the existing extension codes in ICD-11, we can already improve and increase the coverage to almost 90 percent of all ICD-10-CM codes. And if we allowed moderate expansion of those extension codes in ICD-11, we could achieve almost 97 percent coverage. And only a small fraction, about 3.9 percent of the codes that we examined, we required brand new stem codes in ICD-11.

The implication of that is that overall the results we think are quite encouraging. We can achieve a high percentage of coverage of ICD-10-CM codes with ICD-11. But we think this probably represents the best-case scenario of replacing ICD-10-CM with ICD-11, so there at least three prerequisites that needs to be satisfied in order to achieve the good results.

The first one obviously is that we need post-coordination. If we cannot do post-coordination, the coverage will drastically drop almost 50 percent. The use of post-coordination has never been tried in ICD coding. This probably will have significant impacts on the development of tooling, on coder education, and also probably can impact coding variability as well.

And also, if you want to support post-coordination, we have to make sure that the other messaging standards and other health data standards are in alignment and also can support compatibility and this support post-coordination. This includes things like FHIR standards and also NCPDP messaging standards as well.

The second prerequisite that we have to satisfy is that in our study, we assume that residual categories between ICD-10-CM and ICD-11, they are equivalent in meaning. If the wording of the categories like – residual categories, by the way, are things like not elsewhere classified and not unspecified codes. We assume that these codes are fully equivalent in our study.

But we have to look very carefully at the residual categories in real life because for them to be really equivalent, we need alignment of the hierarchical structure of the residual codes and also alignment of the coding guidelines as well.

Finally, overall, we have to ensure that inclusions, exclusions, and index in both systems are in alignment in order to achieve this high level of coverage.

In our previous study, we found that almost 10 percent of things that we found matching, there are potential conflicts in the coding guidance's, which may affect the coding, the choice of codes in specific situations. In the most extreme of the coding guideline conflicts, a code can be rendered unmappable in ICD-11.

This is one example that we found due to coding guideline conflicts. There are certain codes in ICD-10-CM that cannot be mapped to ICD-11. This specific code is K56.41 for fecal impaction. In the top half, you can see that in ICD-10-CM, fecal impaction is put under K56, which is paralytic ileus and intestinal obstruction without hernia. There is a specific exclusion for fecal impaction,

which is constipation.

However, in the bottom half, you can see that in ICD-11, constipation is actually put under – is not put under intestinal obstruction. And under constipation, there is an inclusion, which is fecal impaction, which seems to be a perfect match for the code in ICD-10-CM. However, since this is put under constipation, there is direct conflict between the ICD-10-CM code and ICD-11 so we cannot map fecal impaction in ICD-10-CM to ICD-11.

The conclusion of our study – we think that just using the linearization and existing postcoordination capability in ICD-11, we can achieve almost 90 percent of coverage in ICD-10-CM codes that we examined in our study.

We think that it would be a huge, missed opportunity if we embark on creating a full-fledged clinical modification without considering alternative approaches.

This is important because – there are several advantages or benefits of avoiding a clinical modification when we shift to ICD-11. First of all, we can avoid cost of creating and maintaining ICD-11-CM. By passing a clinical modification, we can probably cut years off the preparation we need to shift to ICD-11 for morbidity coding. This will mean that we can adopt ICD-11 earlier and make use of this up-to-date and international medical classification for morbidity coding in the US.

Thirdly, by avoiding a clinical modification, we can avoid potential divergence between the US version of ICD-11 and the international version. Theoretically, when we look back at ICD-10-CM, it should be fully compatible with ICD-10. There should not be any divergence.

However, as we create our own clinical modification, we can see cases in which their divergence like the code E14 for unspecific diabetes mellitus and is not found in ICD-10-CM because in 10-CM, diabetes unspecified is coded as type 2. There are things in ICD-10-CM that is not found in ICD-10. For example, K68 disorders of retroperitoneum are not found in ICD-10. By making sure that there is maximal compatibility between the US version and the international version of ICD-11, we can also make sure that there is full compatibility with health data statistics as well.

Last but not least, if we use directly ICD-11 for modularity coding in the US, we can also make use of the rich meanings and terms in ICD-11 foundation to do good things. For example, we can help alignment with other terminologies such as SNOMED CT.

Note that in the original design of ICD-11, SNOMED CT was supposed to be used directly to build the foundation. However, that was not realized for various reasons. Recently, there has bene renewed interest to align the foundation of ICD-11 with SNOMED CT and there has been a pilot project between ICD and WHO and SNOMED International to map a fraction of the codes from the SNOMED to the ICD-11 Foundation.

Secondly, if we can use the ICD-11, we can further explore possibilities of using, for example, automated coding that can help reduce the burden of practice for clinicians.

I think that is all I have for my presentation. I will be happy to answer questions later on. Thank you.

Jamie Ferguson: Thank you very much, Kin-Wah. I appreciate that greatly.

Next up, we have Mary Stanfill.

Mary Stanfill: Good morning. My name is Mary Stanfill. I am an HIM and an informatics professional. I represent the International Federation for Health Information Management Associations at the WHO Family of International Classifications. I am also a member of the workgroup.

I was asked to talk to you about specifically the community aspect to sustain the ICD work and maintain the governance and that sort of thing. I thought I would start by just – this is the most recent annual meeting of the WHO-FIC, as we finally call it, the WHO Family of International Classifications. This network, which has grown to approximately 300 experts who represent more than 70 countries and bring expertise related specifically to both medicine and science as well as terminology, informatics, formal statistical analyses and classification practices and that sort of thing. Quite a broad group of experts.

I listed on the right here just some of the different working groups and committees, task forces that are used that represent the structure, if you will, and the different entities that are involved in the maintenance process and the development and the governance processes associated with creating, developing, maintaining the ICD. There are three classifications, in fact, that the WHO-FIC is responsible for, one of them being ICD.

I would say that these workgroups are from – they are well orchestrated specifically to facilitate collaboration. They have consistent processes with organized input, quarterly meetings, annual and bi-annual, mid-year meeting and a meeting with a full network, excellent reports and minutes and notes and really good input. Just a good structure and a good process to do that.

There are multiple experts from the United States that represent US interest across these different groups as you look at the different committees. If you have questions about any of these committees and what their responsibilities are, I can give you a quick rundown on that. But there are folks from the US involved in various levels across all of these groups.

For example, Chris Chute from Johns Hopkins has been chairing the Medical Scientific Advisory Committee for a long time. Some of you may know Samson Tu. He has been the chair of the Informatics and Terminology Committee.

And I represent the International Federation of Health Information Management folks, as I said, at both EIC as well as the Morbidity Reference Group. And I can name other individuals from the US across all these different committees and reference groups. I personally know folks that are involved. But I will say that there is a lack of central coordination for these individuals that are working across these different entities.

In terms of the WHO-FIC and how the governance and maintenance of ICD, in particular, there is a maintenance platform and you have a link there directly to that. This is an online tool. It provides a mechanism for broad input to suggest changes, enhancements of the content, both in the classification itself as in the foundation, in the entities that are represented there as well as the reference guide. And anyone can create an account and submit a proposal or make comments on what they see in the classification.

The ICD-11 proposals can be submitted on a particular entity, a code, a concept that is in the foundation as well as I said for the reference guide. And really anyone with an account can do

that. They also can search to see what existing proposals are there.

In the proposal section, there is a proposal section in the user guide that gives information about how to use this proposal mechanism and what needs to be submitted because proposals must be complete to be considered and they are evaluated both for relevance and their rationale.

There are different types of proposals that can be submitted specifically on content enhancement versus plotting a new entity for reading, recurrent entity, maybe a hierarchical change, suggesting a new post-coordination rule. Those kinds of things.

And really the verification process considers – as long as a proposal is complete, then it will be considered and it will be verified specifically considering both the scientific and statistical validity as well as the use case to make sure that any changes are relevant and can be useful. The WHO-FIC network that I previously described provides both national and international expertise to this verification process.

There is no talk of ICD-12. Instead, ICD-11 will be maintained and updated on a regular release schedule. The annual updates will be released that will represent minor changes and these will be things that do not cause a major shift in the statistics.

Major changes, major updates that would be released less frequently on a schedule very intentionally, perhaps every five years. These are things that in fact do have made an impact on statistics and the statistical continuity. It might be a whole new stem code or a new leaf or a new category, new subcategory where it is really going to mean that there has to be some mapping between prior statistics and moving forward. The statistical continuity is key because it is a statistical classification.

There is a need I will say, to some of the conversation and information we glean and where the WHO-FIC network landed after the recent annual meeting in October. There is a need for optimization of the maintenance process. This is a key priority in 2024. In this year, before the end of this year, the Medical and Scientific Advisory Committee, MSAC, they provided advice and recommendations on 56 proposals, which was about double what they have done in the past. The Classification and Statistics Advisory Committee, CSAC, began voting also on the reference guide proposals and their workload surged as well.

There is good recognition. There are increasing numbers of proposals now that ICD-11 version has been accepted and is beginning to be used. They are going to establish a workgroup to improve the process. In fact, the workgroup will be established before the end of 2023 and then the priority focus of that group in 2024 will be to optimize things. For example, simplifying the process, increase the throughput. They want to synchronize. These are the three classifications, in fact, that the WHO-FIC, the Family of International Classifications is responsible for. It includes ICD that we have been discussing. It also includes international – the ICF. And ICHI, which you may or may not be familiar with, which is the International Classification of Health Interventions. All three of those are in there. They are working on synchronizing those in the process for updating all of those.

They also intend – talked about leveraging both of course the national and international stakeholder expertise, a lot of which is represented presently in the WHO-FIC network, as I mentioned, over 300 professionals and experts. And they want to utilize the technical

knowledge of the collaborating centers. Those are some of their goals with the overarching desire to optimize this process and process proposals more quickly, be responsive, that sort of thing. This is what WHO is working on right now.

The other thing that I can tell you is that they very definitely have identified the need for guidance on governance specifically for the different countries on the national linearization. This is a key priority for the WHO-FIC also in 2024. Some of the governance issues are surrounding licensing, creation, maintenance of a national linearization.

And what I can tell you is some of the conversation there is a focus is the foundation that Kin-Wah referenced – the intent is to make sure we do not compromise that core, the foundation itself, and then identify linearization's that are essentially subsets out of that core foundation.

We do expect that some countries very definitely have made it clear that they need a national linearization. Germany, for example, was very explicit about that. The US would not be the only country that is intending our own some sort of national linearization. There are other countries as well. They know that there is a need. WHO is aware that there is a need for guidance on parameters on what is and what is not permitted nationally. I think that there would be working with the WHO-FIC, collaborating with these other countries. There is a great opportunity for us to partner with them and come up with what would work just in terms of parameters, recognizing that the linearization that Germany might use or that Australia might use could be very different from US uses. But they might meet consistent parameters. There is more to come on that, which will likely help influence our approach and what we might be able to do. That is a little of what I was asked to share from the WHO-FIC network, that community on governance and maintenance.

Jamie asked me also to comment on my experience in the workgroup. I can say that it has been extremely rewarding and the group has worked together. We have a lot of variety of experts and interests represented, which is great. It makes for really great conversation. I just commend the chairs, the committee, Jamie, and others and Rebecca's support to make sure that all voices are heard, that we have a point, counterpoint and we are really exploring what the issues are and what the impacts might be and raising these issues up so that they can be addressed.

Jamie Ferguson: Mary, that was wonderful. Thank you so much. I appreciate that.

Next up we have Patrick Romano. Patrick has his own slides.

Patrick Romano: Good morning. Thank you very much. My name is Patrick Romano. I am a general internist and health services researcher based at the University of California Davis Health System, which is actually in Sacramento, California. I have the privilege of serving as co-chair of the World Health Organization Family of International Classifications Quality and Safety Working Group. This is a group of experts in the field of quality and safety. We interact with the morbidity reference group within the WHO-FIC structure that Mary has described just a few minutes ago.

Jamie asked me to share a few thoughts from our experience. This is from the WHO-FIC website, describing the various use cases for ICD-11. I will say that these are basically all the same use cases that we have currently for ICD-10-CM in the US and ICD-10 I should say also.

We have of course certification and reporting of causes of death, morbidity coding and

reporting. Virtually every clinical encounter in the United States get coded with ICD-10-CM codes. Of course, case mix nd diagnosis-related grouping for payment purposes. I am going to focus on the quality and safety use case for really assessing and monitoring the outcomes of health care. But we also have registries. We have the ability to use ICD-11 for monitoring antimicrobial resistance, clinical trials, clinical research, epidemiologic studies and so forth.

Again, my focus will be on the quality and safety use case. Our working group has literally worked on this topic for about a decade as part of the WHO-FIC system. We are pleased to bring this expertise now to the ICD-11 workgroup and the discussions that are just starting to happen under the National Committee for Vital and Health Statistics.

Here are some key features. As we have discussed, ICD-11 has an underlying foundation or semantic knowledge base that provides greater flexibility and greater update ability to manage new medical concepts as they arise.

ICD-11 is based on clustering as a tool to express relationships among diagnoses, using extension codes together with stem codes to better clarify how diagnoses are related to each other.

And the particular application of this to quality and safety is what we call the three-part model for post-coordination to explain bad things that happen to patients, what we call harms, what caused those things, and how they caused them. The harm, the cause, and the mode or mechanism.

We also have robust coding tools with the potential for automated code-building from free text in the EHR. And of course, this is really just at the ground level and I will show one example of it in a minute.

The concept of extension codes. These are add-ons that are attached to a diagnosis to capture the granularity of clinical documentation. Kin-Wah has already described how important this is to the concept of complete coverage in ICD-11. Whereas in ICD-10-CM, we might have separate codes for different literalities or different anatomies, different severities. In ICD-11, we rely on extension codes to capture these concepts of laterality, severity, histopathology, specific infectious agents, for example, species within a genus, specific substances, the anatomy or the course of a condition.

The three-part model for capturing health care-related adverse events really consists of a cause, a health-related activity that is the original cause of an injury or harm, a mode or mechanism by which that cause operationalized the harm, led to the harm, and then finally, what was the harm itself. What were the harmful consequences that the patient experienced?

The neat thing about this three-part model is that it allows us to open up the entire code book essentially, the entire spectrum of ICD-11 codes in what we call Chapters 1 through 22 to say that any of these conditions could have been a harm that arose in the course of clinical care. I do provide on many of the slides a reference that describes what I am briefly illustrating in more detail.

Here it is graphically. We can identify health care-related activity that may be the source of the harm. Was it a particular drug, a medicament? Was it a device that was implanted in the person? Was it something that was inserted in the person? Was it a treatment that the patient

received? Perhaps it was a manual treatment such as physical therapy or chiropractic. Was it a procedure as we traditionally think of procedures, operations, or surgical procedures?

And then what was the mode or mechanism? Was it under dosed, over dosed? Was there an accidental perforation? Was the device dislodged or did it malfunction? Was there a mismatch of some blood or blood product in various aspects of care? These events of course lead to harm that can be coded. Again, I refer you to this paper for more details on how it works.

Here is an example. A patient had a left knee replacement less than a year ago because of arthritis, degenerative joint disease. The implanted device has come loose, resulting in pain and reduced function. We have a harm, which is pain in the joint. Which joint? The knee joint. Which knee joint? The left one. We have a series of codes that define that harm.

Then we add the fact that it was an orthopedic device that caused that harm. That is PK99.2. And then we add the mode, which was the device became dislodged or loosened, de-attached. This leads to a cluster of codes that fully describe the clinical event of what happened to the patient.

We have done a little bit of fieldwork to assess how well this three-part model works. This was a very preliminary exercise, and we are in the process of setting up to do more such as field trials. But in this case, we reviewed 45 cases and we found that in 20, we could from the full case story in the medical record identify both the harm cause and the mode. In five cases, it was a near miss. There was no actual harm that the patient experienced but we could classify the cause in mode. And then in 20, there was some missing information about either the cause or the mode.

We have assembled some of our work in a series of papers, which has been published by BMC Informatics and Decision Making. Spotlight on ICD-11. We really encourage those of you who are interested to take a look online. All the papers are accessible for free of course and they provide a variety of perspectives on the uses of quality and safety, the use of ICD-11 particularly for quality and safety.

Finally, some personal observations. This slide illustrates from another paper that Alan Forster led as part of the supplement, how this might work from free-text clinical notes. With the artificial intelligence tools, using natural language processing, we can take a statement like what is described in the upper left here and we can translate that statement into a patient harm, a specific diagnosis, and the cause of that diagnosis. This leads to a cluster that is described here.

In the lower left, you can see how this could work to support incident reporting software within health care organizations as well as potentially reporting to accrediting organizations at CMS and so forth.

We believe that ICD-11 will create new opportunities for tracking and understanding harms that patients experience in health care. That allows linkage of the outcomes of care with specific process failures or quality improvement opportunities. And ICD-11 is designed for compatibility with AHRQ's Common Formats and other tools for describing patient safety events. It has the potential to catalyze global advances in patient safety surveillance, as my colleagues have described in this paper.

I think that is my last slide. Thank you very much and I will take questions at the end.

Jamie Ferguson: Patrick, thank you so much. That was very informative.

Next up we have Carmela Couderc from ONC.

Carmela Couderc: Hi. Good morning, everyone. My name is Carmela Couderc and I am a branch chief of Terminology and Content Delivery in the Standards Division at ONC. In my spare time, I am also a co-chair of the HL7 Terminology Infrastructure Workgroup.

Today I have been asked to talk to you about my experience in the workgroup and also interoperability considerations related to ICD-11 and health information technology. I am going to start off with my experience in the workgroup. I would like to echo everything that Mary said a little bit ago. I agree with her that it was a very well-led workgroup, and the co-chairs definitely fostered a positive collaborative and respectful environment where everyone felt free to share their expertise. I also learned a lot. It was my first time participating in a workgroup with NCVHS. I am looking forward to more work with the workgroup.

A very quick overview of ONC. We are part of the Department of Health and Human Services, and we received a great overview of everything that HHS has been doing recently. I found that very interesting. But ONC's mission is to create systemic improvements in health and care through the access, exchange, and use of data. Our vision is for better health enabled by data. Already we can see where ICD-11 could fit in there.

The way we achieve our mission, and our vision is by focusing on priorities such as building a digital health foundation for health IT, by making interoperability easy. I guess easy is relative. But there it is.

Now of course, the use of standard code systems – I tend to bunch even the ICD – even the statistical classification into code systems – HL7 calls them code systems and sometimes we hear code sets as well.

ONC focuses on standards, certification, and exchange across federal, state, and public landscapes. We do this by encouraging the advancement of health IT capabilities and establishing expectations for data sharing.

Along with finalizing rules, some of you might be familiar with the recent proposed rule we put out in the spring, HTI-1. We also steward the United States Core Data for Interoperability, which is a data standard that defines a core set of data that certified health IT modules must be capable of exchanging. When I say certified health IT modules, those are – that is software created by the developers that participate in our voluntary certification program.

There are over 100 data elements in USCDI, which is really a very small subset of all potential data elements that might be exchanged in health IT. However, there are four that are required to exchange ICD-10-CM today. For a reason for a medication being prescribed or a reason for a referral or problems or encounter diagnosis, ICD-10-CM must be exchanged and these data elements would be candidates to update to include ICD-11.

Jamie mentioned SNOMED-CT earlier. For these same data elements, certified health IT must also be able to exchange SNOMED-CT.

As ONC considers and evaluates the impact of adopting ICD-11 and health IT, we think about

aligning with the mission and vision. We think about transition implications on providers and on software developers with the hope that the impact on providers on frontline providers of health care and workflows. And you think about when you go to your doctor for your physical or something like that, the fact that ICD-11 might be exchanged as a result of that data collection should have minimal impact on a provider.

And of course, we are – coordination is in our name. We are always working to coordinate with our other federal partners. We heard from folks from CMS yesterday. We also mention the requirement that ICD-11 would have to become a HIPAA-required code system. And when that does happen, ONC would support that.

The other thing that we work on is evaluating interoperability technical challenges. Not only the policy part of when we want to move to ICD-11 but the technical challenges. We have already talked about post-coordination and cluster codes. We know that the HL7 exchange standards already support that. Dan Vreeman mentioned that yesterday. The reason why is because SNOMED-CT has supported post-coordinated expressions for a long time.

We think about linearization. Mary mentioned that. We also think about HL7 FHIR terminology server capabilities. Do we have an opportunity to make ICD-11 available via standard terminology services?

When we think about ICD-11, we also think about impacts on things like the International Patient Summary, the ability to exchange ICD-11 statistical codes along with SNOMED-CT on an international basis so cross boundary. That is very exciting.

Other secondary uses we think about. Patrick just talked about quality measures. Clinical trials research and registries. We know there are a lot of projects in play. There have been pilots to see how we can use data collected in an EHR directly in – have it flow to registries and to clinical trials and things like that.

We work closely with HL7. We support the recently announced formal collaboration with WHO. These are all the kinds of things that ONC is keeping a very close eye on as we move forward with potential adoption.

I provided some links on this slide so you can go into more detail about some of the things I talked about. There is one link on here. There were two links that I did not really talk about. One is to a program that extends USCDI and that is called USCDI+. Those are also very use case specific data standards and more opportunity to use ICD-11. And then also, I provided a link where you can take a look at our proposed rule, HTI-1.

And then here is some contact information for you. I encourage you to follow us on LinkedIn, on X, and also there are YouTube videos out there about ONC. Thank you very much and I look forward to your questions later on.

Jamie Ferguson: Great. Carmela, thank you so much. Always great to hear from ONC's perspective. I appreciate your participation.

Next, let me turn it to Vickie Mays. And Vickie, your slides are up.

Vickie Mays: Thank you, Jamie. One of the things that Jamie asked us to think about is this issue

of our experience. In thinking about our experience on the workgroup, let me just reflect that I am trained as a clinical psychologist who is also a health policy person.

In thinking about ICD-11, I really see it as a very significant pathway into trying to address health equity issues and in particular with a lot of the work, which I will talk about in here, improve treatment care for mental, behavioral, and developmental disorders.

The question of my experience. Usually when participating in groups, it is a decision for me about making an investment. There is a lot for this group in terms of making an investment because it started out as NCVHS as actually standing on former work that we have done in this area.

One of the things that I was particularly pleased about is that we sent a letter to the Secretary in 2021 and it said investigate whether ICD-11 social determinant codes adequately capture the most important social risk factors needed across a diversity of populations in order to achieve goals of health equity. There is also a need to determine how these codes in support of achieving health equity can be effectively collected and utilized. That is a problem that still exists, and I am going to talk a little bit more about. But the goal and the intention that is invested in our workgroup is something that I just find will potentially lead us to answer this question and hopefully to bring about some change.

The other thing that was important for me is the ground upon which we stand in terms of choosing the work that we are doing. One of the things that we have had is this scoping document. And what the scoping document did is it really looked at the landscape of a lot of different research to answer the question what other research do we need to be doing in terms of ICD-11. My bias as a researcher comes out because I think what we need to know is the landscape before we, the US, just jump out and say we want to change X and Y.

And then finally is the willingness to really look at mental disorders. And a lot of that is just being in the right place at the right time because the reason that this is one of the areas in which there is so many disorders and so much research that has been done is because at the time that the ICD was in process, there was a change in psychiatry to come up with the new diagnostical and statistical manual, which is a big deal no matter when it is. But it was great to have it going hand in hand along with the ICD.

I am going to start by talking a little bit about the social determinants and ICD-11. It is interesting because some people really think that this notion of social determinants is new to ICD-10 and 11. But we were not necessarily calling them social determinants. But we were looking at what are the factors that impact health status. We were doing that as early as ICD-9. What you will see is that in each version of the ICD, there has actually been an increase in these factors that we want to look at relative to the way they influence health.

The problem is that currently there are if you read the literature, there are people asking questions about why did something that was in 10 not move to 11 and why is something in 11 there. They want to know the basis upon which these decisions are being made. We have growth. I do not know that we have all the scientific answers that we need to fully understand why something is there and not there and the basis upon which it was removed or added. What was the need? What is the question we are trying to answer? That is one thing.

And then the second thing is you are going to see some people particularly when we are

working in the health care landscape, is to talk less about just the social determinant of health but instead want to know about social vulnerability and social risk factors. This got real quite a bit for us when we started to talk about COVID because in COVID, what you saw that one of the most important things that was being asked was not just what is the medical vulnerability that this person has but we wanted to know if there were these social risks that made this person either not be able to get vaccinated or that might be in the context such as dense living, places where water like in our American Indian tribal areas, water might not be available in order to engage in prevention.

What we start to learn, particularly when rubber meets the road, and we are talking about health care, is not just this a social determinant of not having education. But what you are going to see when I show you the ways in which it is displayed, it is more important to know something about the education itself so the social determinants of these very big broad categories. But what you are going to see within the Z codes, the codes that we use, is we start to break it down because what we are needing to understand is not just a missing factor but what we are needing to understand is how to intervene relative to moving you from the primary care setting into those social organizations, et cetera, that can help reduce that risk so that your medical vulnerability has the chance to do better to be maintained kind of thing.

The question we often end up dealing with is what do we do within the context of health care and who does what in terms of social risk. Those are things that are still a little bit up in the air.

A question you also will see in the literature is there is a bunch of Z codes. You are not coding for those Z codes. We have to learn a little bit more about why we are not using them. Is there a training that needs to take place? Is it that it is a burden the way we currently do it? This is where some people will start to talk about the use of AI. There are still a lot of questions in this arena.

This was just to give you in case some people do not know and I just took a slice from this particular article of what do Z codes look like when it is trying to capture those social determinants of health. Things like schooling, unavailable, unattainable. Illiteracy and low-level literacy. And part of what the attempt here to do is to get specific in an identification of the problem so that you can be specific about what the intervention will be.

I am going to show you some work that was going on during the time of the discussion about some of the social determinants of health and what to do in terms of Z codes. This was with ICD-10-CM. We are still struggling as well now that we have gotten to 11. This is some work by Jacobs that was published. Again, I left this so that you ca actually see it.

This came from one of the WHO discussions, but it also is kind of his interpretation as well of other things. If you look at the Z codes, he took an example of what I just said. Illiteracy, low-level literacy, school unavailable, unattainable. But I think he wants to see it get even more specific, less than a high school degree, limited English proficiency, low-level literacy. Again, if you are going to have a fix and you are going to reach out to the community to do a fix, it is better that you have a sense of exactly what it is that you think will help to be on a better trajectory for health. Some of this is still up in the air. People are questioning what we do have, what do not have. But I wanted to make sure you got a good sense of how this – could we use social determinants of health. We really should be talking about social risks and social vulnerabilities in the health care setting.

Here is where there is a ton of research. We are very lucky again, if you want to know what I like about being on here. We have experts in this particular area, not just me, but there are some others. We have federal and individuals who worked with WHO. It is going to help us to address this. Some of these comments on taking directly from some work – Michael First, who is a psychiatrist and Geoffrey Reed, who happens to be on our committee and is a clinical psychologist.

Now, one of the things that happened in the course of ICD-11 is that the new DSM manual and any of you in mental health, you know it is our bible. What happens is that this is where we define what a disorder is, what is needed in order for that to be diagnosed as a disorder, and a lot of other background material.

One of the things that changed is in the past, we would actually diagnose a condition and that diagnosis was based predominantly on symptoms. Typically, what you would have is that an individual would have a disorder and in order to be diagnosed with that disorder, they had to four of these seven things or five of the eight or whatever it is.

One of the things we learned over time is that while that gets us in a category by which that individual has that disorder, we are finding that we need to fine tune this better in order to develop particularly pharmacologic interventions and the category, which changed the most dramatically for which this is probably the most critical is in schizophrenia. We have had a hard time over the decades and the different types of schizophrenia, really being able to go in and make sure that we could come up with which medication works for which groups.

In DSM-V, we have started working towards somewhat of a similar but different approach. Of course, we still do diagnose people. But we also want to get that extra information about what are the underlying mechanisms that are going on here. Can we parse those things out to figure out what a behavioral intervention would be, what a pharmacologic intervention would be and likelihood of maintenance for this individual. What happens in 5 is now also reflected in ICD-11. A lot of work was done to try and have that crosswalk. It is not perfect. There has always been a crosswalk between the two and there still needs to be some work on perfecting that crosswalk.

Here is an example and I took this again from Michael's work. Here is ICD-11 and ICD-10. In ICD-11, I want you to just think about what I am saying. We are focusing on things like traumatic stress disorders, prolonged grief disorders, adjustment disorders. These are things that as you see in ICD-10, we would talk about as reactions to severe stress and adjustment disorders.

What we have done is gotten a lot clearer about the things that we are seeing in society these days. Right now, we have wars going on. We have people being displaced. We have difficulty with people who are unhoused, being able to transition. We have gotten better in terms of seeing stresses as an important component of many disorders. This is an example of the ways in which we have kind of redone some of our thinking and the fact that then the ICD-11 has come along with us on that thinking.

We used to have a cute stress reaction as this mental disorder. We are not doing that in ICD-11. We are dissecting the stress, determining where it goes, and being able to better come up with treatment.

Now, the implications of this in ICD-11 is we need not just only the disorders and the diagnostic category but we need to actually be able to have the capacity to do the research to follow this

along to get better and better at being able to treat mental disorders.

I am going to bring this to a close, but I think that is giving you a sense of both how wonderful I think our workgroup is and the work that is still there for our workgroup to do. Thank you, Jamie, for the opportunity.

Jamie Ferguson: Great. Thank you, Vickie, so much. I appreciate that.

I do have an additional slide or two here. What I would like to point out though is that we had planned to go to a break in just a couple of minutes. With the permission of the chair, we are going to keep this discussion going and we will have the committee discussion into what had been planned on the agenda as our break time and then we will break after that.

I wanted to highlight again the RFI that is currently out for comment. As I think I said earlier, we were able to refocus the questions. We are now asking about what are the content requirements. We are asking several questions about what are the potential opportunities for burden reduction? What are the characteristics that are needed for governance? What is the impact on other standards, workforce, and what are the resources?

I am going to unpack this a little bit more in our discussion. We are now in the second phase of work. We need to finalize the formatting and insert the final edits into our findings report and then that will be up on the website. But we are really into our second phase of work.

In our first phase of work, we had obviously a selection of excellent workgroup members from across a spectrum of different interests. But we identified some gaps in expertise that we had. Specifically, we had some gaps in terms of health records technology, implementation experience, and clinical practice. We were able to recruit and onboard some additional external members to the workgroup. We have done that. We are now in the process of planning and allocating resources for the analysis of the RFI results. We will start that.

Some of the comments have already started to come in and we have had a chance to look at those. But obviously, when all the comments come in after January 12, then we will swing into full gear to analyze the second RFI and to identify some of the potential next steps for our approach and strategy and planning and then we will come back and report to the Full Committee.

Just looking out forward, in the winter and springtime as we analyze that RFI, some of the things we expect if the questions get answered and based on some of the early returns, we expect to get significant input on approaches to coordination of the US with the WHO-FIC and particularly on ICD use cases that might be outside the scope of what we are using 10-CM for. Some of those things might be extended uses for social determinants, health equity measures, pandemic preparedness and so forth.

We wanted to be able to do analysis to confirm the alternative options for the US to avoid a full clinical modification of ICD-11. And we anticipate getting significant input on that in the RFI.

We also expect to get input on identifying how both health plans and provider systems will have to adapt and what the potential opportunities may be for burden reduction through additional automation, for example, in clinical documentation, coding for reimbursement, or public health reporting.

Obviously, the workgroup will come back and report to the Full Committee on that but then guided by the input from the Full Committee and our external experts as well as the interagency participants.

We want to develop additional findings that would comprise some of the strategic options for regulatory adoption and implementation of ICD-11 so that we could report those options and that analysis back to the Full Committee. That may require holding additional hearings or additional expert roundtables to develop those findings on the issues that come up through the RFI and our additional analysis.

Overall, we would like to over the – basically by next summer I would say, we want to be able to inform the Full Committee sufficiently to settle – for the committee to settle some of these issues in terms of its recommended approaches to the clinical modification and addressing code set content needed by the US in order to paint a broad stroke picture, identifying what is different from ICD-10 that needs to be governed by the US government. What is the role of EHRs versus other systems and some of the potential workforce development issues? That would be next summer.

We should be thinking ahead though even further into the future. If we are able to inform the committee sufficiently for the committee to develop those recommendations next summer, then that would pave the way for maybe a third phase of work that would go into the fiscal year, fiscal 2025, for ICD-11 planning in order to identify some of the options for both the technical standards issues, interoperability and governance, but also options for workforce development and communications to develop a fuller plan for implementation. But that would be further in the future after we address those issues that I just described coming back from the RFI.

Now, it is time for committee discussion. This is basically our Q&A with all of our presenters and panelists for the committee and happy to take any questions or comments from the committee.

I see Lenel and then Cathy.

Lenel James: I have a question for Carmela about the challenges of ICD-11 in the collection of the data for race and ethnicity. Specifically, Carmela, in some work that I have been doing at HL7 on tribal affiliations, for example – I want to word this carefully. That the EPA has a very good system for tracking when tribal affiliation nations become active codes versus de-active codes. I am pretty sure at both X12 and NCQA, they have a very robust process for that. As they look at some of the future changes to race and ethnicity, the CDC race code, which is maintained as one of the codes that HL7 puts in its standards. My understanding is that at HL7, the process to allow terminology to have dates specific on and off much like ICD-10 has done is in process. Do you have anymore insight from a standpoint of HL7 and FHIR the ability for code sets to be sunset and updated in a way that is automated for the industry? Sorry for a tough question right off the gate but however you can address it will be much appreciated.

Carmela Couderc: Code systems for exchange in the FHIR model so HL7, FHIR, Fast Healthcare Interoperability Resources. It does acknowledge that there is a status for a code system. There is also versioning available. And when we say versioning – now, this is for exchange. HL7 does not cover the workflow for the internal maintenance of a code system. CDC creates a new version of a code system. That is on them. But the exchange of that code system and the content can be supported in HL7 models. There is a facility to say that any value set drawn from that and the

code system can support that a code – a specific concept code for maybe Caribbean or French could be – is in active. It has been retired or it could be deprecated. Deprecated typically means it is still active but you can – use is discouraged. You can still use it but it is discouraged. All that is handled in those exchange standards.

The HL7 standards are not going to address the internal maintenance modes for those code systems. It addresses the ability to exchange it. Does that answer your question?

Lenel James: Yes. Thank you.

Jamie Ferguson: Thank you very much.

Cathy.

Catherine Donald: I do not have any questions quite as complicated or detailed as that. I just wanted to thank all of the presenters for such thorough presentations on each topic. I know I have heard these before but every time I hear it I take away more little nuggets. I really do appreciate it. I think these were all very worthwhile. Thank you.

Jamie Ferguson: Additional questions from the committee or comments or any of the presenters that want to have a discussion.

Valerie Watzlaf: Thank you. I also want to just echo what Cathy said. Wonderful presentations and thank you. I learned something new every time too.

My question was for Patrick. I do not know if he is still on because I am not sure if he said this or not. I loved how he was showing the quality and safety for ICD-11. I just wondered. I do not think that that was captured right at all in ICD-10-CM. Is that correct, Mary? I think Mary is nodding.

Patrick Romano: In ICD-10, it was possible to code some pieces of what I described. But there was no way to put it together as a cluster and say this is what happened to the patient and this is how it happened and why it happened. That ability to post-coordinate or cluster is what is novel in ICD-11 and gives the power of ICD-11.

Some of you may know, for example, that in ICD-10-CM, we have a whole chapter, two chapters of injury codes. But we actually cannot use those codes to describe health care associated injuries. Those codes are only for injuries that occur in the community. With the post-coordination concept, it unleashes the ability to use injury to codes to say that the person's liver was lacerated, for example, because the surgeon made a mistake in a gall bladder surgery. That is also a new opportunity.

Valerie Watzlaf: Excellent. Thank you so much. I appreciate the clarification. Thank you.

Vickie Mays: I have a question and I do not even know who it belongs to. The question really has to do with we keep coming up with more codes and I am going to talk very specifically of like the social determinants of health and all the Z codes and stuff. But they are not being used. The question for me is who is responsible for increasing utilization? Like do we need to do research to find out if it is education, if it is burden, if it is something else. And then do we have the capacity to be able to talk about what should be like it should be required that every patient

record has these codes done?

Jamie Ferguson: Thank you, Vickie. I can just comment on that from my perspective. I think that is something we are going to have to continue to talk about in the workgroup and with our federal partners. I can tell you that in the past, I have participated in work to study the utilization of all the different codes and concepts in the variety of adopted standard terminologies and coding classification systems with the work that previously was done by ASPE to identify the frequency of use of different codes for comorbidities, for example, and work also that was done in conjunction with NLM to identify the frequency of use of all the different SNOMED codes that are used for the problem list in EMRs and work of that kind. We have an opportunity to consider additional coordination on those studies in the future.

Tammy Feenstra Banks: Incentives are always very helpful – discuss that topic, Vickie. And the value-based care and movement of risk base and different alternative payments. I think there is going to be more opportunity. Now is the time to have that conversation as those get developed.

My question, Jamie – I do not know if it is premature or not. But can anyone speak to how we are looking at automating the use of ICD-11 whether either through coding or I know there is going to be dual reporting. Are there vendors that are making it feasible to be able to code ICD-10 and ICD-11 so that it does not have to be manual? Any input in that front –

Jamie Ferguson: This is one of the key subject areas of questions in the RFI that is currently out for comment. We have had expert opinions on that through the expert roundtable that we had in August. But I think that I want to hold off comments because we anticipate getting a lot of input on that question and the potential for automation and how that might work in terms of the responses to the RFI. At the same time, the additional outside experts that we have added to the workgroup are ones who have significant experience and expertise in exactly those areas. We expect to be able to unpack that and provide a fuller analysis back to the committee next year basically. It is probably in the springtime.

Mary Stanfill: You made the comment. The only thing I would add to that – we are very excited to see that kind of feedback and with the additional workgroup members what we can advance in that respect and Tammy, maybe get some more information on.

I would just say from looking at ICD-11, the ICD-11 digital system is a game changer. It has unique resource identifiers for the first time. All prior ICD versions did not have that. The possibility, the potential from an informatics perspective to be able to automate it. We finally have a system that actually could be done. That is why we are so – we are looking for that input on the RFI. We have added folks to the workgroup. We are really looking forward to exploring that further.

Jamie Ferguson: Thank you very much.

I know that we have blown the schedule out of the water and I apologize for that. But I really appreciate your patience in going through this. Really great to hear from our expert presenters. Thank you so much for all the wonderful information that you provided and thank you, everybody, for the discussion. I think, Jacki, it is back to you.

Jacki Monson: Thank you, Jamie, and thank you, everyone. We are going to take a quick five-

minute break and then we will move into the AI discussion.

Rebecca Hines: Thanks, Jacki. We will be back basically at 12:17, 12:18 to get started. We will have almost a full hour. See you all in five.

(Break)

Artificial Intelligence (AI) in Healthcare

Jacki Monson: Let us go ahead and get started. This is really a follow up to the July discussion that we had around AI where we just did not have enough time with Travis to ask questions. He is back along with Grail, who is with us today to allow a deeper dive into AI and to some of the policy movement that has happened that is publicly available.

Grail Sipes is the assistant director for Biomedical Regulatory Policy and the Health Outcomes Division of the Office of Science and Technology Policy at the White House. Her portfolio includes clinical trial infrastructure, related preparedness issues, and other matters related to the development and marketing of medical products.

For the ten years prior to her work at OSTP, Ms. Sipes has worked in a variety of roles at the FDA, most recently serving as the deputy director for regulatory policy in FDA's Center for Drug Evaluation Research. At FDA, she worked on a wide range of matters involving drug and other FDA-regulated products, including reproductive health, drug pricing access, drug shortage, digital health, and First Amendment challenges to regulation.

At FDA and OSTP, Grail's role has been to develop effective public health strategies and policies in light of the evolving science, differing stakeholder viewpoints and various regulatory challenges. Prior to FDA, she was a practicing lawyer in private practice.

Today, she is going to talk about the president's October executive order on artificial intelligence and tell us about the October 6 Roundtable on AI and Health.

Second, we have with us Travis Hoppe. The committee heard from Travis in the last meeting, which piqued our interest and wanting to have more dialogue and discussion with him. We asked him to come back. Dr. Hoppe is the associate director of Data Science and Analytics at the National Center for Health Statistics where he has served since September 2020.

Prior to that, he was a data scientist at NIH, following two postdocs at the National Institute of Diabetes and Digestive and Kidney Diseases. He will soon be joining Grail at the Office of Science and Technology Policy for a one-year detail to continue his work on AI.

Travis is going to talk about the capabilities of generative AI and what steps CDC is already taking towards implementation of the executive order. He is also going to touch on OMB's November 30 request for comments on advancing governance innovation and risk management for agency use of artificial intelligence for which comments are due on December 5, which is next week.

Without further ado, introduce both of these individuals and really looking forward to the discussion.

Grail Sipes: Thank you very much to everyone for being here. I am really grateful to have the opportunity to speak and team up with Travis here. I just wanted to say a word in getting started about the Office of Science and Technology Policy and what we do.

The Office of Science and Technology Policy is an office within the White House, which is a large place. It contains many different offices and councils, as you know. The director of the Office of Science and Technology Policy is Dr. Arati Prabhakar. She is a former director of DARPA and also of NIST. She has a tremendous interest in – she is the top science and technology policy advisor to the president and she has a tremendous interest particularly in artificial intelligence, which lines up very well with the administration's interest in that area.

I am in the health outcomes division. Improving health outcomes is another very important focus for the Office and Technology Policy. As we get through the presentation today, you will see how some of those things dovetail.

OSTP is the home among other things of the National AI Initiative Office. There are a number of other divisions within the office, including a large tech team, which also works on artificial intelligence issues.

With that preamble, I will just jump into – what I am basically going to talk about today is first, I am going to give a high-level overview of the executive order that came out on October 30 and some of the events that led up to that within the administration. I am going to focus in particular on some of the aspects of the executive order that relate to the use of AI in health care. And then, as was just mentioned at the top, I am going to spend a few minutes describing a roundtable on the use of AI in health and health care that was hosted on October 3 by the Health Outcomes Division of OSTP, which is a really interesting event where we got a lot of great input.

As many of you know, the administration's interest in and commitment to leveraging AI and mitigating the risks that come along with this developing technology goes back a long way. We have issued the blueprint for an AI bill of rights in October of 2022, which sets forth five principles to guide the responsible use of AI.

Then among other things, there have been a series of voluntary commitments that the administration has obtained as a bridge to regulation over the course of this year primarily. I believe we now have voluntary commitments from 15 leading AI companies to ensure that their AI technology is safe, secure, and trustworthy before it is released to the public. It is very important to have that alignment. That was a major piece of the administration's approach here.

Now, we have before us the executive order that came out on October 30 on artificial intelligence. It is one of the longest and most comprehensive executive orders in the history of the US. It reflects a tremendous amount of work and it really I think reflects the expertise across the administration and the interest and the strong approach to getting ahead of the challenges of AI while taking advantage of the benefits.

And alongside the EO or rather springing from the EO, one of the things that executive order did was to direct the Office of Management and Budget to issue a draft policy on the use of AI by the Federal Government. That work really expands on the AI bill of rights, the blueprint for the AI bill of rights in many ways. It has a number of goals. One is to strengthen the governance of

AI. Another is to advance responsible innovation in this space and finally to manage risk by directing agencies to adopt clearer safeguards for the use of any AI technology that will impact public safety or the rights of the public.

I think, as was mentioned at the top, that memo is currently – that draft policy is currently out for comment, soliciting comment until December 5. You can find all of this information – you probably know already but there is a new website that is a tremendous resource, AI.gov. Very easy to remember. All the stuff is up there. The executive order, the OMB memo, and many other resources and updates on what is going on in this space.

I guess what I would just say about these documents briefly before diving into the health-related provisions is that we see the government taking a very practical approach here and trying to focus from the safety perspective on mitigating some of the harms that we can currently anticipate as we look at the many different potential benefits and applications of AI.

There is also a strong desire and this has been articulated by OSTP by our director in testimony and before Congress and by many others in the administration that further action from Congress is needed to really ensure that agencies have all of the authorities and resources that are needed to take full advantage of the potential of AI in protecting its risks and the administration really appreciates the interest and involvement of Congress in looking at this issue. We will continue to work with them cooperatively on that.

But the executive order, which works with the existing authorities that agencies have, is a very important first step. There is a really strong emphasis in the executive order on agency accountability and there is a hope and an expectation that as agencies implement the executive order that they will serve as a model for responsible development in use of AI across different sectors. That is an extremely important aspect of what is going on with this executive order.

I am now going to focus in a little bit more on the provisions of the executive order that relates to the use of AI in health care and that is primarily in Section 8 of the executive order. I am just going to run through a few of the provisions that relate primarily to HHS because it is interesting to see how the executive order set this up.

Obviously, there is a lot of potential for very positive use cases and applications of AI in health care, some of which are already well under way and in full swing. But there are also a lot of concerns about potential risks, including the need to address discrimination, risk of discrimination, the risk of misdiagnosis just to name a couple of things.

The executive order directs HHS to do a number of things. One of them is to set up an AI taskforce within 90 days of the date of the order and then within a year of being set up, that taskforce needs to put together a strategy to identify guidance and potential regulation in a series of five years, which I will just mention briefly. And all of these are oriented toward advancing the safe use of AI in health care.

The first of the five is to look at the use of predictive and generative AI both in health care delivery and health care financing. The second is to look at the long-term safety and monitoring of AI technologies in health and human services and that includes a very strong emphasis on incorporating principles of equity in the deployment of AI and reducing administrative burdens associated with it.

The third element is to look at the safety and security of software development in the AI context and obviously the implications there include privacy and cybersecurity among others.

The fourth item is to have a strategy for documentation for users of AI in local settings, which is going to be extremely important just as one example as health care providers and others interpret and use AI in health care.

And then the fifth element is to work together with the SLTTs, with state and local governments and with the territories and the tribal authorities to advance positive use cases of AI and again there is a very important sense in which – if AI is going to be deployed across a variety of environments and settings in this country, we really have to think about equity and how that will play out in different use cases. Those are some of the main focuses for the taskforce at HHS and the safe use of AI generally.

There is also a particular focus on the use of AI in drug development. This is something that we have been looking at very closely within my division in OSTP because of the connection to health outcomes and trying to improve those by speeding the delivery of treatments to people who need them among other things.

Just to mention a couple of the potential applications, AI can help with the design of new molecules for study and for further development. AI can be deployed obviously to analyze large data sets and draw inferences from them and ultimately to make drug development cheaper, for example, by predicting the best ways to test them and to try and streamline the clinical development process, clinical trial process, which is currently an extremely costly and not always very efficient process. There is a huge amount of potential for the use of AI there.

The executive order directs HHS within one year of the order to develop a strategy for regulating the use of AI in drug development. That strategy needs to be key to how each phase of drug development should be regulated, areas for future rulemaking and guidance and also looking at what kind of budget considerations play into the establishment of a regulatory system here. I think all of those are really important considerations that I think HHS is going to be looking at very closely. Those are some key things for drug development.

Just a few more things from the executive order that I think are important to mention in this context at a more general level. HHS has 180 days from the date of the order to develop a strategy to determine whether and how AI-based technologies in the health care space are maintaining their quality and to also set up a safety program to both capture clinical errors that track back to these AI technologies and also to develop a strategy to remedy them. Obviously, that is going to be extremely important and that lines up with some of the key functions of HHS and their mission as an agency. That is very important.

And they also have within 180 days to develop a strategy to advance the application of federal and non-discrimination laws in the AI sector so to make clear how those nondiscrimination laws will apply to AI. Those are some of the key provisions.

And then the last thing with regard to health – the last thing that I wanted to mention is to talk about a roundtable that we had on October 3 at the White House, which was a really interesting and energizing event I think for all of us. We convened a large group of people from a number of sectors, including health care, academic researchers, industry, a lot of people from industry and many patient advocates to talk about the safe deployment of AI in health care and specifically to

improve health outcomes.

We were looking for success stories, cautionary tales and any kind of input that people could bring to really expand our understanding of the benefits and risks currently in this space and also to make sure that we had the latest in terms of ideas from this group of people about how to responsibly develop AI models in this space.

We had three specific use cases that we worked on in working sessions with this group of people. One of them had to do with the use of AI in clinical settings so patient care, diagnosis, treatment. As I mentioned, these are some of the settings where the use of AI is the most developed right now. There was a lot to talk about there.

We had a working session on drug development. As I mentioned, the focus there was on trying to streamline and make more efficient both the discovery – the development of new molecules so the discovery of new drugs and the testing of new drugs in a research setting, including clinical research to arrive at more effective treatments hopefully more quickly.

And then the third working session was focused on public health and the mitigation of public health challenges, improving access, and supporting decision making in this space. This was a very interesting area, as many of you are probably aware. There is a lot of opportunity to use AI in public health surveillance and in other settings, everything like triaging scans to see who is most at risk where resources are limited or just predicting the best outcomes that can be anticipated across a population. AI can be extremely helpful in settings like that.

I know the time is limited and Travis had got a fantastic presentation lined up. I am going to stop there and turn it back over to Travis.

Travis Hoppe: Thank you, Grail. That was such an excellent introduction to all the things that we are going to talk about. Grail kind of set the stage for a lot of the high-level things that are happening at the federal level in the White House. I am going to take it down a little bit, which I did last time and I think that was part of the discussion. Give a little bit more of the agency perspective and let me dive right into it.

You may look at this slide deck and say there are too many slides for the time and we do not have enough time for that and the Q&A. I promise you there will be enough time because a lot of these slides are a review from the last time. I thought it was good to throw some of the same ones up there that we had with the same committee meeting to give a reminder.

Last time I met with you was on July 20th. We had some really robust discussions but not enough time. And I think it is good to set the stage again and remind the people on the call where we are at and also some new things have happened in generative AI because this space moves really quickly. I will not spend any time on this as the introduction. I am just leaving it here for keeping it together but really want to point out that CDC ran a conversational AI kind of tiger team internally. We produced an internal report. This has guided a lot of our work. The White House did some amazing work with EO and there are OMB memorandums out there but that took time to come out. Agencies were looking to come up with their own solutions along the way. And what we are doing is integrating both of the work we have done internally and some of the guidance we have at the top.

I do want to point out this out here. There are a lot of definitions here and the definition of AI

has expanded. When people say AI generally, they are now thinking of this thing that we are calling generative AI. I do want to call out that not all AI is generative AI but we are focusing a lot of our work on that mostly for the transformational qualities of generative AI. But the discussions that are in the EO are broad enough to cover all forms of AI and machine learning when interpreted broadly.

This is not a pipe. It is not AI. Not all generative AI is regular AI. I just want to call this out here. These are some excellent definitions of how NIST has really thought about if you need to for a report or look at the definitions between the distinctions of ML, AI, and generative AI as their subsets of each other, these are really nice links for that.

You saw this slide before. This was one that we presented. And a lot of things that Grail mentioned are on here. The blueprint for AI rights, the NIST risk management framework. But I do want to call out some of the new things that have happened here. This is my updated slide. There have been some really exciting things that have gone on both within the White House, both within this thing called the NAIRR, the National AI Research Resource, that has so much interesting stuff. There is an AI use case inventory that is out there and you see this dotted line. These are the new things that really just come out.

There is the EO, which is amazing and there is lots of stuff in there. It is a really long EO. I put a link in the chat for everybody to read. But there is also this draft, OMB memorandum. And for agencies, there is a lot more direct action for us. EO calls out specific things that some agencies have to do. The memorandum calls out things all the agencies have to do. I think if you want to see how we are doing to respond and how we are going to act in accordance with the EO broadly, this memorandum is really good. It is a lot more digestible, I think, to read this one and Grail had mentioned that there are things that we need to consider and there is a distinction between safety and rights impacting in this memorandum. They do not just say that. They actually delineate many different use cases between safety and rights impacting and it is really good. It is really good that they spent a lot of time thinking about this. If you do have an AI use case that is safety or rights impacting, it does not mean do not do it but it is putting up safeguards for us to consider how to do this.

I just wanted to list that there is a previous EO 13960, the trustworthy AI EO, that required all agencies to put together an AI inventory use case and then submit that back up to the department and that gets published. That is online in that AI.gov that Grail mentioned. You can find out all the AI use cases. These are the ones that my home center, the National Center for Health Statistics, that we had put up together that went up to CDC. If you think this is interesting, again, we can talk offline about this for hours. But all agencies have now published their 2023 inventory. There will be a continuing ongoing publishing of these inventories. They are great resources. If you want to look up who is doing what broadly and find context within the different agencies, we have already started using this to build connections with FDA, with CMS, with NIH, kind of our other health care public health care partners.

Really important to that, one thing that we have started doing is – we had to develop guidance. We had to develop policy long before this EO came out. One of the fundamental things behind this is documenting what is happening with your models. We released a single model at NCHS and we do plan on working on more of these.

One of these is creating model cards and model cards are like a recipe book for what is

happening within your model. It looks at a lot of the things that we should be doing, which is is there bias within your model. The answer is always yes. Where is that bias and what is the scope of your model? This is something we have a little bit of work on. I just want to call it out that these sorts of efforts are happening within agencies. We are starting to align these now with the federal guidance that is coming out.

I want to talk a little bit about this because it is super exciting because this is the first time this slide has actually been publicly talked about. But CDC has developed an AI roadmap to move forward. We are still working on this but we do have six pillars of how we are thinking about aligning some of the things in the EO but also things that really are not talked about too much within the memorandum. They mention this but they do not tell us how to do this. This is things like workforce. This is community of practices. This is putting all these different pieces together. Infrastructure developments in cloud AI.

I will not read into a lot of these but I will call out that all of these are now ongoing and they are super exiting. A lot of them are kind of one offs. How do we decide to build the governance structure in place? How do we align it with governance structures that are already in place for things like scientific integrity, for disclosure avoidance. These are things that already exist within our agency but there are unique challenges with AI. It is kind of tying them together.

And then I do have a few slides before we turn it over to Q&A. These are reminders. You have seen these slides before. But they are kind of prompt questions to get you to think about what is happening with generative AI and what should we consider. As a reminder, generative AI will happily report any falsehood if you ask it to do something. Sometimes it says no. Sometimes it will correct you. But there is no guarantee with a lot of the models that are out there right now that it will give you a factually correct answer. In this example, you can ask about something about some ongoing situation in all 60 US states. Here are some facts about all 60 US states. That is a falsehood but it is happy to repeat that.

AI can generate fake references. This is just one of many things. It is called generative AI and that is its job is to generate a thing. This is not a bug of generative AI. This is a feature. These sort of models – people are working on custom models that can be more factually aligned and I have an example, I think, that will prime the discussion for this. But their job is just to generate new pieces of text. And it is our job, as practitioners, to align them for the context of use. They do have limited knowledge windows.

I made it a couple of months ago. The current state of ChatGPT was all the way back to 2021. For CDC, we do care about the fentanyl/xylazine deaths. It did not have any knowledge that this was a public health crisis. They have now pushed that window to 2023 but there will always be some out of dateness with these models and what their knowledge domain is.

I do have a few slides. Again, I am not going to spend too much time on it. But this is from this internal report that we released to staff about the benefits and pitfalls of generative AI. We do see a lot of really interesting things that we can do with it. We can do HR processes. We can develop scope of work. We can definitely help with programming by editing code, adding comments to code, translating from SAS to State to Python to R. That is a huge thing here. Summarizing email. Summarizing meetings. Translating from one language to another especially when there is a time crunch, and you need to put something out to many different groups. Lots of risks associated with those. We touched on some of these. Just because you can do

something does not mean you should do something. We try to delineate between the two of those here.

Again, this is the agency perspective. But I think it applies to everybody within health care. It does not matter if you use generative AI or if you use AI at all. Everybody else will be or at least a large portion of the population will be. You need to anticipate what that use would be from malicious actors to the outside.

Different stakeholders have, I think, different risk profiles. We consider things from a public health perspective. Our friends at the NIH who are working with lots of genetic data might have a different risk profile. But other people will be using it. AI can be used to de-identify people. AI can be used for deep fakes. AI can be used to fake comments or massive amounts of comments. These are things we just, as agencies, need to be considering.

The last thing I want to show you is we had a comment when we presented this last time that generative AI has "tremendous opportunity for expanding the scope of literature review". This is so interesting because I just showed you a slide where AI can make up all these false references. How do these things come together?

Within the last six months, there has been a huge development in these things called RAGs, which are retrieval augmented generation. Just for the committee's sake since we are here to do a little Q&A, I did want to touch on it because I think it is super cool.

Generative AI is really good at a small subset of all the facts that is seeing. If it is seeing something in its training data many times, it can often reproduce it. It knows historical pieces of knowledge because it has seen those many times and it can recreate those. It has seen references so it can create references that would make sense but may not actually be there.

The problem with generative AI – you can give it a document like an abstract or a piece of paper like a scientific paper and say summarize this for me. But it really only has a limited context window. If you wanted to say look at all of PubMed and say summarize all of the latest cancer research for me, you could not throw that all into ChatGPT. You could but the 36 million publications would just be too many. It would take too long and it would be too expensive.

One of the things you can do though is you can do these things called RAGs. And what RAGs do is they take text or they take some piece of information. They convert it to a vector, which is like a mathematical representation of this. And then what you do is you basically just do search but you do search in this kind of semantic understanding space. Instead of looking over 36 million publications, you might look over 100, the top 100 that semantically matched. And then once you have narrowed down out of the 36 million down to 100 or down to 1000 so this is the crude literature review. When you do a lit review and do a search for a couple of terms and you get this huge list. Semantic search is kind of like that but way better than just a key word search. You get it down to the subset. Then you can use generative AI against the subset and say here is a paper or here is an abstract. Does it match my very specific criteria that I am going on?

We are seeing a lot of success in industry especially that is adopting these retrieval augmented generation techniques. While you are not supposed to use generative AI for lit reviews out of the box, I think that is a terrible idea. They are really good when you start combining it with other computer science techniques that have existed for a very long time.

It is 12:50 right now and I promise you all I will give you lots of time for questions and I think this is my last slide. I will stop sharing right now. Jacki, I am not sure how we are moderating questions but I will turn it over to you.

Jacki Monson: I will be happy to moderate. Let us start with Michael first.

Michael Hodgkins: I wanted to thank both the presenters for their presentations. It seems like we heard a lot about the sexier topics with respect to AI and health care and not much of anything about use of AI in the near term for reducing administrative burden and perhaps the impact on physician and nursing burnout associated with administrative burden. I wonder, Travis, Grail, if that is a focus for any of the work that you are doing or colleagues are doing within the administration.

Travis Hoppe: I can take that one. Grail, did you want to jump in first? One thing that I will call out. If you are interested in this, one of the best places to start looking is the AI inventory and we can see some of these beginnings of this within agencies.

Within CDC, which I am confident to speak about, there are some of these uses about reducing administrative burden. I will point out first of all that generative AI is new and there was actually a lot of technical and governance and logistical hurdles to bring it within the federal environment so that we could use it within CDC. We have only just now started using it with a sanctioned way. But we are starting a whole series of generative pilots. Some of these are related to public health. Some of these are related to just basic administrative tasks like some writing meetings or writing emails. These are not related to health care physicians per se because we are more looking at our internal processes first. But we are thinking about it.

With respect to using AI for the "non-sexy" things, I think there has been tremendous progress in things like speech to text. It has always been there. That has been one of the things that people have been working on. But the models that are publicly available and free are fantastic now. Even the transcription in Zoom and Teams are really good. But the models that are off the shelf that are not working live that you can pre-process are so good and so much better on transcribing both the speakers, assigning it the correct speaker, working with different languages, which is a huge equity consideration. It used to only just be for English. That reducing burden would be huge.

Then you take these transcriptions and you tie them into other things, whether they are hospital administration records, whether they are ICD-10 codes or other – I am sorry – 11 codes. I really messed that one up. Or anything else that would be useful. These connecting processes – these are happening in place.

I think some of the problems are not really on the technical aspects like the models are actually really good now. I think what is hard is getting it aligned with what the physician might expect or just bringing the technology to the practitioners in the first place. But yes, so much work has been done on the administrative side.

Michael Hodgkins: Just as a follow up for Grail and I am sure you are aware of this. But there is obviously a very clear linkage between administrative burden, burnout, and poor clinical outcomes. If you are interest in work is focused on improve clinical outcomes, I think the low hanging fruit frankly is the use of AI to reduce administrative burden and burnout.

Grail Sipes: Completely agree. No argument from you there. Very important.

Lenel James: I have two quick questions, first for Travis and second for Grail. Travis, I put in the text. I believe Gil Alterovitz was at our last presentation with you. Can you clarify if that CDC roadmap – if and how it aligns to the VA work?

Travis Hoppe: We have worked really closely with Gil. He is fantastic and I will say we look up to VA for really pushing the envelope on this. What we wanted to do within CDC is we wanted to be really careful when we started adopting AI. It is one thing to have it read and translate an email for you. It is another thing to help integrate into things that would be – that have public health policy decisions.

What I think is so great about Gil's movement is how he is really pushing the technology within the agency and a lot of his roadmap follows that. We adopted all of that and more and the specific things that work out to public health that VA also works in health care and they work in public health. But their scope is a little bit different than ours. We took theirs but we all took things like the EO and the OMB memorandum and said how does this apply to us so that we can align ourselves to all of them. But we work very closely with them.

Lenel James: Grail, my question from a White House perspective. Any thoughts about some standard documentation to capture the due diligence applied when someone is releasing a specific AI system into the world that there would be some common way to document that they have done some level of due diligence in that process?

Grail Sipes: I think that is extremely important, but I do not think I can comment on that without getting ahead of the processes that are currently underway. I would flag that as something that is important certainly for agencies and for others to consider as they move forward. I am sorry I cannot provide anything more –

Lenel James: More an in-process thing. The industry is looking at it, learning, and you guys will share yours when you have gone further along.

Travis Hoppe: Do you mind if I respond to that one at least from my perspective? Great. Model cards. The answer is model cards. This is one of many tools that industry has already adopted within different domains on how to do this. This is something that I pushed for our center NCHS to do. And we are trying – and I think we are going to make this part of CDC's general guidance is that not only when we write our own models, which is a thing in R&D to have a model card, but when a vendor comes to us and says we have a shiny new toy to do something. We need model cards. We need them to describe the context for use, where the bias is.

When the people who are in the room and they leave, and it is three or four years later and the model is still in use, somebody new can come in and understand the limitations of that model and the bias of that model.

Lenel James: That is fantastic because model cards were a concept I knew but I was not sure how well used it was. I went to generic but thanks because model cards are a thing that is being considered by several organizations. Thank you.

Valerie Watzlaf: I have a question for Grail. I know you had mentioned the AI taskforce strategy, and the guidance and I think the second one or third one maybe that you mentioned was safety

and security of AI. I just wondered if you could just elaborate a little bit more about how one would go about really making their AI data more safe. I was looking at that guidance and I did not see a lot of detail in relation to privacy and security there. I wonder if you could – I am sure it is there but I do not know if you could elaborate more on that.

Grail Sipes: I am not sure which guidance you mean. Are you talking about the executive order itself or a different –

Valerie Watzlaf: I think you mentioned – you said HHS AI taskforce strategy.

Grail Sipes: They have not done it yet. They are tasked with doing it. Again, I would just flag that that is a really important point, and this is something that – obviously, the White House has to defer to HHS. We have a lot of confidence in their abilities to look at this and we know that they are standing all this up right now. At this point, since I think they are in the early days with it, that is about all that I can say but it is an important point.

Maya Bernstein: I put a link to where it will appear. There is a placeholder on the website for it basically. I assume it will be updated as there is more information. There is a link in the chat. I know Grail cannot see that.

Valerie Watzlaf: I did look at that. I just wondered if there was more. Then my comment would be just as you said. It is so important. I am sure that they will give it a good amount of attention. Thank you.

Travis Hoppe: Just adding to that a little bit. There is a tangential work stream here around these and it is called PETs, which are privacy-enhancing technologies. They do not solve the entirety of what you are talking about here. But a lot of disclosure and privacy risk can be mitigated through those. These are things you may have heard of. These are PPRLs, privacy-preserving record linkage. They are things like homomorphic encryption, which allow you to make safe computations on a set of data. There are things like synthetic data. You need to be training off the real data. Does it fit the context for use for this? Can you be trained off generative AI? These sorts of things can help I think in different use cases but there are so many different domains around the privacy and disclosure pieces. I think they are really important.

I think that the synthetic data piece has been really useful for a lot of places. Generating synthetic data that you can give to a vendor just alone has been a really nice use case that you can make. This is mock data that we can use. It is actually generally really helpful and you do not need to send them real patient data for that. But you also do not need to make them all by hand.

Rebecca Hines: Grail, I know this is your first time with NCVHS, and Travis, this is your second go around. You get a sense from the questions of what the committee's areas of interest and expertise are. Keep this committee in mind if there are particular updates you would like to come back with or actually areas you would like the committee to explore as a support to you all as you embark on all of this work. I just want to say we are here. I see that there is a whole AI advisory committee but I think it is not specific to health. I just wanted to thank you both and put that plug in to keep this group in mind.

Grail Sipes: Absolutely and appreciate that. Thank you.

Jacki Monson: I have a quick question and then we will go to you. We have – rapidly AI is touching the health care space specifically. There are levels of sophistication and not sophistication. Quick adoption to AI versus slow adoption to AI. What is your advice to the organizations who are trying to decide what to do right now? Should they be waiting for guidance? Should they be doing pilots because there is lots of tech right now who are coming into health care and saying we can make magic happen. Let us help.

And obviously, there is valuable data that is important that sits in health care. There is this fear of what does this mean, what parameters and controls and there is not a lot of guidance in this space right now. What advice do you both have for health care organizations and small, large, et cetera, community base that are trying to grapple with this topic?

Travis Hoppe: I have found that a developing community of practices is probably one of the best ways to do that. Within the federal space, there is an AI community of practice both GSA, which is federal wide. There is one for HHS. We just started one within CDC. All of them serve different needs and all of them really help.

There is this conception I think in a lot of people who have not really dived into it that is what is happening here is magic or we do not understand what is happening. It is really useful to get some engineers in there that can train a model like a really simple model or fine tune it to see how the sausage is made, to actually do the work. Once you have started developing these engineers, which kind of come from the computer science side and then connect them to your subject matter experts, the ones that may understand the problems, may understand the bias or the harms that these models can cause, that is when you actually start getting growth.

But what happens is that the field has developed so rapidly that there are not a lot of AI experts right now. I would encourage organizations wherever they sit whether they are industry or academia or health care directly to start developing communities of practice and bring the computer scientist type folks in there. Bring your data scientists in there. Have them train models. They do not have to be good. They do not have to solve problems. It is a learning experience so they understand when somebody says a transformer model, when somebody talks about like an LSDM or a CNN. They know what these words mean and they understand how they are going through the processes.

Wu Xu: My question actually follows up with Jacki's question with one use case for Travis. Yesterday the committee made six recommendations to HHS Secretary to string the risk analysis for the health care covered entities, especially for small providers. Do you know any development or research now for the use of AI in risk analysis? The community practice is a good idea. But for small or middle-sized providers, they have no time or expertise to participate in this. I kind of feel this is maybe a federal role to fund this type of study. This will be really helpful to improve the privacy and security for those covered entities. That is my comment.

Travis Hoppe: Thank you for that comment. I am going to pick up on Debra's comment in the chat as well and bring these together. First of all, in terms of funding research on AI both ethics and risks and all these other things, there is so much literature out there. There is a wealth of literature in so many different places. I think part of the problem is bringing it to the forefront because a lot of it is buried in technical journals, on the archive and preprints. It has happened so fast that I do not think there has been the right publicity for it. But there is a lot of research that is in there.

What is lacking is connecting this research that identifies the risks and even very specific ones on that technical language and brings it to practitioners. Without promising anything, I agree with you. That would be a really good thing to exist and I think that is something that we could consider for it.

Moving to your next point, can AI help with these tasks? Getting to Debra's comment that says in the chat, maybe it can translate doctor's notes to ICD-11. There is a lot of potential to do those things. Right now, if you were to take clinician notes and say does this apply to some ontology or some taxonomy like ICD-11 and map them together, it will do a really good job. That is the kind of scary bit to it is that if you just do that, you actually have not thought about the problem really well at all.

What you should decide before you start using AI for something like this for clinician's notes is first of all, how good does this system need to be because all systems will make mistakes, even human ones. We build in safeguards for these sorts of things.

What sort of errors are you willing to tolerate? Is it okay if you have a lot of false positives? Is it okay if you have a lot of false negatives? Are there harms that are different that are associated with those? These are things we already do in clinical practice but they should absolutely be applied to the AI models and then you should be able to quantify them. And once you have been able to quantify them, you should be able to test a model and see how it does on that quantification and then when a new model comes out, it is two years and ChatGPT-7 is out or some new company does something. You have the same testing harness in which you can run your tests against.

Looping back to the literature question, these things need to exist. That is how the larger community, all of us need to be thinking about this, is that we have a specific use case and scenario. Translating doctor's notes to pick up a specific ontology like ICD-11.

Given that, one of the things communities can do like this community, the Federal Government community, the academic community is to put together tests and that is how a lot of the AI field has been advancing through tests. There are so many benchmarks. And the things that have benchmarks get better. There is a benchmark on law exams. There is a benchmark on complicated math problems. You know what? The AI models have gotten really good at that. When benchmarks exist, computer scientists and AI practitioners – they work to optimize those benchmarks.

The more we can think about these things, which is really calling on all of us to quantify them, we can improve these benchmarks. This is a long way of saying make more benchmarks but also consider what benchmarks would be useful for these.

Michael Hodgkins: Travis, I strongly support your passion for model cards. But in addition to model cards identifying the training data used for a given AI tool, I think it would also be interesting for the model card to include demonstrations of where the then algorithms were applied outside of the training database because that is a good way to expose potential errors of bias or other problems.

Travis Hoppe: I think that is a fantastic comment. What you are asking for is more than the original concept of a model card and I love that. Model cards describe basically the people that make the model and they think about it as much as they can and then it is released. It is often a

different group of people that may put it in practice, the ones that run inference against this model.

We have started thinking about this at CDC. It is worthwhile to have a model card, which describes all these things that we discussed. Training data. The potential harms that you could think of and then having something like a system card that it is regularly updated as people use it. The makers did not anticipate when we threw Chinese language into it and it really messes it up. We are adding to the system card like a body of knowledge that is associated with it. That is a fantastic idea. I do not think there is a lot of uptake in that but I think people have started noticing like now we are putting these things into production. How do we keep them going?

And what should also be in the system cards is an idea of sunsetting. At what point should you consider the model to be no longer useful or not out of date? Something that we do not talk about too much are things called drift in AI models, which is where you train it over a subset of data and then if the model is not updated to include new information, then it becomes out of date like COVID is a great example. If you train like an AI model and text from 2019 data and you ask it about the pandemic, it would be like there was a pandemic 100 years ago. It would not have this concept of it. That is like an extreme drift like a discontinuity. But there is gradual drift in all types of language because culture evolves. Excellent comment. Thank you.

Jacki Monson: Other questions? I am not seeing any other questions. I think we will finish a couple of minutes early. Grail and Travis, thanks so much for your time today. Thanks for all the information. Lots of great information for us to chew on and think about and also follow the work that you all are doing and HHS' work so thank you so much for your time today.

We will break for lunch now. Rebecca, what time will we return?

Rebecca Hines: 2 p.m. Eastern. If you could all be back at 1:59, that would be great. Thank you. Thank you, Grail. Thank you, Travis. That was super.

(Break)

Rebecca Hines: Welcome back, Lenel, Rich, Tammy. Let us know, Angela, Michael, Steve. Just want to make sure everybody's back. I think we are ready to start our afternoon, right at 2 o'clock on the nose. Thank you, Val, over to you.

Changes in State Laws on Access and Use of Reproductive Health Data

Valerie Watzlaf: Thank you. I'm going to introduce Kelly Baden. She is the vice president for public policy at the Guttmacher Institute, and she brings nearly 20 years of experience in reproductive rights to her role as vice president there, and she joined there in 2023. In her position she oversees the institute's public policy team to advance evidence-based policies at the state, national, and global levels. And previously, Kelly was the senior vice president of strategic initiatives at State Innovation Exchange, where she launched the country's only national cohort of state legislators committed to reproductive freedom. And she also built the organization's first issue-specific program while originating the roles of director and later vice president of reproductive rights.

She also convened a delegation of state legislators to visit El Salvador to learn about the devastating impact of abortion bans, and previously Kelly was in charge of the state advocacy

and policy portfolio at the Center for Reproductive Rights.

She has also worked at the National Institute for Reproductive Health, Physicians for Reproductive Health, Planned Parenthood Affiliates of New Jersey, and Emily's List. She also served on the board of URGE, which stands for Unite for Reproductive and Gender Equity, and she was a recent reproductive and health rights and justice fellow with the Rockwood Leadership Institute.

Kelly also has several recent publications on her website that focus on the state abortion policy landscape and how policymakers can protect abortion access. Today, she will be speaking to us on the changes in state laws on access and use of reproductive health data.

Welcome, Kelly, and thanks so much for being here.

Kelly Baden: Thank you so much. Thanks for having me. As you heard, I'm with the Guttmacher Institute. We are a global research and policy organization committed to advancing sexual and reproductive health and rights worldwide. I'm today going to spend some time giving an overview of the state landscape of abortion policy and legality, including a look specifically at policy trends in the states in the almost year and a half, almost to the day, since Roe v. Wade was overturned in the Dobbs decision, and some of the newer policy innovations we've been seeing in some key states, especially around issues of data and privacy.

I will couple that with a look at what we know about some of the impacts of the Dobbs decision so far, and also some of the open questions and things that I think we are all kind of collectively holding our breath to see in terms of other impacts and in terms of other ongoing legal implications stemming from the Dobbs decision.

I will try to pause for questions at certain key points but also plan to leave plenty of time at the end for conversation and questions as well, and you can see my contact information there.

This is a still of what is on our website at guttmacher.org, actually an interactive map, but I did not have the tech skills to make it interactive here. But if you go to guttmacher.org, you can hover over a state and see more about their policy information as well as some statistical and demographical information in each state.

This is really consistently updated, both for policy changes and we have some planned other updates early next year, and into 2024, around the statistical and demographic information as well. We use a scoring rubric, I won't get into detail here, but I just want to distinguish, I'm going to talk about the 14 states where abortion is currently banned; there are more than 14 states that are listed as most restrictive here, and that's because of the rubric that we use. For example, South Carolina actually has abortion legal up until just early in pregnancy, they have a very early gestational ban in affect at about six weeks in pregnancy, but you can see there it's categorized as most restrictive in part due to some of the other restrictions that they have in statute there in this state, which, again, according to our scoring rubric, then kind of kicks it into that most restrictive category.

I want to just remind us that the last decade or so has really been marked by an increasing series of state-level abortion restrictions even while Roe still stood. The Dobbs decision in June of 2022 really triggered some immediate abortion bans, right? Several states had passed what were called trigger bans, kind of preparing for that moment that they were hoping for from the

Supreme Court, so what happened after the Dobbs decision was really a flurry of legal activity. We had several state AG opinions, some immediate lawsuits stemming from existing state policies, which I'll talk about, and so kind of a good handful or so of states really immediately enacted an abortion ban, and then again some of that kind of ping-ponged back and forth as some cases had to make their way thought eh courts.

So where we are right now though is with 14 states that have what we call near-total abortion bans. Some of them might have exceptions written into the statute, perhaps for pregnancies threatening someone's health or life, but we also know that in practice some of those exceptions are very difficult to access, in fact, so much so that they might even be called meaningless in some cases, and I'll refer back to that later when we talk about impact.

But other than South Carolina, the dark red states are where abortion is near totally banned, and I'll just visually draw your eye of course to that sea of red in the southeast region, which I think is important to note, and again I'll reference it later, because of the multiple state kind of domino effect in a region, and when you're talking about how someone in Louisiana, for example, might have to cross several state lines to get to a state where abortion is legal to access in-clinic care, certainly that has an impact, and so I always like to say that a state's abortion laws extend well beyond the borders of that state. I think that was always true, but it feels particularly true now, and I'll just give another example of some of the legal ping-ponging I mentioned.

For example, Arizona actually has an 1864 abortion ban on the books that predates statehood for the state, and so once the Dobbs decision came down this question of what law went into effect, or what didn't, really became a legal question, and so the courts had a series of decisions right after the Dobbs decision through to now that kind of resulted some rapid-fire abortion legality-illegality-legality in the state, which you can imagine is quite confusing for patients and certainly for providers. So abortion right now in Arizona actually is legal until 15 weeks gestation. Wisconsin had a similar situation but just started providing abortions again earlier this fall.

In terms of this year, 2023, the state legislative session, it really was defined by some more of these questions around if a state was able or not able to fully ban abortion, depending on the legislative makeup, what else could they do? And early abortion bans are very much a trend that we saw, so this question of six-week abortion bans which I referenced, we saw those enacted this year in South Carolina and then passed in Florida. Its enactment is not in effect yet, it's actually tied to a legal case in the courts in Florida connected to their existing 15-week abortion ban. So we're actually waiting truly any moment for that decision to come down in Florida and kind of implicate again what the actual state law will be there.

Bans on abortion at 12 weeks in pregnancy were enacted in North Carolina and Nebraska. All of these really did see some political headwinds, and I say that because I think it does offer some context into the landscape across the country since Dobbs, which I'll reference a little bit later as well. When you look at the flurry of ballot initiatives and other things that have really shown that the public is not really in support of all-out abortion bans and was not supportive of overturning Roe v. Wade.

In addition to bans on abortion at various stages of pregnancy, one early trend to note is this question around our ability to freely travel across state lines to access abortion care in a state

where it is legal. We've heard a lot about this in the last couple of years, and there's been a lot of talk from lawmakers. For example, Missouri tried to ban interstate travel for abortion care, but what has only passed so far, I should say, actually passed, is an Idaho law that would criminalize an adult helping a minor leave the state to get care where it is legal, although that's currently being litigated.

And then these local measures in Texas, at the city and county level, that are really aiming to outlaw again that act of transporting somebody on their roads. You can imagine lots of questions would stem from an enactment of a policy like that, and I would underscore this isn't a widespread trend yet, but I think it is going to continue to be a question that lawmakers are going to be forced to grapple with and ultimately I think the courts will be forced to grapple with, and I'll talk a little bit later about some data we're releasing next week here at Guttmacher around what the numbers of interstate travel for abortion look like, which, again, I think will make this a question that at some point is going to have to be answered.

And then going in the opposite direction, of course, there are lots of states who have been enacting different kinds of protections, both for abortion legality and then also going beyond that and thinking about how to expand access. These are both statutory protections, executive orders, other kinds of programs. Also some local ordinances and programs as well, to expand access to abortion care. Again, not just for residents in their own state, but thinking about folks who are going to be traveling from states where abortion is banned.

I won't certainly go through every example, but there's a couple I'll just mention here. State-created funds for patients who need financial support for abortion, like Oregon. Michigan, of course, had some restoring of the basic legal protections for abortion. That can also happen via ballot measure, which we just saw in Ohio a couple of weeks ago, you might recall.

This also includes things like insurance coverage for abortion, particularly public insurance coverage for abortion, which our data and other data really shows is a significant barrier to abortion care for people. You'll recall that the federal Hyde amendment, which has been in effect since 1977, bans public insurance coverage for abortion in the federal Medicaid and other programs, and then states can use their own matching Medicaid dollars to offer insurance coverage for abortion via their state Medicaid program. Most don't. This year Rhode Island did proactively make that policy change to ensure that public insurance coverage in their state could cover abortion care just like it covers pregnancy care and childbirth costs, but only 17 states do so.

And then in terms of clinic infrastructure and security, we've seen some grant programs established for clinic safety and infrastructure, for example, even before the Dobbs decision. New York State allocated $10 million in funding for safety and security capital grants for providers and reproductive healthcare centers to think about patient safety and security.

I'm going to talk about two more specific topics, so on the next slide I'm going to do an overview of the Washington State My Health My Data Act. This is a first of its kind law that was signed in April of this year. It has various provisions taking effect, some of which took effect this summer, some next year, depending on the business. And this was really described by the legislature as a, quote, gap-filler to protect consumer health data not otherwise protected by HIPAA or other privacy regulations.

Obviously this is a Bloomberg Law story that can go into much more depth than I could about this particular law, but it aims to protect consumer location data, restrict the gathering and sharing of health data without consumer permission, including the ability for consumers to ask for its erasure. The act also makes it unlawful to implement a geofence around an entity providing in-person healthcare services where the geofence is used to identify or track consumers seeking healthcare services, collect health data from consumers, or send notification, ads, et cetera.

Attorneys general and consumers can bring lawsuits under this law against companies who don't comply, which can carry fines of up to $7,500 per violation. And on the next slide, this is just going to be a snapshot of some of the other data privacy policies that we've seen. Again, this is not a comprehensive rundown of every one that has been introduced or enacted, but I think it's a good snapshot of some of the ways states are tackling this particular topic.

A new Illinois law goes into effect in January around banning automated license plate readers, saying that they cannot sell, share, or allow access to, or transfer their information to any states for the purpose of investigating or enforcing a law that denies or interferes with a person's right to choose or obtain reproductive healthcare services or other lawful healthcare services. That is, as I said, set to go into effect in January, and I think we'll see a couple more of those.

California has some examples, as well. One of their bills prevents the sale of precise geolocation data for people who visit family planning centers. So if you are visiting a reproductive healthcare center and get an abortion or any kind of healthcare, this kind of law would prevent this the collection and retention of your phone tracking that information, which could then be used by, for example, anti-abortion organizations who are targeting patients such as with ads for things like so-called medication abortion reversal, or for criminalization.

As this is where that, if you think about the visual of the map before and the 14 states where abortion is banned, and those attempts to ban travel, this question of will a state find out that a resident of their state is accessing abortion care in a place where it is legal, could they use data from somebody's cell phone to be able to know that and then try to go after them, even though abortion is legal in the state that they were accessing care.

So I think there's some really significant questions there, and the geolocation is defined in some of these as a geographic area. Many of these bills have a specific number of feet derived from a device that is used, and they're intended to be used to locate a person. So again, prohibiting -- most of these bills take the tack of prohibiting a business or a person from collecting or retaining or selling that personal information when that person is physically located or within a precise geolocation of a family planning data center. I hope that starts to address the question.

Again, other examples around this very same thing, is around another California law that would prevent out-of-state law enforcement -- again, think about a state where abortion is banned -- preventing them from enforcing warrants to a California-based corporation for their records or data related to abortion. That was actually signed in 2022 in California, but I think it's worth mentioning. And then another California law just recently signed this fall prevents, for example, period apps from selling menstrual health data.

Both thinking about data privacy, policies in the states, both related to when a person is physically at a clinic, and also thinking about the apps that they might use such as apps that

track your menstrual cycle.

California and Maryland also both this year moved to limit health information exchanges and electronic health networks from disclosing information related to abortion care, other than for the adjudication of claims or to a specific provider with appropriate written consent. And I think that is also similar to -- it's not on this slide here -- but Maine actually changed some of their abortion reporting requirements this year and really just clarified the existing law to indicate that reporting on abortions in the state should focus on just four things: the date and place the abortion was performed, the age of the person, the method, and the gestational age of the fetus.

And I think this bill just reiterated that other patient-identifying information doesn't really need to be in reports. So I think it's again thinking about how we collect data and to what end when we're talking about this new kind of setup where abortion care is illegal in 14 states and knowing that that number could continue to change.

The Massachusetts example here has not been passed yet, but that is the Location Shield Act, which would ban the sale of cell phone data, cell phone location information.

Next slide because I want to merge us into another topic, which is shield laws. This really has arisen as a key component for states who have already said, okay, abortion is legal in our state, we've secured the legality, we've thought about other access measures to recognize that folks might be coming here, and we want to be able to make it as seamless as possible to meet patient demand. And then said we want to kind of go beyond that, and thinking about what might be a risk to somebody coming from out of state.

So this is not a Guttmacher chart, you can see here this is from Manatt, and I dropped the URL at the top. This is a category of laws that tries to protect either abortion providers, patients, and/or things like support organizations such as an abortion fund, which helps provide money to folks who are seeking abortion care, from investigations by other states.

You can see they can take different approaches, and so some states expand on existing privacy protections to prohibit the disclosure of a patient's confidential information, preventing a provider for a patient who has come from a banned state from sharing that patient's information with anyone in the person's home state where that information could put them in legal jeopardy.

Other shield laws prohibit the shield state or the place where abortion is legal from cooperating with an investigation by a banned state into the provision of abortion care, or seek to limit perhaps consequences from providers' professional licenses if they are providing abortion care that is criminalized in one state but they're providing that in a place where it is legal.

Let me pause before I move to evidence, I see there may be a Q&A. And I know that is a lot of policy information. This question is around the status of the HHS HIPAA privacy proposed rule, and so others might be more inclined to answer that or set to answer. My understanding is the final rule has not been issued. But I'd welcome folks --

Valerie Watzlaf: I believe they are still going over the what is it, over 25,000 comments that they received, and hopefully something in the spring, I think, we're hoping for.

Kelly Baden: Thank you. Let me pause for any other policy questions, around just some of the trends or the legal or police landscape that I've really buzzed through in the last 15 minutes.

Maya Bernstein: I can say slightly more about the question in the Q&A.

Jacki Monson: I can restate it. It says does anyone have information around the status of HHS HIPAA privacy rule proposed rulemaking to support reproductive healthcare?

Maya Bernstein: Right. So there's no direct information about that, as Val mentioned, there were over 25,900 comments that the department received about the rulemaking that was issued on April 12. And when I'm finished talking I'll stick a link into the chat so you can see where to find, at regulations.gov, you can find that rulemaking, and many, not all, but many of the comments you can sort through them and look through what people had to say about that.

I think a couple things. One is the department publishes a regulatory agenda every six months or so that telegraphs when they're planning to issue rulemakings. The current agenda, the latest one, only lists the proposed rule, which we already know was issued on April 12. So I would look to the December, I think the next one comes out, and may have some more information about specific timing about that.

But if you're a person who understands how the rulemaking process works and what's required for the current administration, essentially there's, for all HIPAA rules, there's 180-day compliance time. There's the Administrative Procedure Act has 60 days before you can make a regulation final. So that's now we're kind of up to eight months. And you can imagine if you know something about the Congressional Review Act, which permits the Congress to take up a rulemaking and have a vote to vote it down, you can imagine that the administration would want that to happen, that timeline to run out, during the current administration, when the makeup of the White House and Congress are such that that would not happen.

But we don't know what will happen in the election, so given all that timing, Val's right that one would expect a rulemaking by spring, April or May or something like that. If you were thinking about all those things, that's presumably when the administration would shoot for. But I have no particular personal knowledge, just those are the public parameters that you could take into account and kind of deduce that that's about when you could expect such a rulemaking, but I would look to the regulatory agenda that comes out again in I think December, and will give you a better idea of when they predict that that will be released.

Kelly Baden: Thank you. Other questions before I continue to some impact evidence?

I'm going to drop another link in here with another interactive map on our website. We love those. There is emerging evidence on the impact of the Dobbs decision and the subsequent banning of abortion in 14 states so far. Our monthly abortion provision study just started to come out in September and we release new data every month. We'll have some new information next week. Unfortunately, I can't get ahead of our embargo to share that with you, but this provides monthly estimates on abortion provision state by state and is starting to paint the picture of where or whether people are able to leave those banned states, those dark red states on the first map, and get to a place where abortion in the formal healthcare system is legal.

Our first set of data, again, released earlier this fall in September, showed a sharp increase in

abortion rates in states that border abortion-ban states. Those are the dark green ones here, and again, you can just kind of think about that. If you're looking at that chunk of red states in the southeast region that we referenced earlier, and you have Illinois and Colorado, New Mexico, and Kansas kind of bordering them, our research has shown that folks are able to navigate some of the substantial financial and logistical barriers that it might take to leave the state to get to a bordering state or a nearby state to access abortion care there.

As I said, we're releasing more data a week from today, and that will focus more on this travel, so we will be able to share what proportion of a state's abortion patients, where abortion's legal, are actually coming from out of state.

Notably, banning abortion does not just impact people seeking abortion care. This is just a smattering of headlines, we could have several slides looking at this, that talks about some of the experiences of people, women who want to continue their pregnancy but face some kind of health emergency, obstetric emergency, and have had their health or life or the health of their pregnancy threatened because of confusion or fear from hospitals or physicians about how to navigate their state's abortion ban, and what exceptions might or might not exist in that state.

Just this week, actually, there was another hearing at the Texas Supreme Court where 22 plaintiffs, 20 of them are patients, two are physicians, argued with their own personal experiences that the medical exceptions to the state's abortion ban in Texas are too narrow to actually protect patients with complicated pregnancies. Some of the patients bringing that court challenge, which is led by the Center for Reproductive Rights, were able ultimately to leave the state of Texas to get legal abortion care that they needed for their health somewhere else, but some were not. Two of the women even developed sepsis while waiting for Texas hospitals to approve the abortion procedures they needed.

I say that because if a state has banned abortion and has significant penalties for a doctor or hospital who violates that, even if there is an exception, many of these laws as you know are not written by physicians. So they're really not able to kind of cover all of the many things that could go wrong with a pregnancy or with an obstetric emergency, so there are real impacts for people who, again, want to continue their pregnancies but have a health crisis.

The climate created by abortion bans also has other ripple effects. You can see here there's some evidence that people may be factoring a state's abortion policy into their choices for OB/GYN residencies, which can further potentially exacerbate some of those already existing challenges such as what we call maternity care deserts. Places where there's not a lot of access to even childbirth centers or maternity care, and things like college choices for young people, medical students having trouble getting needed training. All of these things that I think are just an interesting starting look at some of the additional impact that some of these policies are creating.

There's also some new, very new, data on birth rates, and I think this is something that is really interesting and again is just starting to come out. There's a new study by the Institute for Labor Economics, showing that indeed birth rates have increased in states with near-total bans on abortion. Every state that had a ban had some kind of increase in the number of births.

You can see here there was a separate but similar Texas study that showed that that is particularly true in a place like Texas, whereas I think in a state like Missouri, which again, if you

think about our geography, is a little bit closer to a place like Illinois, for example, where abortion is legal.

I think this data is interesting because it kind of further nuances what I just started to reference a few slides ago with our monthly abortion provision study, because I think there are multiple things true right now. The abortion rate in the United States had been increasing pre-Dobbs already. About 2019, 2020, the rate started increasing, and our data, again, shows that states bordering abortion-ban states have seen an increase in abortion rates, again indicating widespread travel for abortion care.

As I said, we'll have more numbers and more details on that a week from today. And the increased birthrate in these states where abortion is banned does also imply that many people are perhaps not able to leave the state to get the abortion care that they might otherwise have accessed, had abortion been legal in their state. So both people are traveling, and also the increase in birthrates, more than what would have been expected, shows that not everybody is able to navigate what could be significant financial or logistical or other barriers to actually leaving a state.

I just want to kind of wind down with some of the things we know at this point, one-and-a-half years since the overturning of Roe v. Wade, and some things that we really still don't know anything, are going to take a while to unpack and untangle. I would reiterate, abortion remains popular. Poll after poll, election after election, seven out of seven ballot wins when it comes to abortion being directly on the ballot in states since Dobbs, starting from the Kansas ballot initiative back in August 2022, just right up to earlier this month in Ohio. And I just think that's an important context for where we are.

We do know these bans are impacting people, both those needing abortion care, those wishing to continue their pregnancies but facing a health situation or concern with their pregnancy. Again, I'll reiterate, we know birthrates are up in states where abortion is banned. And abortion rates are up in states where abortion remains legal and they are next to or border a ban state, indicating that widespread travel for care.

And it seems likely that abortion funds, other similar organizations who really do that work in helping people directly get to the care that they need, even if they live in a ban state, it's heroic work and it's probably not sustainable. I think folks talk a lot about rage-giving. Following the Dobbs decision, there was a huge increase in individual donations to places like abortion funds. That is probably not sustainable in the long run, and I think the question of how that will implicate some of this data remains to be seen.

I would say that we know that the Dobbs decision did not really settle anything but instead likely raised more questions, both legal and policy questions and others, and that we're really just starting to be able to track and understand some of the impacts of that, and I think that'll of course continue as more science, which takes time, continues to be released and be under way and as we see more continuing changes in the policy and legal landscape.

The shield laws I talked about that have become quite popular. I think 22 states and D.C. have some kind of shield law, either via executive order or statutorily on the books. Those have not been legally tested yet. We don't quite know what might happen with that. I think there's some real curiosity and some real things we don't know about if or when there's a legal test to a shield

law in practice.

I think we don't know how courts may respond to some of those attempts to restrict travel as I talked about before, whether it's something like the Texas example, thinking about how to somehow not allow a county's roads to be used by someone helping someone get an abortion elsewhere. Or the Idaho law, or even beyond that, again, knowing that we've heard threats from lawmakers in Missouri, for example, to actually try to enact a law that would block an adult from leaving the state for abortion care.

And then lots of still questions around some of these data privacy and protection policies, and how far those will continue, what other new kinds of needs or gaps might arise or be identified, and have some policy solutions from folks seeking to address those gaps. So lots more I'm sure that we don't know.

I'm going to pause there and just say thank you for allowing me to share some of this information on impact and policy landscape. There's my contact information again, and I'm happy to pause there and see if there's any questions or conversations that folks want to engage in.

Valerie Watzlaf: Thank you so much, Kelly. I do have a question for you. I know you brought up the monthly abortion provision study, and I know you said that you're going to be putting out some information about travel. Are there other types of data that you would like to be tracking? And I guess if you could share some of your challenges around that and doing some of your great -- I know it's wonderful research that you're doing around reproductive health.

Kelly Baden: Yes. My research team would love this question. I will say, obviously I've focused today on some of the abortion-specific data, but certainly the implication is far beyond just abortion, and so we do have some studies under way around the impact of the Dobbs decision on family planning clinics, clinics that just provide birth control. What are they, for example, hearing from their patients? What confusion, concerns, maybe changes in behavior regarding contraception might be coming up? So those are some. We have a couple studies like that that we'll start to have some preliminary results from in hopefully, the spring of 2024. So not too far from now.

As a policy person who's often looking for quick answers, I think there's been a real lesson for me around sound scientific research takes quite a while, and I think it's incredibly important to have, and I think that's the beauty of the monthly abortion provision study was that we do get monthly data. I'll share an example too that I think our October release of that focused on, gave us information up through July of this year, around the state-by-state abortion numbers, and July is when North Carolina's 12-week abortion ban that I mentioned earlier took effect. And we saw a 31 percent drop in the abortion rate in the state at the -- once that 12-week abortion ban took effect.

But what's fascinating is that in talking with providers and advocates in North Carolina, it was clear that we actually had to complicate and nuance that a little bit more, because while the abortion ban, the ban on 12 weeks on abortion, certainly played a role in the drop in the abortion rate in that state, other things played a pretty significant role as well.

So part of that abortion ban policy actually was the implementation of a second requirement for a patient to come in person to the clinic. So you have to get mandated counseling in the state.

You used to be able to do that over the phone. This law actually required that a patient come in person and just both from a patient ability to travel, child care, time off work, all of those things, but also for the ability of a clinic to kind of have to have essentially double the number of appointments for the same number of patients, you know, really was kind of a healthcare workforce scheduling issue, and I think made it -- again, they're doing heroic work. I think really speaks to how some of those policies that maybe don't get as many news headlines as an abortion ban can have a really significant impact on a state's ability or provider's ability to provide care or someone to get care.

Valerie Watzlaf: I think didn't they give them a timeline too or something they had to do that counseling session within a -- what did you say, like three days? Or a few?

Kelly Baden: I think that's a 72-hour one.

Valerie Watzlaf: Yeah, 72 hours. Are other states you notice doing something like that as well?

Kelly Baden: Yes, mandatory delays with state-mandated counseling have been a longstanding policy trend. So I think of most of the states that have that have since banned abortion since Dobbs. So off the top of my head, I'm not sure other than North Carolina, there's a couple, but I can't recall which ones are in effect. But most of them, you know, South Dakota years ago enacted that first 72-hour waiting period, but again, South Dakota then made abortion illegal. So the waiting period is beside the point now there.

Other questions? Comments?

Valerie Watzlaf: Go ahead, Wu. Go ahead.

Wu Xu: I have a simple question. Maybe I missed this. When the state report to you, is it from their vital records office or you have from other source? Who is the state report to you?

Kelly Baden: On the monthly abortion provision study on the numbers? We work with clinics directly. So in this situation, we are working directly with abortion clinics in a state using a Bayesian model, again not a researcher. Don't ask me to explain that. To then make estimates on the number of abortions provided in that state.

Wu Xu: Okay. So I have worked with the Utah the vital records registries. I know their abortion report is way underreported. Thank you.

Kelly Baden: Yes, thank you. There's much I think -- my colleague actually I think participated in a conversation earlier this summer with the department on the question of CDC, how they count abortions, how we count abortions, and how states count or don't count, and yeah, I think it's an imperfect model.

Lenel James: Kelly, it's Lenel James. One of your slides talked about 10,000 more babies born in nine months in Texas, and as I recall, there are multiple states or counties where there's no OBGYN docs, because they've either left the state because of those restrictions. Are there any initiatives that you're doing there or anymore findings about that distinction between more births but there's not necessarily the experts there, depending on your state, to take care of them?

Kelly Baden: That is a fabulous question. I don't think we have a study under way there, but I think it is a great idea and so I will check in with our Texas friends to see what they know, but I think it's a fabulous question.

There's been some anecdotal coverage, too, of -- I want to say Idaho, that has shown OBGYNs leaving the state because of the abortion restrictions and kind of shutting down, yeah, shutting down maternity care wards. I'm going to drop this NBC link.

Lenel James: It seems like a catch 22, Kelly, that the states are saying you can't have any abortions, they have no babies, but the OBGYN docs are gone. That's a real dangerous mismatch. But thank you.

Kelly Baden: I agree. Thank you.

Valerie Watzlaf: Michael.

Michael Hodgkins: Hi, I was wondering if you could comment on trends regarding efforts to prevent the use of Plan B, either within states or through the mails.

Kelly Baden: Thank you. So Plan B emergency contraception is available over the counter. We know it is a form of contraception that does not work or do anything, impact at all, an existing pregnancy. We've actually not -- I think they were prepared to see more legislative attacks on contraception overall, including on emergency contraception or Plan B, and we actually haven't -- we haven't seen much yet. I'm going to knock on wood.

But what we have seen a little bit and we have a contraception policy trend report coming out in January. But what we have seen is more this year of an opportunities for state legislatures for example to vote on or pass a bill such as a right to contraception. Something that's just like let's just clarify, we have a right to contraception.

And legislators are just not taking that opportunity to actually do that. So there's been fewer direct attacks policy-wise on contraception, but there's also not been any real motivation I think for people to get on the record and say we support the legal right to contraception. Which I also think tells a story. So we'll see what happens next session, but what there has been, of course, have been significant attempts to restrict medication abortion or abortion pills.

So we have the lawsuit that was filed in Texas attempting to take away 20 years of FDA approval and real-world use of mifepristone in the United States, which is obviously a safe and effective way to end a pregnancy early in your pregnancy, and that is actually before -- we're waiting to see if the Supreme Court will take that case and kind of put further restrictions on mifepristone or not, and certainly some states have, in addition to banning abortion overall, have tried to restrict medication abortions specifically.

For example, requiring that it be provided in person, so thus kind of taking away some of the telemedicine or telehealth advancements that we've seen that really do help folks, especially in rural areas. So I think we'll continue to see more of that as well.

Denise Chrysler: I was just going to mention one impact I saw of Dobbs is I just recently read the federal district court decision in Texas regarding Title X and minors' access to contraceptives and basically using Dobbs and other rationales as a way to say that Title X clinics could not follow

federal regulations that prohibit contacting parents or requiring that you have the permission or knowledge of your parents to get contraceptives from a Title X clinic. So I did notice that one.

Kelly Baden: Yes, thank you. Thanks for mentioning that. Very important.

Valerie Watzlaf: Are there other questions from anyone else? I do have one on the training I think that you mentioned for people that I think we're finding that trainees who don't want to go to sites where abortion is banned, but sometimes it's hard to find another facility for them to get their hours in and so that they can get their training. So are there any other resources, for example, some sites that might take more trainees that you know about? Or alternatives. I guess alternatives in training as well.

Kelly Baden: That is a great question. I would kick that to -- I am going to drop their link -- Medical Students for Choice is an organization that works on medical students who hope to secure this training or offer this care or Physicians for Reproductive Health also might have some information on that. I do not know off hand. Great question.

Valerie Watzlaf: Any other questions at all? I don't see anyone else's hand up, but am I missing anybody?

Tammy.

Tammy Feenstra Banks: This is a little off the wall, but is there any extension in policy away from the procedure to the mother and father or other types of policies being created in that regard?

Kelly Baden: Can you say a little more?

Tammy Feenstra Banks: Well, like you have whistleblower laws, all that different kind of stuff. Is anything moving in that direction besides in Texas?

Kelly Baden: So the Texas SB8 which was passed even before Dobbs and was in effect and has that what we call the kind of bounty hunter provision, that was replicated in Oklahoma, and I think we haven't seen much more specifically like that, but I do think -- I think where some of these other attempts to restrict travel kind of might come up as well, and so again I think that's one of the questions where I think we'll start to see when someone tries to make a claim, how that can actually play out, how somebody might actually go after -- you know, again, in Texas example, if I was driving my friend to New Mexico for an abortion, technically under some of these ordinances, they could go after me.

I think the question of like will they or how would that work in practice feels very complicated to me and feels like a little bit not quite sure how that would work, but I think that's what -- I think those are all related questions. How will we start to see how some of these really I think extreme examples of policies that are trying to not just ban abortion in the state but actually try to ban what somebody does in another state kind of comes into play. Yeah, I think we don't know.

Tammy Feenstra Banks: I hope not.

Valerie Watzlaf: Great, any other questions? I think we -- I think we do have a few minutes if anybody does have any. Is that right?

Jacki Monson: Yes, we have nine minutes.

Valerie Watzlaf: Okay. I wanted to ask you one more. I know you mentioned this about Washington State, My Health My Data, and how very specific they are with all of that information. Do you foresee -- I think you might have mentioned other states like New York coming up with them. Do you foresee any other states though being as specific as Washington state?

Kelly Baden: I don't know. I would really just be speculating, because I think as you said and as my next slide had shown, there are other policies around the bigger question of data privacy and how to tackle protecting consumer information and other kinds of information is going to play out. Again, I think I don't know that anybody will go as specific as that. I would just be speculating.

But I think in terms of a topic area, that we'll continue to see a lot of policy innovation, I definitely think we'll start to see more and more bills on that topic to try to figure out what is possible.

Lenel James: Kelly, I wanted to ask a follow-up question that relates to health equity. Given the discussions of maternal health and behavioral health as one of the critical areas is health equity and health disparities, where does this discussion fit in there? Are there any health equity initiatives to tie to it or that would you see links to, to share with us?

Kelly Baden: Absolutely, thank you. Yes, I think we have long known overall that the people most impacted by the abortion restrictions that exist even while Roe stood are people who are already marginalized by the healthcare system, who already face structural racism, who already are impacted by the challenges of our society in general, and so looking now at 14 states where abortion is banned, thinking about somebody in Louisiana or Mississippi, where it would take several tanks of gas to get from their state, or a plane ticket, to a state where abortion is legal. It would take several days off work, perhaps several days of childcare.

Like, who are the people who are least likely to be able to make that happen are folks of color, low-income folks, rural people, young people, and so I think the existing inequities of abortion restrictions that a lot of data has already borne out, that's why I pointed to public insurance coverage for abortion being one of the most significant policy solutions to abortion access, especially from an equity perspective. Those will just be exacerbated as abortion is banned in certain states.

So that's a lot of the unpacking and research that we still -- it will take some time to untangle to start to see specifically the inequitable impacts on people and communities coming from some of these policies.

And let me, I would be remiss if I did not add to that, when we start thinking about who is going to be criminalized, who is actually going to have the long arm of the law, really trying to see who is a test case to move into the criminalization parts of some of these, again, I think we know who is already overpoliced in this country, and so I think we certainly fear it will be Black women, it will be poor women, who really bear the brunt of some of these horrific policies.

Lenel James: Thank you. Excellent.

Valerie Watzlaf: Thank you. We still have a few minutes left if anyone does have additional questions. If not, thank you so much, Kelly. We really appreciate your wonderful presentation and staying with us and answering lots of questions. So we really appreciate it. Thank you.

Kelly Baden: My pleasure. Thank you all. My contact information is there and hope you have a great day.

Jacki Monson: Thanks so much. I think we should take the next four minutes and stretch our legs out and get off our chairs, because I don't know about you guys, but I'm sick of sitting. So let's just take four minutes for a quick bio stretch break, and then we'll come back.

(Break)

NCVHS Workplan Development - Part 2

Jacki Monson: All right, so let's get started again. Val and Tammy kind of want to, thinking about changing things up a little bit and given that really robust privacy conversations, Val, that we had yesterday and today, wondering if you want to first take a run at a discussion around PCS and potential workplan items just based on what we've heard over the last of days, and perhaps we could go into standards, discuss the same thing. Tammy, I know you have a slide deck for standards.

And then we go into the joint conversation, finishing up what we were discussing yesterday, and I know you have an additional topic. How does that sound?

Valerie Watzlaf: I think that sounds great, because I know we didn't really have -- I don't have an update, because we were really hoping to go into the workplan and see based on all of these things that are coming forward, if we're missing anything, if we're on the right track. So very much.

Jacki Monson: Okay, Val, if you want to -- Tammy, are you good with that?

Tammy Feenstra Banks: So Val, you just want to stick to plan? Go through.

Valerie Watzlaf: Yes, because I don't have the update, but if you wanted to do yours, Tammy.

Tammy Feenstra Banks: So let's do the standard update, which will fall right into the topic areas under the scoping document, and that goes right into privacy and then we'll go right into -- unless you want to have a more open-ended conversation before we get there, or we can have that conversation --

Jacki Monson: My thought, Val, was that we could have an open-ended conversation just based on the last couple of days, not necessarily formal discussion, but just get the group's feedback on, given what we've heard over the last couple of days, is there things that they'd like to see PCS focus on? Additional follow-up, and then we can move into the standards conversation, which I think Tammy has a little slide deck prepared for.

Participant: That also includes privacy, but then we can update the privacy when we get there based on your output here.

Jacki Monson: Okay. So go ahead, Val. You want to just tee up, kind of summarize what we heard at the last couple of days and then get people's feedback? That would be great.

Valerie Watzlaf: Well, I think if we can start with what we just heard, I guess, on the reproductive health information and privacy issues. I know we wanted to -- that really was going to be our next topic that we were going to focus on. However, we have gone back and forth a little bit on whether we should make that -- should we include it into our Beyond HIPAA information? So including the reproductive health information privacy issues under other sensitive information that might go into Beyond HIPAA.

So any comments on that? Or any feedback on that would be helpful. Or should it be a separate area that we focus on? I know when we did the response to the NPRM, I know we did table some things too that we put aside, because we didn't -- I think a lot of it had to do with timing. We didn't have all that much time to put that together.

So we could bring up that, too, and do something that just focuses on reproductive health information.

Go ahead, Jamie.

Jamie Ferguson: Since you asked for comments, I would look to keep them separate. I think Beyond HIPAA is a big topic on its own, and I wouldn't want to confuse it with reproductive health, which may have aspects both within and outside of HIPAA.

Valerie Watzlaf: Anyone else have any comments, concerns, on doing that like that?

Okay. I know something else that I have -- I have really been looking a lot at the Beyond HIPAA documents that we have already, the environmental scan and also the letter, it was really a letter and a focus on policymakers, what they should focus on, and it has so much rich good information that still hasn't been really touched on. So I don't know if -- I know most of us, I know I haven't, I was not a part of it, that those products that I think we should really look at them and possibly think about how we can expand on much of the information. It's already there.

So that's another thing that I think that we have so much -- and then we also have I think in our PHE letter, public health emergency letter, where we talk so much about data access and the sharing of that particularly for public health agencies and being able to still share that information but still make sure that it's protected. There are areas in there, too, and those recommendations that I think we could probably take a few and break that out into more detail as well.

So that's why we did put that information in there, when Tammy and I were going over the scoping document yesterday. But if you haven't already, I really urge you to look at those, that Beyond HIPAA, those reports, because they're excellent and haven't, I don't think they've been really fleshed out enough. We haven't looked at them enough, and maybe really kind of expanded on some of the recommendations that are already there.

Go ahead, Maya.

Maya Bernstein: I just wanted to ask or respond to Jamie's comment about inside versus outside

HIPAA. Do you foresee any further work that you want to do sort of inside HIPAA after having commented on the proposed rule already. Is there something else that's still within HIPAA that you foresee you might want to do, or are you really -- I guess that's the question. Is there something there that you foresee still, given the comments on the proposed rule?

Jamie Ferguson: Sorry, were you asking me? I mean, I think that that's going to depend on the final rule, probably, in my view. So that's why I would do a robust job on Beyond HIPAA first and leave any further work on reproductive health until after the final rule.

Valerie Watzlaf: I like that. Thank you.

And then I think we had a lot of other items I think under the security letter, too. We did focus, again, it was more of a focus on risk analysis and risk management, but I think we did talk briefly. I think we do need to talk a little more about this in our subcommittee, but that was possibly breaking those out into more detail, too, particularly the one I think we mentioned on artificial intelligence possibly as well as some other ones. So that might be something, too, we may want to consider. But we had a whole listing, I believe, of all the different areas under the security letter. Most of them we did address, but I think there were still some.

Go ahead, Jacki.

Jacki Monson: Yeah, I think the AI conversation is just sort of the tipping point on that, and it's one that might fall into Beyond HIPAA but also might be in the scope of HIPAA just not contemplated beyond what we're including in our security risk letter. And I just think it's vastly being adopted and implemented in healthcare. So it might be interested to have follow-on to the discussion that we had earlier and hear from sort of healthcare, big tech, and organizations how they're using it today, because the example that I think Deb had of ICD-11, like that's happening. It's happening right now.

There's a lot of widespread adoption of AI across the board, and I think you're seeing it probably in bigger healthcare systems than smaller ones, just because they had with resources and just the risks and benefits of it. But I just wonder if that's an area to continue exploration on to see where we could potentially add value.

Valerie Watzlaf: So are you saying looking at it separately or --

Jacki Monson: Well, it depends on how we're going to look at it, right? Arguably it could be Beyond HIPAA, but also HIPAA is pretty old and particularly security didn't really contemplate, obviously didn't contemplate AI, because it didn't exist at the time.

So I know we made recommendations with respect to that contemplation on risk, but there's probably further to go, both in privacy and security exploration, and I know that HHS is going to stand up their own focus group that I'm sure will focus on it. So maybe it's just something we watch, but I also think it would be interesting to hear from healthcare on what is the widespread adoption of this and are their risks, both within HIPAA or Beyond HIPAA that we should contemplate.

Valerie Watzlaf: Yes, and I think it was -- was it Grail who had mentioned the AI strategy and how the focus was on cybersecurity, and some of that really hasn't been done yet, too. So will be interesting to see that they come up with as well.

Jacki Monson: Yeah, and AI thrives on data, and so the more data you give it, the richer the dataset is, but what does that create from a privacy standpoint from a risk standpoint, is it any different than the risk today? Maybe, maybe not. But I don't think -- I think that's sort of unfettered territory.

Rebecca Hines: Jacki, are you envisioning continuing having briefings on this to sort of explore the question of where advisement might be on the risks to privacy or the unknown risks to privacy due to AI being so quickly implemented?

Jacki Monson: Yeah, and I think we discussed this in July a little bit in the debrief and subsequent, but yes, I see that as a potential and I actually see it at the next meeting potentially at a panel discussion with tech and healthcare organizations to give us a better flavor of what they're doing, because now I feel like we have a very good perspective on what the government is up to, and I think Travis mentioned a bunch of times, this is moving fast, and we know that nothing against my colleagues in government, but things move faster in industry than they do even in government, and so I'd like to know what's going on in industry and how we correlate that.

Valerie Watzlaf: I would love that, and I would love to hear more, much more of a focus on privacy and security, because they really I think in both times we've heard the panelists speak, I don't think they talk about it. So they keep saying it's there or it's coming, but they don't talk about it.

Jacki Monson: Well, and it's there. I mean, I've seen it. I've actually seen an ED AI model where they identified diabetes based on the testing before the patient was even seen by the provider. It's pretty incredible, actually.

Valerie Watzlaf: So you're saying -- but that's more not in government, but more in the tech.

Jacki Monson: Medicine, tech and healthcare, because they're partnering.

Valerie Watzlaf: Do we want to discuss who we might want to have on the panel, or is that something we could do later?

Jacki Monson: I think we can discuss that later. I don't think we have solidified on dates yet for the next meeting. I think we're trying to figure that out. Rebecca, correct me if I'm wrong, though, because I wasn't on -- I don't think we've talked since the last polling. So I don't know if we found specific dates. I know we know general timeframe is going to be beginning of April, end of March. So I think we can do more planning offline. I just kind of wanted to share that I think we need to do more in that space, because it's moving at a rapid pace.

Valerie Watzlaf: Good, and then are there other areas that I'm just not remembering, because I think we've been here over two days. But anything I missed that some people might be thinking about that we should be covering?

Oh, I know we had another area on there about is there a public health version of HIPAA, and I think a lot of that too came out because of some of the things we had, were in the recommendation letter on public health emergencies. A lot of it came to light, I think, due to COVID, and some of the issues around data access, with public health and healthcare and how the information was not really flowing or if it was, sometimes was not protected. Or sometimes

redisclosed and not protected, things like that.

So there were a lot of things again in that same letter that I think we could break out, too.

Go ahead, Maya.

Maya Bernstein: There is still a list of other topics. I'm not sure if this is exactly in what you mean to raise now, but there's a list of other topics that Tim Noonan gave us when he briefed us of things that are related to HIPAA that are not about reproductive health, not about the things, AI, but about things like civil monetary penalties, about accounting for disclosures, about other long-term issues that they would like help with that have been kind of on our back burner that you haven't gotten to because there's been other priorities. But I don't want to lose sight of those. Those are still relevant. If there's something there that you wanted to take up.

Valerie Watzlaf: I think that our biggest thing, too, is that we need to prioritize what we would want to tackle first, and I'm thinking it's going to be the Beyond HIPAA possibly or the AI. You know, we'd have to see how we would want to do that and prioritize. So any comments on that, any feedback? And this can be from anyone. It doesn't have to just be from our PCS Subcommittee members. So please, this is great. It's very, very helpful.

Go ahead, Jamie.

Jamie Ferguson: Well, having said that of course I want to do Beyond HIPAA first, there are a couple of things in HIPAA that have been top of mind for me that we have talked about to some degree. One is the issues of minimum necessary with the use of APIs, where the way that API token access works means that the minimum necessary has to be the least and I think that's an interesting issue, and I have another one top of mind that I just forgot. I'll come back to it in a minute.

Oh, sorry, the second one is redisclosure through TEFCA and health information exchange operators. So there have been some issues with redisclosure, let's just say unexpected redisclosure.

Valerie Watzlaf: Thanks. Yeah, we did talk about this before, and I think the minimum necessary with API might have even been mentioned in the security letter. But probably just a sentence or so.

Jamie Ferguson: As an example of a potential problem with APIs, but that may since TEFCA is planning to use FIHR-based APIs for nationwide exchange of all health information, both inside and outside of HIPAA, that could be something that's worth looking at, and we should certainly talk to ONC about that.

Valerie Watzlaf: Is ONC someone too we could bring in to talk more about this like we did with OCR?

Rebecca Hines: Absolutely.

Maya Bernstein: Steve was willing to come talk yesterday. He can talk about a different project. Yeah.

Rebecca Hines: So you have many, many topics that have been raised and I think for the next executive subcommittee planning discussion, it would be good to just sort of lay it all out and prioritize, Val.

Valerie Watzlaf: Yeah, we could do that.

Jacki Monson: And it would be great, Val, to hear what the topics suggested were from OCR, because it's always a good thing to look at those potentially in higher priority than other things, because they're asking this forum and this is a need by HHS and OCR.

Valerie Watzlaf: Yes, I'll have to refresh. I wasn't sure, I know that most of what when we met with Tim it was really about what we did include, I thought we did include most of that in our security letter, but as Maya mentioned, there's other things there. So I'll have to go back and look at those notes and put those in as well. So I can lay out a new kind of a workplan. I know Tammy has done that really well. So I can do something similar and prioritize these topic areas. So this is great, thank you.

Jacki Monson: Anything else for Val before we move on to Tammy and standards?

Seeing and hearing nothing, Tammy, take it away.

Rebecca Hines: Mike, can you bring up deck T please?

Tammy Feenstra Banks: okay, what we're going to do is just I'm going to go very quickly through just our standards subcommittee report-out, and at the end, I talk about topics that we discussed to pursue that we wanted your input, but I'm going to ask to switch over to the project scope PowerPoint, and then we'll just continue that conversation from tomorrow. So it will be the standard topics and then Val, we'll jump to your topics, and then Val and I would like to bring the proposal based on -- and topics that we're going to show you when we lay out both our original areas of possible -- I'm struggling for words -- continued work, just because there's a lot of alignment and we tried to jointly put those documents, put those thoughts in one document for conversation. And then, again, we're going to want your input. So that's kind of where we're laying out this afternoon.

Anybody have any questions? Does that work for everybody?

Participant: Yes, that's good. And I think because we do have some joint work that we would like to do, bring up, so thanks, Tammy.

Tammy Feenstra Banks: And then if we have time, we can go into any of those topics in detail, but that's the major focus of us to accomplish this afternoon.

First of all, I just want to thank the members of the standard subcommittee, as well as the staff, executive staff and NCVHS staff. There's a lot of effort and work behind the scenes that occurs and a lot of subject matter expertise. So really appreciate all the active members on this standards subcommittee as we create these planning documents to bring to the full committee for discussion.

So year in review. X12, CAQH CORE proposals. Those of you who have been following along are very well versed in this. Public correspondence, want to touch on collaboration/presentations,

and then jump into the planning documents that I just mentioned.

On the right, you'll see a link to the X12 Set 1 proposals as well as the CAQH CORE proposals. We do have an open issue with the X12 Set 2 proposal. I know that CMS has asked that we hold off the review of that proposal. Is there any concern or conversation the full committee would like to have in regard to honoring that ask?

The other is that we really value your input, and I don't think that we can emphasize that enough on these calls. We need you and your expertise to respond to the request for information, to provide your testimonies, and I just again want to reiterate how important those are and we listen and we did receive post-recommendation correspondence in follow-up to the June 14 meeting in regards to the X12 8020 recommendation, which was for the claims and ERA.

This is the correspondence that we received, and we really appreciate it. Each one of these was routed to each of the members of NCVHS to review and determine if there was next step action or not. At this point, since there wasn't additional information further than the testimony and RFI, there were not responses not made, but we want to acknowledge everybody who sent this information in, especially the correspondence with the FDA. Appreciate to have that relationship to be able to respond back and forth on issues of interest.

We also gave presentations, two on ICD-11 and three on the standards subcommittee in various forums throughout the year.

So what's next on the subcommittee and standards agenda? This all falls into the scoping document that we talked about yesterday.

Our 2024 workplan. Discuss next steps for the X12 Set 2 proposal with the full committee. Compile lessons learned from our SDO conversation and discuss with the full committee, and then complete the planning documents that we were talking about, which includes the scoping documents and we're going to be going through the areas of interest and where we will target our workplans, and then obviously if any -- there's always other projects, and I stole that language from you, Valerie, because I really liked it, because you just never know what's coming down the pike. So I left that open one there.

Participant: Tammy, the first item there, discuss next steps for X12 Set 2, it sounds like there aren't any, given that nobody spoke up.

Tammy Feenstra Banks: Exactly.

Participant: Okay. So I just want to make sure everyone's clear. The committee is not going to move forward on the April proposal that we got in April on X12 8030. That was the suggestion from CMS and there doesn't seem to be any issue with that. So I think we can consider for the workplan now, that's just been tabled.

Tammy Feenstra Banks: Right. Thank you for that clarification.

I think we can now skip over to slide 9 of the scoping document. I'm just trying to be conservative with time. So I apologize for the quick run-through.

What you're going to see when the slide comes up is the workgroup was again, as we talked

about yesterday, reviewing the history, reviewing all the work that was done with the predictability roadmap, the Convergence 2.0, and pulled out the topic areas that still seemed to be of a high priority in the current healthcare environment that we laid out in that scoping document.

So we came up with four high priority topics and we just wanted to share them with you and get your feedback on if there's support for continuing putting resources and fleshing out a workplan for these topics, and if so, also, who would we want to anticipate, who would be our anticipated partners, collaborators, keep informed?

So the topic would be where might the NCVHS vision and objective recommendations fit into the ONC and HHS strategic plan, and how can we connect those dots and demonstrate alignment? The second topic was examine mature and emerging standards and how they can coexist to support current and future business needs and their workflows.

The third was to review relevance of HIPAA in the current healthcare ecosystem, and the fourth was harmonization of standards and data. The second one, just to expand a little bit on what that means, is the emerging standards with the APIs. More commonly there's an API for prior authorizations. We also have X12 278, which is a prior authorization. Moving forward, visioning down the road, how can they coexist to support the business needs or not support, exist. So we figured that really requires some additional research in collaboration with ONC, CMS, the standard, the SDOs, and is there anyone else that would need to be included in that conversation?

Lenel James: I'm sorry, say again? Which conversation you want us in?

Tammy Feenstra Banks: Well, what this is, Lenel, I know you just jumped back, is the four topics of interest that the standards subcommittee came up with for the full committee to determine if they support us to continue putting resources in these areas, or if there's other topics that we should be considering. So why don't we move back and just see if there's any additional comments or topics that should be included or if you would like additional explanation of any of these topics.

Lenel James: My initial reaction is the comment that says examine mature and emerging standards and trends, that's you can put a lot in that one topic. For example, my initial thought was, oh, I don't see any health equity on here. But that is an emerging standard, because it just got announced a year ago at HL7 and we're still trying to get people to use it, and along comes the White House playbook that names it. So much like the DaVinci project got a bunch of push from the feds naming it and announcement, that appears to have just happened with the SDOH and health equity. So it seems like that second bullet covers a lot of flexibility for us.

Tammy Feenstra Banks: Thank you, Lenel. Anybody else have any comments?

Just for our nonstandard colleagues, the review relevance of HIPAA in the current healthcare ecosystem, it's really a conversation about the name standards and the lack of flexibility within HIPAA. Is there other avenues to help update standards quicker, and also with the expansion of the different covered entities, our noncovered entities that are exchanging healthcare information, should they -- is there a way to take a look at HIPAA to also have them included or raise all those different questions that were raised in that scoping document under that topic as well?

And then harmonization of standards and data I think is pretty self-explanatory as the standards keep moving forward.

Michael.

Michael Hodgkins: Tammy, in later documents, it seems that we've concluded or it would be reasonable to state a position that HIPAA has somewhat lost relevance, or it's insufficient in the current ecosystem. So is the topic that we really want to be dealing with reviewing the relevance, or really being more proactive in terms of making recommendations regarding appropriate changes for HIPAA, given the current healthcare ecosystem?

Tammy Feenstra Banks: So what topic are you recommending it be changed?

Michael Hodgkins: Well, the topic C seems just very retrospective, and in the workplan documents, it seems like especially in the Word document, it seems like we've already saying that HIPAA is out of date. There are any number of things that HIPAA doesn't address in the current ecosystem. So I just felt like the topic review relevance has already been -- we've already sort of addressed that. We say it's --

Tammy Feenstra Banks: Oh, I understand what you're saying. Yes, you're right, in the standards subcommittee we reviewed these and we also added considerations under each of these topics. The reason that I'm bringing them up as topics is to get the full committee input to see if the planning that we did makes sense to the full committee and if there's agreement with these topics, Michael.

When we have time, I really wanted to go through each of these with our considerations, but we don't have that much time, and so this is just to get the support from the full committee and the direction of where the standards subcommittee was going, as well as get additional input on is there other partners, collaborators, that we weren't aware of that we should be putting in under these topics as well? So your point is dead on, yes, and we'll bring up some of this information. As a matter of fact, one of the joint topics is in relation to the review relevance of HIPAA. So we're going to dive in that further, but at this point, we're just at the top level of any disagreement with the topics that we're looking to put resources in to flesh out.

So Jacki, just looking for your support blessing on where these are going with the overall NCVHS vision at this point in time.

Jacki Monson: Yeah, I support it, and I think what we're trying to do at this meeting is really just allow for dialogue of both the subcommittees in conversation to provide feedback and kind of the general direction that we're going. So that's really the purpose of this, and I support it. If I didn't, you'd be listening to me ask a lot of questions.

Tammy Feenstra Banks: Okay.

Participant: And Tammy, following up from the helpful discussion we had yesterday on topic C, are you talking specific to transaction standards or is this the joint looking at HIPAA from sort of both sides, privacy, security, and transaction standards?

Tammy Feenstra Banks: I'd love to table that question for just a moment, because that's the proposal Val and I would like to bring up, but I just wanted to share and get the blessing on this

first.

So seeing no questions, I'm going to move along in the interest of time, or any additional partners to throw in here.

So Val, the next slide is your Privacy and Security, if you want to -- and is the document that you want to update?

Valerie Watzlaf: Yes, this will change then based on the wonderful feedback that we got today. And I think what we may want to -- I could even add additional topics, and I think our biggest thing will be to prioritize what we want to focus on first. But under strengthening the HIPAA security rule, we had listed out a whole bunch of different things there in the appendix that is in the scoping document, but a lot of that is in the security letter, which you all approved. So we thank you for that.

So some of that will certainly come out, and then we could focus, as we had mentioned, about AI and also I think Jamie brought up a couple of things on minimum necessary and API and the TEFCA and HIE redisclosures, unexpected redisclosures, and then we will break out because we've heard from you, we'll break out the Beyond HIPAA would be separate from the reproductive health information and possibly other sensitive health information. But we could break that out in the second, in part B there. Is that B or C?

And then when we talked about the public health possibly public health version of HIPAA, that was really going to break out more from our public health emergency recommendations that we have there. And then we also could add, you know, the additional topics that we heard from OCR from Tim Noonan. I think that's everything. I'm just looking at my notes now. I don't think I missed anything, unless if I did, please feel free to chime in. But I love this conversation. So it's very helpful. Thank you.

Tammy Feenstra Banks: Cool, and then the point of these, number one, is make sure that we are aligned as a full committee and Michael and Rebecca brought out the relevance of HIPAA as well as Valerie as the Beyond HIPAA. So as we looked at these across the privacy and security committee and the standard subcommittee, if we go to the next slide, this is where we really wanted to get to.

We realized that there were a lot of commonalities between these two topics, and so Val and I reviewed it, and we would love to take time to go through the different criteria or considerations that we think fall within these two topics and form a joint workgroup of interested members to review the current state of HIPAA law and propose updates as needed.

Do you want to go to the next slide and kind of flesh it out and then ask that question? So what we're looking at is, again, the topic can change, the topic title, I just threw in what we had. Review relevance of HIPAA. We know who the anticipated partners are. We may be missing some. But these are the ones that were identified from both of the subcommittees, and under considerations, I'm not going to read them, but that was really what the focus, initial focus is, to help the start of the planning conversation of what else should be in there. And so we'd really love feedback from this group, Val and I would love the feedback, if there's anything missing, if something needs to be more clarified, any input in order to make this a stronger planning document for this joint task group.

Valerie Watzlaf: And I think just to clarify then, we would probably be pulling out what looks like the fourth, fifth, sixth, seventh bullet there, that would be then separate areas. So some of this under potential considerations would change, because that includes some of the reproductive health information, as well as the AI security, looking at AI privacy and security. So some of that would come out.

As far as the federal agencies, that would change, too, because most of those that we added not at the top, but the ones where it says other federal agencies, that would probably come out, too, because a lot of them were under reproductive health information or privacy. Does that make sense, Tammy?

Tammy Feenstra Banks: I need a little more direction on that, but that's okay.

Valerie Watzlaf: Okay, I can fix that. That just came up from today.

Tammy Feenstra Banks: Okay, so what would the taskforce be focused on, because it was looking at HIPAA and these are all the different considerations of the change in the environment, and what HIPAA really needs to take into account. So I don't know if removing them is needed. It still needs to be a consideration, but it won't result in action, right? Because you'll have another.

Valerie Watzlaf: Yeah, because they're saying --

Tammy Feenstra Banks: Because you're going to work on it within your workgroup.

Valerie Watzlaf: Right. But it would be probably a separate possible letter of recommendation or whatever we would decide. But I think I could add more by looking at our Beyond HIPAA documents. You know, that could be part though of the joint work, because I think there is some excellent stuff in there that we could pull out and expand upon.

Tammy Feenstra Banks: Well, and I think what started this conversation is the expansion of -- I know Maya is not going to love this -- personal, PII or just personal health information that is covered under HIPAA, but then it goes to a noncovered entity, and then it becomes not -- there's no protections anymore. And that's used with the standards and it's used with the exchange of the data from a privacy and security and confidentiality perspective.

And those seem to be very -- two topics that dovetailed very closely in regards to when we take a look at HIPAA, so I think those first, what is it, the first three bullets or first four bullets are probably the main considerations.

Maya Bernstein: You said that just right. In the document, we're going to get it precise.

Tammy Feenstra Banks: Okay, Maya. I was trying not to get in trouble with you. I'm learning.

Maya Bernstein: You got it.

Lenel James: All right, I have something. I put it in the chat, because it's partly in response to Michael's comment about the original state was review the relevance of HIPAA, and as I listened to his comment and was thinking about my concerns, maybe one of the challenges is this isn't about just HIPAA. It's about what's the applicability of HIPAA, because we may or may not be

able to change it, and even if we could change it, it's not tomorrow.

Changing HIPAA could be done, but that's years away. We want to affect healthcare now so potentially it's the applicability of HIPAA and its potential future and new options to enhance the uptake of standards and technologies to improve outcomes in the current healthcare system, not trying to necessarily wordsmith that, but just saying it sounds like the intent of this work together is to figure out how do we move the technology so it's adopted quicker, adopted easier?

We have new tools beyond HIPAA. We have AI. We have the federal interest in supporting health equity. There's a lot of moving parts that all ought to be considered. But I'm recommending a frame that it's about HIPAA and how we can get people to use this stuff we talk about, which is we don't want to talk about it. We want people to use it and do it and maybe that's a different frame to talk about it. So that's my input to the discussion.

Tammy Feenstra Banks: Thank you, Lenel.

Any other comments?

Participant: There's a question. I don't know if we want to address that right now, from Michael Phillips about adding CAQH CORE to the collaborators here.

Tammy Feenstra Banks: Oh, under harmonization and standards, yes. That's good. That's a really good catch.

Participant: So I guess then, given the discussion you all just had, the plan is to identify members from both subcommittees basically from across the committee to flesh this out into a specific workplan that you would start work on?

Tammy Feenstra Banks: Exactly. If anybody doesn't have anything else in regards to what information we'll need to actually be able to come up with a workplan, we can go to the next slide and it lays out next steps. Is there anybody who has any other comments, directions, considerations, to help this taskforce be effective?

Lenel James: When will be the next opportunity to look at -- because the other collaborators, we just added CAQH; based on who has presented to us at this meeting and previous meetings, there may be some others we need to make sure we don't forget to be part of this process.

Tammy Feenstra Banks: That's what we're asking. Is there any other collaborators? Again, now we're looking at relevance of HIPAA. The Q&A was from the previous slide with harmonization that we need to make CAQH CORE is on the collaborators.

Lenel James: Well, there's a new coalition that I guess ACO and HHS is part of for -- I think it's the coalition to align health equity. I will find the link and put it in the chat, because Robert Wood Johnson has put $350,000 in it and at least parts of HHS are part of it, too, along with a variety of major industry stakeholders. So I am not an active member of the group. I just know in looking in who's in it and the webinar they did last week, it looks like that's a pretty sophisticated group in terms of what they're trying to do and it might be appropriate to consider them as one. I'll find the link and put it in the chat.

Tammy Feenstra Banks: Sounds great. And one thing I just want to reiterate that the scoping document that we went through yesterday as well as these topics in consideration have been sent to ONC and CMS. So we are waiting to get their feedback as well. So there may be revisions based on the priorities within those agencies over the next few years or so. So, we're not working in isolation, but today is the day to get the input from the full committee in order to make sure that the work is effective and on target for where, again, NCVHS wants to go.

Michael, I apologize, you had your hand up.

Michael Hodgkins: I didn't know what you were thinking of with respect to Lenel's comment. But if we're going to take his suggestion under consideration, I just didn't want to limit it to outcomes. It should be administrative improvement as well as outcomes, I think.

Lenel James: Good catch.

Rebecca Hines: And I note there's a whole range of anticipated partners and collaborators, and as you start sketching out plans, right now there are no virtual hearings planned for FY24. It may be that we can use the resources for one of those to have an expert roundtable discussion for example, to get all of the basically information-gathering, getting in perspectives once ONC and NSG also have a chance to weigh in on what would be helpful.

Tammy Feenstra Banks: Okay, with this fleshed out a little bit more, is there support from the full committee to create a joint taskforce? Is there members who are interested in spending an extra hour on fleshing a workplan on these topics?

Jacki Monson: I think the only thing that I would say is prioritization. This is a lot, and we have challenges with staffing, challenges with the co-chair, et cetera. So is this really realistic and is there a prioritization of it that could be done?

Lenel James: Does it have to be a new initiative, or can it just be a joint meeting where the two groups get together so it's part of our regular work we're just jointly getting together? I mean, that's a thing HL7 does. We have workgroups, and every once in a while, they decide we're going to have a scheduled call where we are together working instead of having to establish a new entity, we just get the two key groups to agree on a joint date every other month or every month, depending on people's schedules.

Tammy Feenstra Banks: Excellent, Lenel, so you just volunteered. That's terrific.

(Laughter.)

Lenel James: I'm in.

Tammy Feenstra Banks: This is a joint taskforce of the Privacy and Security and Standards subcommittee, but there is an option not to participate. And so we just want to make sure that there's people who are willing to contribute their time and anybody from privacy and security or standards can participate at any time, but we do need people who are eager and willing to focus in on this task.

Jacki Monson: And I think I would just reiterate again, like, the way you do it or the way that you suggest is fine. I'm just -- there's not very people on both of those groups, and we don't have a

lot of resources and there's other focused areas and priorities, too. So you got to be realistic about how much time of whom you're going to get to be able to do this. That's just my point.

Tammy Feenstra Banks: Exactly, and that's the question to the group. And from I think Val's comment, it's the first three bullets that would be in consideration based on the input that we have so far today.

Participant: And it's not just committee time. It's staff time, right?

Valerie Watzlaf: But it can even be new people. We had talked about that. That could co-chair it. It doesn't have to be Tammy and I as well, right?

Jacki Monson: Yes, but there's not very many -- I mean, there's like people total --

(Crosstalk.)

Participant: I am just wondering, we're still talking about committee members. What about -- are there sufficient staff resources to support this joint subcommittee activity?

Jacki Monson: I think that's a question for Sharon. You know, on ICD-11, that's an example where we do have additional external resources supporting that group, and it's not just members of this, of NCVHS. It's also members of the public who are participating through a nomination process. So that's sort of an example of where I think that's been pretty effective, but I'm sure you could ask Jamie how much time it consumes of his, and it's a lot.

So I'm not trying to stop this. I'm just saying we have to be realistic about the resources that are available, and I just think that between the conversations with standards, PCS, and this, it's a lot.

Sharon Arnold: I will speak up and say that staff resources are really hard to come by, and I think we'll need to make some tradeoffs about what doesn't get done if we add this on to the plate. So I don't anticipate that we'll be able to garner new staff resources to support additional work at this point. We can try, but I'm not optimistic.

Tammy Feenstra Banks: Jamie?

Jamie Ferguson: Well, I was going to build on Lenel's idea of a joint meeting of the two subcommittees, and what if we had one or more joint meetings of the subcommittees for the purpose of prioritizing this work and figuring out a subset of the work that we might want to come back and really establish a workgroup for, but not to do that today?

Participant: I would agree with that.

Lenel James: That's what I meant. He got it.

Tammy Feenstra Banks: So every other week we have a standards subcommittee; in one of those weeks we don't have one, we would have one of these meetings, whether it be once a month or whatever, depending on staff resources.

Jamie Ferguson: We would arrange the subcommittees to meet together jointly one or more times, as much as we need, in order to figure out a subset of this that would be the really the

priority that we would want to tackle.

Tammy Feenstra Banks: Val, thoughts?

Valerie Watzlaf: I like that. I know I have to -- I want to put something out to -- well, I had a few questions too. If we break things down to specific areas, do we need separate scoping documents for those areas? That's a different question. But I know I need to break things down that I could present that would take on some of these other issues that we talked about, and it's not here. so this will change. So we do need that discussion. So I'd be very much in favor of that.

Jacki Monson: My perspective is why don't the two subcommittees meet? Why don't you guys confer, and then I would bring this back to the executive subcommittee where I think we have the decision on prioritization, topic focus, et cetera. So what I'd look for is a recommendation, joint recommendation, from the two of you, just get everybody's feedback on what we can do, and then we can talk with Sharon and Maya and Rebecca on staff support for how we kind of want to or can manage to do that, and that has to be part of the contemplation, and then obviously the contemplation and appetite and time of our membership. So I think let's bake all those things and let's bring it back to the executive subcommittee.

Tammy Feenstra Banks: Sounds good to me. You, Val?

Valerie Watzlaf: That's good.

Rebecca Hines: And just to get -- I just wanted to get clarity that we've used project scoping documents to remind, keep ourselves in a lane about what it is you overall plan to work on, and then you can have individual workplans for particular, like task plans if you will. You don't have to have a project scope for absolutely everything. It's really for you to help keep yourselves organized. It's a collective reminder and over the years, I've observed that they have been very helpful. You don't need to, though, have something laid out in that much detail for everything. It's really what helps you plan and stay on track and communicate with each other and outside collaborators.

Tammy Feenstra Banks: So I don't see we need to do another project scope, because we already did. This is in relation to the project scope we did. So we would just lay out the workplan, what is the information we need, how we're going to get it, just like that in the scope doc when we talk about how. Do we need to have, bring in subject matter experts at an onsite meeting to grab different information? Do we need to do an RFI? Do we need that type of workplan, flesh that out so we know what type of resources would be needed so then that prioritization can occur in the executive committee?

Valerie Watzlaf: I guess that's the part -- and I think you both answered it well. I'm not sure like when do you need the scoping document, when do you need a workplan or a task plan? I do think we are probably ready for the task plan of what we would do to get there.

Tammy Feenstra Banks: Yes, and then you and I on our call that we have scheduled, we can figure out when to set that joint committee meeting and then do some preplanning to make it easier to have that conversation. Like pull out the things that you wanted to pull out and that good stuff.

Okay. Now, the other where we wanted to go after this is we can dive in any of the previous topics that we laid out if this work plan -- if the full committee would like to dive in to any of the standard or the privacy and security topics. I don't think we have to go through all of them. They're in the appendix of the scoping document. Unless, Jacki, you feel that we do need to go through all the considerations and get additional feedback, but everybody has reviewed this document and provided input. What are your thoughts on the next steps?

Jacki Monson: I don't think we need to go through the whole vetting process. I think we just talked about next steps. So I'm comfortable with those, and I would defer to anything else that you want to discuss and have the time for open conversation right now. So if you want to go deeper in open conversation to get folks' feedback and direction, fine. I'm comfortable with where we're going, with what we discussed, and the game plan.

Tammy Feenstra Banks: Okay. If you want to go to the next slide, then. So I think this just kind of lays out where we're going to go, which follows, Jacki, with your recommendation. And then getting the initial workplan up to the executive committee to look at for prioritization.

You're going to see in that scoping document, for those who have not, you will see more areas of different criteria that are considerations for each of these topics. I know we'll probably send out the project scope another time. I just want to reiterate just to take a look at those considerations.

If you go to the next one, this is kind of a hard one to see. But we included all the different considerations to think about when we're looking at each of these topics. So that feedback would be very well received, but again, since it's late in the day and I don't know if we really want to go through each of these topics.

Standard subcommittee members, is there any that you would like to pull up, have me pull up and have a full committee discussion on that that touches more closely to privacy and security than the others? I just think that one was a natural fit.

Lenel James: Tammy, it's Lenel. Based on what's on the screen, it seems to sound a lot like the discussion we just had about what to do with the next generation of HIPAA seems to be this same topic, just worded a different way.

Tammy Feenstra Banks: That was the topic that I had showed on the first screen. This is the additional considerations under it. So it's the exact same topic. We just had the conversation on that overarching slide deck when we were looking at just the areas and topics.

So Val, what's your step? Do you want to go through each of the privacy and security -- or the --

Valerie Watzlaf: No, I really don't, because they're totally different.

Tammy Feenstra Banks: It's a long day.

Valerie Watzlaf: Yes, and it is late, and I have notes on the feedback that I know I can build out a nice new workplan, task plan, whatever we're going to call it. So I think this has been very helpful.

Participant: And on this slide deck, Val, you might want to start with all of the work you all did to

prepare for today, slide 22, 23, and 24, you have that whole set of lists that you all pulled together actually, and slide 25. So you have four slides that have some of this level of detail that you can start there as well. Your list making to start prioritizing.

Valerie Watzlaf: Were you saying to show that now? Or you're just saying to start there.

Participant: No, it doesn't sound like that that's a good use of our time, but just to say that you had prepared those, and I think they're a good resource for you to look at. They're also posted on the meeting page. So if people want to see what the thinking coming into today was, those lists are there.

Tammy Feenstra Banks: If you want to go to the next slide, just kind of run through to give people an idea of what's in there.

Valerie Watzlaf: I mean, the discussion too that we just had around some of the things to cover is not all that different than what we had kind of proposed anyway. But you've expanded on it, and you've just provided us some I think more detail, which is very helpful.

Tammy Feenstra Banks: So like the topical analysis, including removal of named standards, cross-standard collaboration. Again, considerations just means to make sure we discuss it.

The harmonization of standards really taking a look at all the different new and existing standards and making sure that there's alignment and mapping and information exchange format. Steve, I don't know if you want to mention anything on or pull out anything on the harmonization of standards and data request topic.

Steve: I think this describes it fairly well at the level that we need right now anyway.

Tammy Feenstra Banks: And if you go to the next slide, it just continues and this is where, again, this is where your social determinants of health is included as well, Lenel. The topics about gravity project, et cetera.

Again, all of this is in that scoping document.

This is all the underlying stuff of the privacy and security, while we had just the topics, there was a lot underneath in regards to getting to that topic area that would need to be considered and discussed and I know you're going to be revising this, Val, but I think this is what Rebecca was alluding to.

And if you go to the next slide, this was again included in that topic, all those different areas, including the AI, including some of the other topic areas that you mentioned.

Valerie Watzlaf: And much of this is in our security letter that was approved, but when this was written, we weren't sure what was going to go in. So a lot of this is done.

Tammy Feenstra Banks: So that's good, a lot of it's done.

Participant: That's why I wanted you to know, you forgot, you already did so much work on this.

Tammy Feenstra Banks: I think there's one more topic that you had.

Valerie Watzlaf: Oh, right, this was again some things that we had talked about. This was the previous, the first cybersecurity letter. These were just some notes that we had around what was good about the rule. You know there are some good things, great things, about the security rule and how we need to say that as well.

Tammy Feenstra Banks: And I think there's one more. This was the last one, protection of public health data.

Valerie Watzlaf: Yes, which we would really look at the public health emergency letter and expanding on that and some of our issues around data access, as well as protection.

Tammy Feenstra Banks: If you want to go one more slide, I think that's all that we had. But then I think the takeaway, Jacki, is that we can flesh out the workplan so that there can actually be a discussion on resources and where those should be.

Jacki Monson: Yeah, and I think prioritization is important, because I feel like with PCS right now, we have stuff from OCR that they'd like us to focus on and current administration and there are some pretty meaty topics. So I just want to balance that with some of the heavy load standards work where perhaps PCS could be an advisor and provide input versus sort of co-running the work together. So just kind of my two cents, but go off and do the work, bake it, and then let's bring it back to executive subcommittee and then we can have a more robust conversation there.

Tammy Feenstra Banks: Sounds good, and again, apologize for running through this very quickly late afternoon on our second day, but is there any other comments, feedback, more clarification that any of the committee members would like?

Lenel?

Lenel James: No, just wanted to make a comment. I'm glad you went through this, because I can't speak for Steve, but as the new person, I was like wait a minute, now I see why we've actually got plenty of stuff in the inventory. It's more a matter of getting input from the feds to guide us and input from our members to go now going into 2024, in the current status of reality, what's the priority.

You've just shown me we've got a fantastic good list and as I looked at it, I could -- I'm sure others of you saw things or that's not important anymore and this other thing is more important. I think it will be pretty -- I won't say straightforward, but it will be a good exercise to cull the list down to what are real priorities and then the executive group and staff going, okay, you culled the list, but we still don't have enough staff. Pick one.

So I see a process that will hopefully in the next several weeks we will be able to have something really good to work on with some consensus. So this looks like a fantastic start.

Tammy Feenstra Banks: You're making a good point. Thank you to the standards subcommittee members who worked through this process. We had 10 to 12, we got it down to what we presented today with all the considerations. It was a lot of work, and I know again we need to do more focusing. But again, prioritization is always a step-by-step iterative process.

So that's all we have, Jacki, since you're allowing us to run through this quicker than we

originally intended.

Jacki Monson: That sounds good. Rebecca, are we ready to move to public comment?

Public Comment

Rebecca Hines: Very good. So if you could bring up the public comment slide. We have 35 attendees right now on the public side. So this is the public comment period.

Please raise your hand if you would like to make a public comment. We'll wait a moment, get our Jeopardy! music playing.

I'll check the NCVHS box. We got one letter yesterday, which I sent out to everybody, specific to standards topic.

I do not see any hands going up. It's a quiet meeting.

Maya Bernstein: It may take people a minute or two to pull themselves together since we pushed up their time.

Rebecca Hines: Right, exactly. Yeah, I apologize. We're going to need to do a better job of forecasting when public comment will be.

Tammy Feenstra Banks: I apologize for that. I just didn't think there's a huge appetite to dive in the weeds this late.

Rebecca Hines: I think you read the room, right, Tammy.

So Jacki, Maya, I don't see any need to stay.

Maya Bernstein: Rebecca did warn people at the beginning of the meeting that things might shift, they should be on by 4 o'clock if they wanted to make public comment.

Rebecca Hines: Just a reminder to people, NCVHSmail@cdc.gov if there's something you would like to send after the meeting, we will include it in the meeting summary. So any time during the year, you are welcome to send input to the committee, but it's nice to do it during the meeting as you hear that the conversations are in the process of leading to next steps.

Lenel?

Lenel James: Just a quick question. Both today and yesterday at the end, people didn't have too many questions. Have we ever given people the option to have questions after lunch so that we potentially catch it before we run out of gas and they're out of gas to see if anybody has comments? I just don't know if that's been done before as a good or bad idea.

Rebecca Hines: We did that at the January hearing, actually, and like I mentioned at the executive subcommittee, when we plan out the agendas, I think one of the takeaways is to try to shore up, tighten up some of the agenda, timing, and have an earlier public comment period.

The other thing is it's just very different over Zoom, and some people put their comments in the Q&A. Yesterday we got a very rich Q&A, which we have that file available to look at. When

we're in the room, it's just very different in person, and so I think it is the end of the day and our colleagues in the public, 34 who are with us right now, don't have anything to add. They all know how to reach us.

So I think with that, Jacki, I'll turn it over to you. Public comment period has ended.

Jacki Monson: Okay, that sounds good. Rich, just want to thank you again for all of your service over the last eight years to NCVHS. We're certainly going to miss you a tremendous amount and just deeply grateful for all that you've done over the last several years. So you have been kind of a cornerstone to NCVHS for me, because you've been here the entire time I've been here, and then some. So just deeply, deeply appreciate you, and we're certainly going to miss you.

And with that, I just want to thank all the staff, Rebecca, Maya, Stefanie, others, that have helped. It takes a village to put this together, and they work really, really hard on doing all the behind-the-scenes work. Our tech team today and yesterday, trying to make everything go so seamlessly. Just deeply appreciate all of you, all of the extra work that you put in, and then to my committee colleagues, thanks for your great engagement over the last couple of days. Lots of opportunities, lots of work to do. So looking forward to further discussion, further priorities, and Lorraine, I somehow missed you, I don't know how, but she's basically critical to standards.

So thank you all very much, and it might be your end of day, but it's only probably the middle of my day. So thank you so much for your time, and we'll see you soon. Have happy holidays.

(Whereupon the meeting was adjourned at 4:15 p.m.)