National Committee on Vital and Health Statistics

Transcript
April 11, 2024 9:00 a.m. – 5:30 p.m. ET
Hybrid Meeting

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 Molchan Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	Network for Public Health Law	Member
Tammy Feenstra Banks	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Healthcare Consultant	Member
Valerie Watzlaf	University of Pittsburgh	Member
R. Lenel James	Blue Cross Blue Shield Association	Member
Steven Wagner	University of Pittsburgh	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Marietta Squire	NCHS	Staff
Gwen Mustaf	NCHS	Staff
Naomi Michaelis	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Somava Saha	Wellbeing in the Nation Network	Executive Lead
Meagan Khau	Centers for Medicare & Medicaid Services (CMS)	Director
Vanessa Candelora	Point-of-Care Partners (POCP)	Senior Consultant
Prerana Laddha	Epic Systems Corporation	Director of Social Care and Behavioral Health
Rachel Harrington	National Committee for Quality Assurance (NAQP)	Senior Research Scientist

Julia Skapik	National Association of Community Health Centers (NACHC)	Chief Medical Information Officer
Gniesha Dinwiddie	National Institutes of Health	Health Scientist Admin
Farzad Mostashari	Aledade	Co-Founder and Chief Executive Officer
Todd Couts	Centers for Medicare & Medicaid Services (CMS)	Deputy Director
Aneesh Chopra	CareJourney	Co-Founder & President
Michael Cimmino	Centers for Medicare & Medicaid Services (CMS)	Director
Erin Richter Weber	CAQH	Chief Policy & Research Officer

Call to Order/Roll Call

Rebecca Hines: A warm welcome to all of the members here in the room. And I see we have some members here on Zoom. So, I'm delighted you can join us remotely. Angela Alton and Wu Xu. Welcome to the committee staff who are here for their first meeting. Delighted you could be here with us, joining the team and the members of the public in attendance with us here today.

Rebecca Hines: Delighted to be here together. My name is Rebecca Hines. I'm the Executive Secretary and Designated Officer for the National Committee on Vital and Health Statistics, NCVHS.

Our last meeting of the Full Committee was in November when the Committee met virtually. And just a reminder, during that meeting, the Committee voted to approve recommendations for HHS to strengthen the HIPAA security rule. And those recommendations are posted on the NCVHS website. And in addition, the NCVHS ICD-11 Workgroup published its Phase 1 findings report right after that meeting. And that also is on the website. And for those of you on Zoom, I will pop those links in the chat for you shortly.

But let's begin by taking care of roll call. Please state your name, your status as a special government employee, and any potential conflicts with today's work, starting with our chair.

Jacki Monson: Good morning, everyone. Jackie Monson, Sutter Health, NCVHS Chair. No conflicts.

Rebecca Hines: Cathy Donald.

Catherine Donald: Good morning, Cathy Donald, Alabama Department of Public Health. I'm a member of the Full Committee and the ICD-11 Workgroup. And any discussions around reproductive health, I will recuse myself.

Rebecca Hines: Thank you. Deb Strickland.

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

Rebecca Hines: Michael Hodgkins.

Michael Hodgkins: Michael Hodgkins, a member of the Full Committee, the Standards Subcommittee, the ICD-11 Subcommittee, and I have no conflicts.

Rebecca Hines: Denise Chrysler.

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

Rebecca Hines: Val Watzlaf.

Valerie Watzlaf: Hi, everyone. Val Watzlaf, I'm with the University of Pittsburgh. I'm on the Full Committee, chairing the Privacy, Confidentiality, and Security Subcommittee.

I'm a member of the ICD-11 Workgroup, and I have no conflicts.

Rebecca Hines: Thank you, Val. We keep you busy. Lenel James.

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

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Jamie Ferguson, member of the Full Committee and the PCS and Standards Subcommittees, currently chair of the ICD-11 Workgroup, have no conflicts. But when we talk about ICD-11, Kaiser Permanente did submit a comment letter, and if there is any discussion particular to those comments, I'll recuse myself.

Rebecca Hines: Thank you, Jamie. Tammy Banks.

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

Rebecca Hines: Steve Wagner.

Steve Wagner: Steve Wagner, member of the Full Committee, Executive Committee, co-chair of the Subcommittee on Standards, and I have no conflicts.

Rebecca Hines: All right, that's everyone in the room. Moving over to Zoom, Angela Alton. Good morning.

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

Rebecca Hines: Thank you, Angela. Wu Xu.

Wu Xu: Good morning, everyone. I'm with the University of Utah. I am Wu Xu. I have no conflict. I'm a member of the Full Committee and also a member of ICD-911 Committee.

Rebecca Hines: Thank you. We have a quorum, so we are ready to move over to staff, starting with Sharon Arnold.

Sharon Arnold: Thank you very much. I'm really pleased to be here with you. It's really good to see many of you in person, and it was great to see you in November, and I know our forward-looking plan is to try and meet at least once a year in person. Other times virtual, so we are coming back from COVID, which is really nice.

I know you've all seen Rebecca's note on her impending retirement next month. Rebecca has been tireless in her work on behalf of the Committee, and we will miss her dearly. I know you'll join me in wishing her all the best in her retirement.

(Applause)

At this point, I want to share a change for me as well. As many of you know, the COVID pandemic highlighted multiple supply chain vulnerabilities, including for chemotherapy drugs, infant formula, medical devices, and over-the-counter children's ibuprofen and acetaminophen.

On November 23rd, 2023, President Biden issued a White House fact sheet and announced new actions to strengthen America's supply chains, including a White House Council on Supply Chain Resilience and the designation of a new HHS Supply Chain Resilience and Shortages Coordinator. So, I have been named as the coordinator, at least on an interim basis, while a search is conducted for a permanent coordinator, but that has lagged a little bit. And so, I have been the coordinator for a bit.

In my first couple of months on the job, we have developed and released a white paper highlighting the work already underway and outlining some potential legislative opportunities aimed at preventing and mitigating drug shortages.

We've also established an HHS-wide working group to develop a three-year action plan to coordinate existing activities and identify gaps and opportunities. We've been busy reaching out to organizations doing work in this area to identify all the great ideas out there and commence coordination.

So, as you can imagine, this role is keeping me pretty busy in addition to my day job. So, I will be leaving NCVHS as executive director. And I want to say I leave you in excellent hands. Sarah Lessem is a senior data scientist in ASPE and will be serving as the NCVHS executive director going forward.

Dr. Lessem has had a rich career working for a variety of direct service and evaluation-focused nonprofits at the Fors Marsh Group, where she led the evaluation of a COVID-19 prevention campaign, and at RTI International, where -

(Off mic)

Sharon Arnold: We were doing roll call? Oh, I'm so sorry. I just launched in. Okay, so Sharon Arnold, executive director.

Sarah Lessem: Yes, I've been introduced. Sarah Lessem, ASPE.

Rebecca Hines: Lorraine Doo is online with us, and she will be live with us shortly. She's lead staff to the Standards Subcommittee. Maya Bernstein is lead staff to the Subcommittee on Privacy, Confidentiality, and Security, and she will be joining us as well. And over with us on the staff team is Naomi Michaelis, who will be acting DFO shortly, and Shirley Castillo, you've met both of them, and Gwen Mustaf, who I think is busy bringing people up from security.

So, with that, can we bring up the public comment slide, please? Just want to note that for this meeting, there will only be one public comment period live, that'll be this afternoon, somewhere around 5 p.m. Eastern. If you're planning to participate in the public comment, please be attentive to where we are in the agenda. We will try to do it at 5 p.m. If we're in the middle of proceedings, but for members of the public, whether you're on Zoom or those who may come in the room, we will provide these instructions again.

As you can see, there is an address on the screen there. If you don't want to make an oral public comment, you can send it in writing to ncvhsmail@cdc.gov, and we can read it into the record. And if you haven't already, you can sign up to receive email notices from the Committee to subscribe. It's on

the homepage. And in a moment, I will put the link to today's agenda and the other documents I mentioned. And with that, let's turn it over to our chair.

Agenda Review

Jacki Monson: Good morning, everyone. Happy spring. And as Sharon mentioned, we're excited to be coming back in person. And hopefully this year we'll have at least two in-persons.

So, let's review the agenda real quick. So, we're first going to start with an update from Sharon, which she's provided some of it, but we'll finish it. And then we'll move to a CMS update. And then the Workgroup on Timely and Strategic Action to Inform ICD-11 Policy led by Jamie. We'll take a break, and then we'll move into the report to Congress, which I will lead. And then we'll take a lunch break.

And then in the afternoon, we're going to focus on standards for SDOH data elements and have a panel for that. We're going to take a break. And then we'll be talking about value-based care models versus fee-for-service implications for HIPAA standards led by Deb Strickland. Then we'll break for public comment. As Rebecca mentioned, we'll try very carefully to be at 5:00 if at all possible. And then we will transition to a Subcommittee on standards update and we'll wrap and adjourn for the day around 5.30.

And I'm going to turn it over to Sharon to finish her update.

Update Office of the Assistant Secretary for Planning and Evaluation

Sharon Arnold: Thank you so much. I've just been moving 100 miles an hour. And so, I was just moving 100 miles an hour this morning. So, apologies.

So, let me continue a little bit of an introduction for Sarah. So, she worked at Fors March and at RTI International where she led data support contract for a new NCHS rapid survey system that combines two probability web panels to develop official federal statistics.

She's also worked for CDC at the National Center for Health Statistics in both the Division of Research and Methodology as a qualitative researcher and in the Division of Health Statistics where she coordinated the redesign of the Health Interview Survey.

Dr. Lessem's research is focused on survey research, public health, and chronic conditions, particularly diabetes. And so, please join me in welcoming Sarah to NCVHS. She and I are planning to tag team the rest of the ASPE update.

So, when we last met in November, I mentioned the department was operating on a continuing resolution. I am very pleased to share that Congress has funded the department through December 30th of this year, which is great news.

As usual, I'd like to call your attention to some relevant key activities and milestones that the department has achieved in the last few months. Towards the end of 2023, HHS unveiled its data strategy, demonstrating our dedication to leveraging data as a strategic asset to foster innovation and enhance outcomes in health and human services. This strategy envisions data that is readily available, easily accessible, timely, equitable, meaningfully usable, and safeguarded, empowering HHS, its partners, and the public.

Aligned with President Biden's Unity Agenda, the strategy outlines five key priorities aimed at enhancing data infrastructure and capabilities across HHS. These are to cultivate data talent, foster data sharing, integrate administrative data into program operations, enable whole-person care delivery by connecting human services data, and responsibly leverage artificial intelligence.

The strategy highlights two anchor use cases that represent the highest priority areas where cross department data action can significantly advance critical mission objectives. The Cancer Moonshot and Preparedness and Incident Response. This data strategy is the culmination of coordinated efforts across multiple agencies within HHS, reflecting a unified approach towards harnessing the power of data to drive meaningful impact. To explore further, the HHS data strategy is readily available for reference on hhs.gov.

In addition to the HHS data strategy, HHS, through the Office of the National Coordinator for Health Information Technology, or ONC, released the draft 2024 to 2030 Federal Health IT Strategic Plan, which is available for public comment until May 28th. This draft plan outlines federal health IT goals and objectives aimed at empowering access to health data, delivering a more equitable healthcare experience, and modernizing our nation's public health data infrastructure.

It places significant emphasis on the policy and technology components necessary to support the diverse data needs of all health IT users, aligning with recent initiatives, such as the HTI-1 final rule and the HHS Data Healthcare Sector Cybersecurity Concept paper.

Moreover, health IT is integral to how healthcare is delivered, managed, and tracked across populations and communities. The draft plan underscores the importance of ensuring all populations benefit from health IT, including sectors beyond healthcare, such as public health. It also addresses emerging technologies like artificial intelligence and their impact on healthcare delivery.

In alignment with the administration's National Cybersecurity Strategy, HHS released a cybersecurity concept paper in December that outlines key pillars for action, including publishing new voluntary healthcare-specific cybersecurity performance goals, working with Congress to develop supports and incentives for domestic hospitals to improve cybersecurity, increasing accountability within the healthcare sector, and enhancing coordination through a one-stop shop. And I think this is particularly important, given recent events with a changed healthcare.

In light of recent cybersecurity concerns, it becomes imperative to bolster cybersecurity measures within the healthcare sector and safeguard sensitive health information. We also encourage all providers, technology vendors, and members of the healthcare ecosystem to double down on cybersecurity with urgency.

The Trusted Exchange Framework and Common Agreement, TEFCA, became operational toward the end of last year with seven organizations now designated as qualified health information networks, enabling nationwide health data exchange governed by TEFCA.

Recent CDC data from February 2024 highlights the efficacy of updated COVID-19 vaccines against the virus and its variants, including JN1 and XBB. Vaccination remains pivotal in mitigating infection and mortality risk, prompting the CDC's recommendations for all individuals aged six months and older to receive updated COVID-19 vaccine.

However, as of the last figure, only 14 percent of children and 22 percent of adults aged 18 and above, including 42 of those aged 65 and older have reported receiving the updated vaccine. So, that is quite worrisome.

COVID-19 vaccinations were primarily administered at retail pharmacies and physician's offices for adults. As of March, approximately 29.8 million doses have been dispensed in retail pharmacies with an estimated 2.3 million doses administered in physician's offices.

In parallel, the COVIDtest.gov initiative has made substantial strides, distributing over 870 million tests to households across America. Although the option to order free tests via COVID.gov was suspended as of March 8th, the government maintains its dedication to ensuring access to no-cost COVID tests for uninsured individuals and underserved communities through established programs.

So, long COVID still presents a challenge to public health, but the U.S. government continues to make advances to mitigate its impact. In response to this challenge, in November, HHS established a Federal Advisory Committee Act on Long COVID. The Committee advises the U.S. government on research and innovation in the whole of government response to long COVID.

Also in November, NCHS, National Health Interview Survey released data on long COVID. The data showed that in 2022, 6.9 percent of adults ever had long COVID, and 3.4 percent of adults had long COVID at the time of the interview. Additionally, NCHS Rapid Survey System released round one topic on long COVID. This data gave insight into the U.S. adults' knowledge, attitudes, and beliefs about long COVID and what this might mean for vaccine uptake in the U.S.

Using 2023 data from the Rapid Survey System, NCHS shows that about 68 percent of the U.S. adults have heard of long COVID. This data suggests much more work is needed to continue to educate the public.

In March of this year, CDC issued updated guidance for respiratory viruses, stressing the importance of cleaner air, and staying current on vaccines like COVID and flu as fundamental prevention strategies to reduce risk. As of the last week of March, seasonal influenza activity is gradually declining alongside decreasing COVID activity nationwide. RSV activity is also decreasing across the country.

In other infectious diseases, despite the waning of COVID-19 as a public health emergency, the department remains steadfast in its dedication to safeguarding individuals, families, and communities against both infectious and noncommunicable diseases. On February 6th, in accordance with the 2019 Kay Hagan Tick Act, HHS, alongside 16 other federal agencies unveiled the National Public Health Strategy aimed at preventing and controlling vector-borne diseases in people.

These vectors, like spitting index and mosquitoes, ticks, and lice, play a significant role in transmitting pathogens, contributing to widespread illness and mortality globally.

In light of escalating syphilis cases nationwide, HHS took proactive measures by establishing the National Syphilis and Congenital Syphilis Syndemic Federal Taskforce. This task force will harness federal resources to curb rising rates, promote health equity, engage affected communities, and allocate resources to support those most impacted.

Additionally, in response to the ongoing shortage of Bicillin L-A, the FDA exercised enforcement discretion to allow for temporary importation and use of another antibiotic, Azithromycin, an antibiotic utilized in the treatment of syphilis. This is to ensure availability of treatment options.

And in honor of World AIDS Day on December 1st, the Health Resources and Services Administration unveiled the latest Ryan White AIDS program data, revealing that nine out of 10 people with HIV receiving medical care through the program are virally suppressed. So, this is great news. And I'm going to turn it over to Sarah now for the rest of the update.

Sarah Lessem: Thank you, Sharon, and thank you, everyone. I'm honored to be here and looking forward to working with you all in the coming years.

So, turning to our work on opioids and the department's overdose prevention strategy. Late last year, the department, in partnership with the U.S. General Services Administration introduced the updated guidelines for safety station programs in federal facilities after 15 years. The new guidelines expand recommendations to include opioid reversal agents, like naloxone and hemorrhagic control solutions, such as Stop the Bleed, alongside automatic external defibrillators, AEDs.

Any former AED location can now be converted into a comprehensive safety station. These stations now equipped to address opioid-related emergencies and bleeding incidents are vital additions to federal buildings. It's now strongly advised that each station not only includes an AED, but also integrates an opioid reversal agent or hemorrhoid control component, or both, for effective emergency response.

On March 27th, the Secretary extended the opioid public health emergency for another 90 days. This renewal empowers the Secretary to take various actions, including modifying telemedicine practices, making temporary appointments of personnel, and waiving Paperwork Reduction Act requirements, all crucial for swift response to the opioid crisis.

Leveraging these flexibilities, the department can more effectively tackle the ongoing challenges posed by the epidemic.

In regard to national disaster public health emergencies, the department regularly deals with natural disasters that may become public health emergencies. Since we last met, the Secretary declared a public health emergency in Georgia and Florida in response to Hurricane Adelia. These declarations have now expired. The public health emergency in Hawaii that was a result of wildfires in Maui was renewed in February. With this declaration, the department continues to support the impacted communities.

Regarding behavioral healthcare, I want to turn to some other important activities that HHS is now directly implicated in by the strategic plan and our agency priority goals. The department HHS roadmap for behavioral health integration showcases significant achievements made over the past years, aiming to expand access to behavioral health services by integrating them with primary care and other community settings.

This includes initiatives like CMS's policy guidance, encouraging the direct reimbursement for interpersonal consultations in Medicaid and CHIP, facilitating better integration of mental health and substance use disorder treatment into various healthcare settings.

Efforts have been made to enhance the behavioral health workforce through initiatives such as NIH's study on substance use stigma in mental health care settings aimed at reducing professional stigma and

SAMHSA's core curriculum elements for integrating substance use disorder content into early academic training for healthcare professionals. These endeavors aim to bolster the quality and effectiveness of the behavioral health workforce to address substance use disorder effectively.

HHS has been actively involved in strengthening the implementation and enforcement of behavioral health parity, proposing critical rules alongside the Department of Labor and the Department of Treasury to ensure equitable access to mental health and substance use disorder care.

Additionally, targeted outreach efforts have been directed towards high-risk populations, including youth, individuals experiencing homeless, and those involved with the justice system to engage them in integrated behavioral healthcare tailored at their specific needs.

Moreover, HHS is driving innovations in care integration and technology adoption, such as CMS's announcement of a new state-based payment model for integrated services and SAMHSA's investment in advancing health information technology and behavioral healthcare settings. These initiatives aim to bridge technology gaps and promote data integration to enhance the quality and efficiency of behavioral health service delivery.

For maternal health, our nation faces a maternal mortality rate that surpasses that of any other developed country with staggering numbers of pregnancy-related deaths deemed preventable. The Biden-Harris administration is dedicated to reversing this trend by addressing maternal health disparities and enhancing the overall pregnancy, birth, and postpartum experience for all individuals nationwide.

Recently, CMS introduced the transforming maternal health model. This innovative 10-year initiative aims to revolutionize maternal health care delivery for pregnant and postpartum people covered by Medicaid and CHIP, prioritizing personalized care and increased access to maternal health providers.

Through this model, states will implement evidence-based practices to monitor high-risk pregnancies and address health-related social needs, fostering healthier outcomes for mothers and infants alike.

Now let me tell you about some recent rulemakings of interest. On February 29th, the Administration for Children and Families Office of Childcare announced a new rule that makes much-needed updates to the Childcare and Development Fund, the nation's largest funding stream to help families afford childcare. Policies included in this final rule will lower childcare costs for families, improve payments to childcare providers, increase childcare options for families, and make enrollment easier and faster.

In 2023, the Administration for Children and Families Office of Head Start,proposed rulemaking to stabilize the Head Start workforce and improve the quality of comprehensive services for young children. Proposed policies include significantly increasing compensation and benefits for Head Start staff, integrating mental health services into Head Start programming more broadly, including through enhanced mental health consultations and other quality improvements to help Head Start programs effectively and equitably meet the evolving needs of the communities that they serve.

In January, CMS finalized a rule that will improve electronic exchange of health information and prior authorization processes for medical items and services. Policies included in this final rule will facilitate a more efficient electronic prior authorization process between payers and providers, reduce administrative burden on healthcare workforce, empower clinicians to spend more time on patient care, and prevent avoidable delays in care for patients. Together, these policies will improve prior

authorization processes and reduce the burden on patients, providers, and payers, resulting in approximately $15 billion of estimated savings.

In December of 2023, the Office of the National Coordinator for Health Information Technology, ONC, announced a new rule that advances patient access interoperability and standards. Key aspects of the final rule include discontinuing - (audio drops) 18 to 64, and 3.4 percent of children are uninsured, reflecting a decrease from quarter one of 2020.

Public coverage slightly increased for both adults and children compared with quarter one of 2023, while private coverage slightly decreased for both groups, albeit insignificantly.

ASPE's brief, Medicare Enrollees and Part D Drug Benefits, Improving Financial Protections Through the Low Income Subsidy, LIS, highlight significant findings. Research indicates that in 2020, 461,000 partial LIS enrollees stood to gain from the IRA's expansion of the LIS program. Moreover, an additional 2.9 million individuals with Part D coverage eligible for LIS could benefit from the program (audio drops) data set for secondary analysis, a roadmap for data sharing and linkage between Medicaid and child welfare agencies, and analysis of treatment outcomes under Medicaid for parents and their children in the child welfare system, shedding light on the impact of services on treatment success.

So, some HHS appointments of note. As of today's meeting, there is still no confirmation for ASPE. However, it is worth noting that on January 8th, President Biden re-nominated Rebecca Haffajee to serve as the Assistant Secretary for Planning and Evaluation.

Also on January 8th, Secretary Becerra appointed Ms. Stacy Sanders as the Chief Competition Officer, a newly created role in HHS to lower healthcare costs or increase competition. Ms. Sanders will spearhead efforts to promote competition in healthcare markets, working closely with the FTC and DoG to address market concentration through data sharing, reciprocal training programs, and develop policy initiatives.

Some other efforts of interest. On Thursday, March 28th, the Chief Statistician of the United States published a set of Revised Statistical Policy Directive Number 15, which provides the standards for maintaining, collecting, and presenting federal data on race and ethnicity. This is the first revision since 1997. This revision reflects recommendations from the interagency (audio drops) working group of the federal government career staff from 12 principal statistical agencies, 22 chief (audio drops).

In addition to a range of research and statistical information, this working group considered 20,000 public comments and held almost 100 listening sessions. The revisions are intended to result in more accurate and useful race and ethnicity data across the federal government.

The most significant changes to the directive are: collect data using a single combined race and ethnicity question, allowing multiple responses. This will replace first asking about Hispanic ethnicity and then race. Add Middle Eastern or North African, MENA, from the white category. Require the collection of more detail beyond the minimum race and ethnicity reporting category, unless the agency receives an extension from OMB's Office of Information and Regulatory Affairs, because the potential benefit of the detailed data would not justify the additional burden to the agency and the public, or additional risks to privacy and confidentiality.

Updating terminology. The revisions went into effect immediately and agencies have 18 months to develop an implementation plan and five years to fully implement the updates. The HHS Office of the

Assistant Secretary for Planning and Evaluation will be convening staff from across HHS to contribute to the HHS plan for implementing the new directive to coordinate the public feedback.

And finally, recruitment. Some members will be transitioning out this year, including Denise Chrysler and Deb Strickland. They're attending their final committee meeting this week. We want to express appreciation for their dedicated service and emphasize our hope that their time at the department and the Committee has been both stimulating and fulfilling on a professional level.

As we move forward, I want to remind you that we're always looking for qualified new members who possess the relevant experience to contribute effectively to the Committee. Your firsthand experience with the Committee uniquely positions you to identify folks who can make valuable additions.

It's important to emphasize our commitment to fostering diversity across various dimensions, including race, gender, ethnicity, sexual orientation, gender identity, disability status, geographical representation, professional backgrounds and sectors within the health and healthcare industry.

I encourage you to nominate individuals whom you believe would bring substantial value to both the Committee and the department, fostering collaborative efforts moving forward. To streamline the nomination process, we have established a dedicated section on the NCVHS website entitled About Membership, where interested parties can find information on how to nominate themselves or colleagues.

This brings us to the end of our prepared remarks, and we'd be happy to answer any questions you may have.

Jacki Monson: If there are any questions in the room, feel free to put up your tent card. And on Zoom, either let Rebecca know or put your hand up. Go ahead.

R. Lenel James: Yes, Sharon, I wanted to follow up on your discussion. You mentioned the Cancer Moonshot is part of one of the priorities. I know that started under the Obama administration and extended when Biden became the president. It seems to be reactivated or moving. If you could elaborate on that, that'd be helpful.

Sharon Arnold: So, I think it has continued to be a priority. We have gotten additional funding and additional focus with the creation of ARPA-H. Also, thinking about Cancer Moonshot goals, we're trying to focus activities around that beyond NIH and think about all the activities we can pull together to prevent and cure cancer. So, it continues to be a priority. Yeah.

Jacki Monson: Thank you. Michael Cimmino, who is on Zoom for our CMS update.

CMS Update

Michael Cimmino: Good morning and thank you. So, as Rebecca said, I'm Michael Cimmino, Director for the National Standards Group here in CMS's Office of Burden Reduction and Health Informatics. As many of you are aware, NSG is charged with adopting and enforcing compliance with healthcare transaction standards under the administrative simplification provisions of HIPAA.

So, first, I want to talk about some of the work we did in the past year. I think it'll be important just to set the stage for what we're doing now and what we will do in the future. And then I'll get into what

we're focused on for the remainder of 2024. And finally, some of what we're planning for as we look ahead over the next few years.

So, much of our work in 2023 and the first half of 2024 really focused on creating a larger presence in the industry, especially after COVID, by ensuring that we were doing a number of things from listening sessions and forums to capture your feedback to then providing guidance on key issues so that we could be responsive to the concerns that we were hearing in many of those sessions.

So, just a few notable examples include our guidance on NPI enumeration, which provides health plans with the authority to require that providers enumerate subparts based on differences in, for example, their address or specialty type.

The other one I wanted to highlight here is the recent enforcement discretion around prior auth and the use of the 278 transactions. We're currently working to release an FAQ document to clarify some of the questions and policy issues that are coming up in those discussions.

And then finally, my team was very active in putting out educational materials to help address some of the misperceptions that we're hearing on the exceptions process, which we're interested in learning more from industry on as far as why it's so underutilized. And we are planning for some of those discussions in 2024.

So, what is our focus for the remainder of this year? Obviously, we have our regulatory work still ahead of us. Many of you are aware of our proposed rule to adopt updated retail pharmacy standards, as well as our proposed rule to adopt standards for healthcare attachments. My team started working on those in late 2022. We spent much of 2023 analyzing the public comments that were received on each of those. And we're aiming to finalize both of those rules in 2024.

Also on our docket is the potential interim final rule, which would aim to adopt the recently recommended core operating rules.

And then finally, as you may have heard me discuss in the past regarding the X12 Version 8020 standard for claims and the RA transactions, NSG is continuing to explore options for a possible path forward, including regulatory actions. Over the past year, we've had discussions with many of you, as well as received correspondence on the issue and have listened very carefully to past testimony, all to understand what may be the best option. And we hope to be able to discuss more with all of you on that soon.

Next, I want to walk through some of the enforcement work that we're currently doing. Our enforcement purview includes non-compliance with adopted standards for any of the electronic transactions, not adhering to the adopted operating rules and misuse of code sets and unique identifiers.

Our more commonly used tool for identifying non-compliance is through our complaint process, which if you suspect non-compliance or feel as though you're being required to conduct a transaction in a way that is not compliant with the standards, you can submit a complaint via our Administrative Simplification Enforcement and Testing Tool, otherwise known as ASETT. And I have included that link here for folks.

I want to add that based on your feedback, my team is currently working to ensure that this process is more streamlined and responsive so that we're able to adjudicate complaints in a more expeditious manner. And we're actually hoping to gather additional industry feedback on this work at the next WEDI conference in May.

The second process or tool that we use to support our enforcement efforts is the Compliance Review Process. This process was implemented in 2019 in response to stakeholder feedback that suggested our enforcement efforts needed to be more impactful. And also in that vein, we are currently looking to increase our annual sample size for these reviews so that we're able to reach a larger volume of covered entities.

This review focuses on health plans and clearing houses. And the purpose is not only to identify covered entities that are non-compliant with HIPAA, but also to determine if a corrective action is warranted. The goal for this process is to help covered entities identify vulnerabilities in their compliance with standards, as well as identify areas for improvement and to determine if they have consistent policies and procedures in place to prevent future non-compliance.

And then here, I wanted to provide our website link for any resources. Also, in regard to this work, again, in response to what we've heard from all of you is that we are always looking for ways to have a larger impact. As I mentioned, my team has very recently made improvements to shorten the timeframe for adjudicating complaints and is working to create a more transparent process, as well as working towards our ability to have a more substantial consequence for repeat non-compliance. For example, the issuance of civil money penalties, which HIPAA authorizes us to do.

And then one last item I want to note is in regard to the recent change healthcare breach. If you are experiencing compliance issues due to the breach, please feel free to reach out to us and we can work with you on those, especially if it's impacting your ability to implement a Corrective Action Plan.

And then finally, for our current work, I wanted to draw attention to the changes we've recently made to the NPPES database, specifically in the application for an NPI and your options around data that's displayed publicly. You may have seen the federal register notice announcing the addition of two new options for gender. These are X for unspecified, for those not identifying as either male or female, and U for undisclosed, for individuals who wish not to disclose their gender.

The other update includes the acceptance of PO boxes for a practice address, specifically for circumstances where providers solely practice out of their home. And both of these changes were made in response to feedback from providers, especially some citing safety concerns.

And finally, I want to discuss some of the work that we see coming on the horizon for us. Many of you have probably heard me mention our HIPAA modernization efforts by now. We've had many discussions with industry on how we can improve the standards development and adoption process. We've heard the current process is slow and unpredictable. And so, we've looked at ways to make the adoption of standards more consistent by examining areas where we can create changes to make time savings in the process, and some by as much as 50 percent. So, maybe cutting a portion of that process down from six months to 90 days.

We're also working to identify ways to better evaluate standards prior to adoption and understanding how we can better gauge the return on investment and develop a better cost benefit analysis. We hope to be able to start working through some of those changes in the coming year.

And I know I touched on this briefly earlier. Many of you may be aware of our recent enforcement discretion on the 278 transaction, but I wanted to discuss what this could mean for future work. First, let me say this. This is a unique circumstance that came out of the exceptions process combined with Medicare regulatory provisions. We will be listening very carefully for stakeholder feedback as entities work to implement an all-fire prior auth process. But I also want to recognize the need for such a standard to undergo the evaluation process consistent with our statutory provisions. And we look forward to whatever outcome or recommendation that may produce.

In the meantime, we are working towards releasing more clarifying guidance. Again, most likely an FAQ that we're hoping to put forth.

And then finally, I wanted to touch on ICD-11. We appreciate the input and look forward to any future NCVHS recommendations and industry feedback regarding additional work that may need to be done on analyzing the costs and benefits for consideration of adoption or implementation of this version of the ICD code-set under HIPAA.

In thinking about the lessons from ICD-10 informed by feedback from payers, providers, and federal partners who experienced that implementation, we recognize that any transition would require a careful, thoughtful, and resource-intensive evaluation of need, timing, and priority after receiving any recommendations for adoption, as well as assessing industry feedback, all in relation to other priorities at that time.

And finally, I just wanted to provide our website and email address should you have any questions or need additional resources. Thank you.

Rebecca Hines: Questions? Put up your tent card if you want to engage with Michael.

Tammy Banks: Michael, just want to say thank you for the report out. We really look forward to your work in expediting the review of future standards and also look forward to the FAQ with the 278 exception. Is there anything else that you can share, or do we need to wait until the FAQ is released in regard to the scope of the exception?

Michael Cimmino: I think that is something that we'll hope to address in that FAQ.

Rebecca Hines: Angela or Wu, any questions for Michael with CMS?

Wu Xu: No, no questions.

Jacki Monson: Okay, well, Michael, thank you so much for the update.

Michael Cimmino: Thank you.

Rebecca Hines: So, just logistically for this next presentation, we have people in many places. We have Jamie Ferguson over here. We have in the room with us Patrick Romano, and several of the Workgroup members are online as well. So, for our tech team, just be aware, we're all over the place. So, I think, Jackie, we're good to go.

Jacki Monson: So, Jamie, I'll turn it over to you.

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

Jamie Ferguson: Okay, thank you very much. This is an interim update from the ICD-11 Workgroup. We're in the middle of our second phase of work. Our first phase of work concluded with the findings report that was published last year. So, this is information about how we're doing.

Just a little bit of background for those who may not be familiar with ICD-11. It was adopted by the World Health Organization in 2019, became effective for use for coding and reporting in 2022. And this includes components for mortality reporting. Mortality reporting is a condition of membership in WHO. So, it's a UN treaty obligation. And morbidity coding, of course, is what we're most familiar with for many of us in terms of both reimbursement, risk adjustment, quality safety reporting and other purposes. And so, that splits out into those different aspects of morbidity reporting.

The mortality, we had a report in, I think it was two meetings ago from NCHS on their progress in developing the mortality statistical reporting. And that was very interesting. Maybe in our next meeting, we can get a further update on that, but that seems to be progressing well. And so, this report and the work of the Workgroup is all about the use of ICD-11 for morbidity and not for mortality.

Before the Workgroup was established, NCVHS previously held an expert roundtable meeting and delivered two letters with recommendations to the Secretary. In 2019, the Committee recommended evaluating different approaches to the transition. That letter of recommendation had a long research agenda. It also included a draft communications plan and emphasized the need for timely leadership, outreach to the industry, and communications about the transition to ICD-11.

Of course, then shortly after that recommendation letter was issued, we had a public health emergency. Some things like this might've been put on hold. And so, back in September of 2021, the Committee thought it was urgent and important to issue another letter of recommendations, many of which just reinforced the first letter and said, no, we really mean it. We need to get going on coordinating, communicating, analyzing the impact of ICD-11, looking at the different impacts, the costs, and benefits, so that if we're going to have this transition for morbidity coding, how should it be done, what's the impact, and so forth.

And so, the Committee identified some goals for U.S. implementation. Again, this is for morbidity reporting to avoid some of the issues and problems that we had in the transition from ICD-9 to ICD-10, which was long and drawn out, started, and stopped. And ICD-11 is fundamentally different, structurally very different, conceptually different from all the previous versions of ICD. We'll get into that a little bit here. And so, there is a need to conduct more research to understand how to transition to this new and different coding system for morbidity coding.

We also wanted to identify what was needed if we were to avoid having a full clinical modification or basically a national customization of the WHO coding system. And so, this would save money, obviously, would increase flexibility and the international comparability of our statistics and reporting. It would have the ability to use some of the things that are built into ICD-11. For those who have read any of our previous reports, ICD-11 is built to be continually updated. So, it always reflects current medical science, medical knowledge, and so forth.

And so, we also identified some other key topics and messages and the need to foster communications and preparation for this transition.

The timeline of the Workgroup was established back at the end of 2022. We really onboarded our members early in 2023. We had an environmental scan. We had some great support from some of the folks in the room here to conduct an environmental scan of all the research that was conducted to date so that we could understand if we were adopting it for the U.S. and morbidity purposes, including for a reimbursement, how has this been implemented or studied? And at that time, I think ICD-11 had already been fully implemented by about two dozen countries around the world.

But the different health systems are very different. And so, the use of the coding system was different and therefore the research on it was different. We also had excellent engagement from the National Library of Medicine conducting research into ICD-11.

And so, we took all that into consideration and posed a number of questions in a request for information, an RFI, published in the Federal Register in June of 2023. For various reasons, that one had a short timeline for responses. And so, it had, I would say, a relatively limited number of responses to that first RFI.

We also conducted in August, in the summer of last year, actually, I think it was in this room, an expert roundtable with 50 invited experts from across the spectrum of academia, clinical practice, public and private sector, a number of different government agencies involved in order to study the questions that we had on ICD-11.

And then we issued a meeting summary and our report on findings from the first phase of work, which I would urge anyone who's interested to go and find that on the NCVHS website, or it will be in the chat for this.

Following that, though, we saw the need for issuing a second request for information in the Federal Register. This was published in October. It had a full 90-day comment period ending in January of this year. We got very robust responses. I'm going to talk a little bit about the analysis of those responses, which is still underway.

And we also identified the need to augment some of the membership of the Workgroup so that we covered the full spectrum of actual implementers as well as users of the ICD system. So, this analysis of the second RFI currently is underway.

I'll back up a little bit to the themes that emerged from the roundtable that we held last August. And I think Dr. Patrick Romano is here to talk about those themes.

Patrick Romano: Thank you. I'm Dr. Patrick Romano. I'm a general internist, general pediatrician based at the University of California Davis Health in Sacramento, and I'm a member of the ICD-11 Workgroup.

So, this slide summarizes some of the themes that emerged from our expert roundtable discussion in August. First, I think there was general recognition, consensus that ICD-11 presents opportunities supporting modernization and it offers potential for burden reduction. Whether that potential will be realized is an open question and also potential for automation to support transformation to a 21st century digital healthcare data infrastructure.

Second, I think a theme from the expert roundtable was that there is really a need for attention to a coordinated governance strategy and funding. And when we talk about coordinated governance, we mean both a process within the United States for developing and maintaining a linearization that can be

used for morbidity purposes in the U.S. and then coordinating with other countries through WHO to ensure that that linearization is consistent with the basic architecture of ICD-11 and with linearization that may be adopted in other countries.

ICD-11 maintenance processes will have to be, of course, well understood and managed for the U.S. and they're likely to be somewhat different than the ICD-10-CM maintenance processes that many of us are familiar with.

On the research side, I think we recognize that there is really need for more work on the content analysis for ICD-11 to understand where are the coverage gaps in the current STEM codes that appear in the linearization that we know is MMS. We have to understand those coverage gaps so that we can really assess implementation approaches for the U.S. and what a U.S. linearization might look like if it's different from MMS.

We also identified the need for greater stakeholder understanding of the technical implementation methods and costs. One of the benefits of ICD-11 is improved tooling offered by WHO. This will translate into improved user interfaces. For those of us who are actually entering information into electronic health records, it potentially will also lead to AI tools on the backend, but we have to really evaluate the usability of those tools, their accuracy, and the ability to which they can be implemented across the entire healthcare system.

And we need to better understand the use cases for ICD-11, both the clinical documentation use case that all of us as clinicians are aware of, but also other new uses. My particular research focus has been in a quality and safety use case, but there are obviously others related to payment, clinical research, and so forth, which really require better understanding to assess the value and impact of ICD-11.

And finally, on the impact side, I think we understand that the education and workforce challenges could be profound, and we really need to have our eyes open to what the training needs are for the workforce and the associated resource implications for healthcare organizations and stakeholders.

Back to you, Jamie. Thank you.

Jamie Ferguson: Thank you, Patrick. I appreciate that. I just want to emphasize something that was one of the themes in the RFI responses that also is one of the themes from the expert roundtable that Patrick just talked about. And that is that it's critical for ICD-11 implementation to be coordinated across all the different government agencies and entities that are involved in healthcare, because it is complex.

And as you just heard, there are many different kinds of use cases that are guided and regulated by many different offices and agencies used in the public and private sector for a wide variety of use cases. And so, the need for coordinated governance and coordinated funding is critically important so that it can be implemented well.

At this point, I think I'm going to turn it over to Cathy Donald for the next two slides, please.

Catherine Donald: Okay, thank you, Jamie. As Jamie mentioned, we had some previous recommendations and findings. And what we have here is a heat map, which is a work in progress. As he said, we're still doing some analysis. And this shows the alignment of the second RFI, the responses with the previous NCHS recommendations and findings.

So that you don't have to read that heat map or get out your magnifier, what we've done here on this slide is pull out how the new or the second RFI, how those responses align with previous NCVHS recommendations and findings and pulled out the high points.

So, as far as the NCVHS recommendations, alignment was certainly with, there is a need to conduct more research to evaluate the impact of different approaches to ICD-11, especially around costs and benefits. There is a need to conduct outreach, communicate and to encourage stakeholders to commence planning for the transition.

In addition, provide education on ICD-11, including how it's designed to work with EHRs in an electronic world. That's something that's new from the previous implementation of ICD-10.

Regarding the findings from the RFI responses and where there was alignment, something we've hit on quite well and mentioned several times is governance and funding is needed for all aspects of ICD-11 adoption, implementation and maintenance, especially U.S. ICD-11 governance options should be evaluated for potential to best manage and coordinate with WHO-FIC, the World Health Organization Family of International Classifications.

There is an additional national ICD-11 research agenda, and that requires coordination with federal funding to optimize value and reduce costs. There is strong interest and willingness to engage in ICD-11 planning from organizations across the spectrum of healthcare, wellness, academia, public health, and healthcare financing. In addition, we found alignment with additional research is needed on benefits, costs, and impact of ICD-11 implementation.

As mentioned previously, artificial intelligence and automation in ICD-11 implementation deserve extra attention for potential burden reductions and quality improvements. And then the ICD-11 transition needs strategies for pilot testing, education, and communications.

And I believe that's it, Jamie, thank you.

Jamie Ferguson: Thank you very much, Cathy. I should have mentioned before that these presenters are members of the Workgroup. And so, we meet frequently, we're all very involved in this. And I wanted to have a variety of perspectives from the different Workgroup members.

And so, with that in mind, I will now turn it over, I think, to Sue Bowman to talk through this page and go through some of the important challenges that we have to face.

Sue Bowman: Thanks, Jamie. I'm Sue Bowman, senior director of Coding Policy and Compliance with the American Health Information Management Association. And as Jamie mentioned, I'm a member of the ICD-11 Workgroup.

So, we previously just talked about some of the themes that were reiterated through the responses to the RFI. There were also some new things that emerged in the responses to the second RFI or things that maybe had been mentioned in the previous recommendation letters but had a bit more expansion or a different twist in the RFI.

So, one of these is, if a U.S. clinical modification of ICD-11 is not developed, then ICD-11 governance and maintenance processes will need to be established in order to make sure the U.S. needs are met. Respondents expressed concerns about relinquishing total control of the coding maintenance process to

the World Health Organization and concerns about the World Health Organization's adequacy to meet U.S. needs in a timely way.

Also, U.S. specific rules and coding guidance will need to be developed and users will of course need to be trained.

It was clear, however, that some of the respondents at least lacked sufficient knowledge and understanding of ICD-11 to really be able to evaluate how or if ICD-11 can reflect U.S. cultural issues and question its ability to meet specific U.S. data needs.

To gain the support of key stakeholders and healthcare payment processes for a transition to ICD-11, it was clear from the responses to the RFI that demonstration of a financial return on investment will be very important. This means realistic cost burden estimates as well as solid evidence of the benefits will be needed.

Also, ICD-11 presents, not surprisingly, a range of some new challenges. For example, the different structure of ICD-11 versus ICD-10 and the knowledge gap it creates such as the understanding of how to implement post coordination within the U.S. healthcare system raise some fundamental change management issues, technical issues, human resource issues, cost issues and questions, all together comprising a host of new unknowns to take into consideration.

Mary Stanfill: I will just give you some context around this slide. Also representing some of the, in this case, specifically benefits in particular that we synthesized out of 35 different RFI responders.

Interestingly, Cathy McDonald mentioned the need for research around benefits. 37 percent of the respondents were able to identify one or more benefits of a transition to ICD-11. 9 percent of the respondents or three of them, in fact, felt there weren't benefits. They were relatively negative in that respect. They didn't see any benefits.

But more than 54 percent, more than half, aren't sure. They either don't know yet, or they didn't really choose to address it because probably they didn't have much to say because they're just not sure yet. And this is why this supports the fact that it should be on that research agenda to really understand what will benefit us.

Interestingly, some of the benefits are conditional depending on the particular use case, what you're using ICD for, and in some cases, how it's implemented.

So, for example, if ICD-11 is automated, embedded, integrated within the EHR workflow, and really actually enabling providers to capture codes, then it could reduce provider burden and have quite a few other impacts on timeliness, productivity, accuracy. So, whether or not it can be implemented in an automated fashion is something that needs to be investigated.

And also found it interesting that when you do that, if we can automate it, there is a sense that we would, from the responders, the sense that that would mean we would be able to get increased diagnostic granularity and the cluster coding and that sort of thing if it's done in an automated fashion. And that could be very helpful to improve a lot of different initiatives, value-based care, accountable care, quality, safety, some of these other use cases were things that responders specifically identified that could be helped by an automated process.

And then of course, simply having an updated digital system or ICD, some of these other benefits were indisputable. It is more current. We often forget that ICD-10-CM was actually released in 1990 because it's relatively new for the U.S. to be using, but it actually is an outdated system. So, the ICD-11 does keep current with medical science and with current practice. And it's more consistent with current technology that's available, improves our statistical analysis.

Certainly, the international comparability is a well-recognized and shared benefit. The ability to do that and the research and surveillance aspects that we would gain from that. So, some different perspectives on what the benefits are really tied to, how the use case is, how it ends up being deployed and what the responder's perspective was.

Back to you, Jamie.

Jamie Ferguson: Okay, thank you, Mary. I wanted to also comment on some of the other new information that came out of the second RFI. And this really has been, this first item has been in the background the whole time, but we don't know the financial system impact of moving to ICD-11. And frankly, it hasn't been studied sufficiently. Is it going to be budget neutral for Medicare? These are very important questions.

What's the impact of having much greater granularity and precision in risk adjustment coding, for example? These financial impacts still really should be studied.

We also have identified some potential licensing issues because of the particular license the WHO uses for ICD-11. It does require specific licensing agreements for derivative works, which could include mappings that we would use here in the U.S. I am confident that these things can be worked out, but this work has yet to be done in order to actually implement it here.

At the same time, the research done by the National Library of Medicine, and Dr. Kin Wah Fung, I think is actually on the line here on the Zoom, identified some concerns with semantic standardization. So, not just how do you ensure semantic equivalence in terms of the transition from other coding systems, but also because ICD-11 uses a post-coordination or clustering of codes, this can be accomplished in different ways. And so, we need standard rules so that the post-coordinated codes can be used for interoperability in a consistent manner, for example.

And then of course, the relationship of ICD-11 and how it will be implemented with SNOMED-CT, which is required for interoperability purposes in EHR certification, these things also need to be studied.

One of the things that came out in a number of the RFI responses was the potential for the use of artificial intelligence to provide significant benefits, cost production, and improvements through the use of ICD-11 being a completely online system made to be used with modern technology. But we found that the responses that we got to the RFI indicated wide variation in the use of AI, some, I might say, responses indicated more of a fearful or very overly cautious approach, others perhaps overly confident and having some experience, but saying that these benefits were there already. So, this certainly needs to be studied because we had, as I said, a wide variation in those responses.

And so, the next steps for the Workgroup, we're continuing to analyze the responses from the second RFI, and then we will use that analysis to develop some additional report coming out of this analysis and other inputs that we're getting in order to have a report for the second phase of work. And then we need to look forward to what else is needed. And this would be a third phase of work.

So, the second phase of work we anticipate would take the rest of this fiscal year. The third phase of work would be for the next fiscal year. And so, then we'll have an additional list of questions and research topics that need to be studied as you've heard about some of them.

We need to get into the different implementation approaches, that analysis, the semantic standardization questions that I just mentioned, and how we're going to work with WHO to have a content development and maintenance process that really works for the United States. So, those things have yet to be outlined in terms of the options and the impact of those. So, that would be a lot of the work for the third phase of work.

And of course, overall, the purpose of the Workgroup is to inform this committee sufficiently so that the Committee can make recommendations to HHS about how or if to implement and maintain ICD-11 as a regulatory code set other than for mortality reporting. And so, that's the overriding purpose that we have. The Workgroup has identified a number of questions that we're grappling with now.

And we certainly would welcome input from the Committee on these questions, but these are really for the Workgroup, as I said, to work through. And one of the questions is the scope of our work. So, the scope of recommendations of the Committee could vary and could be wide ranging, could have to do with, as you heard, we had input that it should be automated into the EMR. Well, that would be a recommendation to the department that likely would flow to ONC, for example. And so, a number of these scope questions have come up for the Workgroup.

We also had, as we reported, I think over the last two meetings, we previously participated in meetings with AHRQ and WHO on the use of ICD-11, both for patient safety and healthcare quality measures. And so, the conversion of those measure sets and the value sets to ICD-11 is something that also requires additional work and study. So, these are scope questions in terms of the scope of the Workgroup's work and informing the Committee that we're grappling with.

You've already heard several times, I think just even here today, that a lot of planning is needed to understand how to manage the coordination of content and maintenance and how to transition from the ICD-10-CM content development and maintenance processes to ICD-11. So, that obviously is work that will have to be done.

We want to be able to identify and have some findings about the transition, the timeline, what might be optimal. So, this is something that we're likely going to have to get additional input on, whether it's through hearings or RFIs, we haven't yet determined. And then one of the key findings in our first phase findings report is that the U.S. will need its own linearization, a linearization being a subset of ICD-11.

So, we will need our own linearization for morbidity coding purposes, specifically to be used for our current reimbursement, the fee-for-service reimbursement system will not work adequately well on the MMS linearization, which is the one that's currently available. And the MMS linearization is intended for mortality reporting and statistical reporting. And that's a different use than what we need for morbidity.

So, how this will be created and maintained and how it relates to the extension, which extension codes we need in this work has been started at the National Library of Medicine, was the subject of some published research papers there, but more work is needed on those questions.

And that brings us to this main issue for the Committee to consider. So, I want to wind back to earlier in this presentation, you heard that the RFI responses that we got in both the first and the second RFIs had

a theme that central coordination, a central point of governance, is needed, that it needs to coordinate across all the different agencies and offices in government that would touch upon the use of ICD in any different way.

But also, in the private sector. There are, again, a wide variety of stakeholders who need to be included in this coordination. So, we heard that was one of the RFI themes in our RFI responses, going back to the first one even. And then in the expert roundtable, one of the findings that came out of the expert roundtable was HHS should coordinate and ensure federal funding and the national ICD-11 research agenda involving multiple agencies and departments should be coordinated centrally and managed by a single officer agency.

And then we had an additional finding from the expert roundtable about how ICD-11 governance options needed to be evaluated for their potential to best manage the maintenance process and the content creation process for ICD-11. Again, going back to the need for a central point of authority that acts in a way that's coordinated and that can coordinate with all the wide variety of stakeholders and government offices and agencies that use it.

This also was in actually the expert roundtable summary report. So, it's in the report of findings. We've heard this in the first RFI, the second RFI, the expert roundtable, all the input, it's a very consistent message. But we have, as is noted here in the second bullet, there is a new urgency about this because other countries are now talking to WHO about creating country-specific linearizations.

We don't have that underway yet because we don't have a central point of authority for morbidity coding. We have a central point of authority for mortality reporting. That's working well. Bob Anderson can speak to that. But all these different morbidity coding use cases are different and require different coordination.

And so, the fact that other countries are now talking to or negotiating with WHO about licensing their country-specific morbidity linearizations, this is the time for us to be involved in that because they may set a pattern for how WHO will license national morbidity coding linearizations that we will have to live with what they come up with. And so, we should be involved in that. And that's why there is increased urgency in this finding that the Workgroup has around linearization and having a central point of authority and coordination.

Rebecca Hines: Jamie, can we pause and answer or clarify the difference between country-specific linearization and country-specific clinical modification?

Jamie Ferguson: Okay. Yes, I didn't see that question coming up, but a linearization is a subset of ICD-11 that's derived from its foundation and its underlying ontology that presents to the users the set of codes that's used within ICD-11 and it then can work with country-specific extension codes that are optional extension codes that may be needed, versus a clinical modification is basically a copy of the whole thing that's completely customized for a country.

And so, if we wanted to have our own completely custom version of ICD-11, that would be a clinical modification and it's complete, whereas a country-specific linearization is really a subset extracted from the international edition of ICD-11. And so, it's compatible with all the other tooling and reporting and measures that use the international edition. So, it's not a national edition. It's our national version of the international edition, if you will.

Rebecca Hines: And so, that compatibility really is at the heart, at the rationale, for linearization rather than a separate clinical modification?

Jamie Ferguson: Well, that is one of the reasons, yes. The other thing is that a linearization is updated and maintained along with the international edition, so it doesn't require the extra editing and maintenance that if we had our own custom version.

Okay, I see a number of cards up here. Let me get through the Workgroup finding and then I'll take all the cards, I think, and I'll try to do them in order. So, we came up with this wording and modified it in response to input since our last workgroup meeting. But the finding of the Workgroup is that it's imperative that HHS designate one office or agency to be responsible for overall coordination of ICD-11 morbidity coding in the United States.

And that this office or agency should further be charged with and allocated sufficient resources for federal government coordination of all ICD-11 morbidity coding research, funding, rulemaking, and resources relevant to adoption, implementation, and maintenance of ICD-11 as a U.S. regulatory code set. So, it's about using ICD-11 as a regulatory code set for morbidity reporting. And now I'm happy to take, I think I saw Michael's card up first, and then Tammy and then Lenel. Tammy, were you first? Okay, sorry. All right, Tammy's first.

Tammy Banks: No, first of all, I just want to commend you, Jamie, and the members of the Workgroup. the wealth and the breadth of the expertise on this panel is just amazing and really commend everybody to coming around this early in this process in order to identify what is the work paths that have to be followed simultaneously and that we're not surprised on the road. Because a lot of people hear ICD-10 who have not been in your workgroup and there is a little anxiety.

So, there are two comments. One for those who have not been part of the Workgroup is when ICD-10 was discussed, one of the challenges that we had is we heard, well, ICD-11 is being built and we're discussing ICD-10. So, we're behind before we even put it in. Can you speak to that? Is there an ICD-12, number one?

And then the number two clarification just for me is what I'm hearing from you. And I think you explained it, but I've got to use different words just to make sure I hear you. The clinical modification would be outside of the WHO's work and it would be owned by the U.S. for lack of better words, while the U.S. linearization will be done with World Health Organization maintained with all the other linearizations. Am I understanding that correctly?

Jamie Ferguson: That's correct.

Tammy Banks: Okay, cool, that's great.

Jamie Ferguson: And a linearization is being built since a linearization is really, it's a subset that is created off of the ICD-11 foundation. And so, it gets all of the updates in the relationships as well as the concepts as they're updated in the underlying ontology in the foundation database of ICD-11. And the question on 12, there is no plan at present for an ICD-12. That's because of this new structure of ICD-11, it has a foundation database that's built on an underlying ontology, which is continually updated.

And so, this idea of having continuous updates means that we could determine our own update frequency for the U.S. subset, but it's always updated with current medical knowledge because medical

science is evolving rapidly. And so, the idea of using the international edition is that it takes the cost and resource burden off the United States to maintain all the updates that are needed. So, the plan is not to have a 12 because ICD-11 will be updated continually. And then I think, Michael, you were next.

Michael Hodgkins: Thanks, Jamie. And if there is going to be a 12, we'll have to skip 13, because nobody likes 13. Yeah, I have both a comment and a question. The comment, and I suppose it's obvious, but when we're talking about cost-benefit analysis at the system level, that's one thing, but at the individual stakeholder level, that's altogether a different thing.

And the whole idea of burden and benefit is going to fall unevenly depending on who you are as a stakeholder and how this lead agency is going to sort through that. Is it just going to tell, for instance, EHR vendors, it's a cost of doing business, too bad? You need to make those investments. And oh, by the way, maybe you can't pass them through to your customers or you're limited in how you can pass them to your customers. So, I think there is a lot of nuances when it comes to cost-benefit.

And on the subject of AI. I saw the comments from the RFI. Obviously, there are varying levels of sophistication at an organizational level on AI implementation in general, but it's hard for me to imagine that if we're going to be successful in implementing AI in a way that it really facilitates automation, that it's not going to have to be a centralized activity where we're going to come up with a centralized model for how to automate based on the linearization that gets developed. If we leave it to individual organizations, it's going to be chaos, I respectfully pose.

But my question reveals a certain level of naivete on my part. As different nations come up with different linearizations and even different extensions, what impact will that have on one of the virtues of the U.S. adopting ICD-11 along with the rest of the world in terms of being able to do international comparability and comparisons? Does it affect that? If so, how much? Is it an area of concern or not?

Jamie Ferguson: So, of course the answer to your question is, well, it depends. And also, we don't know yet because we don't know the degree to which other countries will use unique extensions that are really fundamentally different, conceptually different from ours.

In terms of country-specific linearizations, there should be little impact on international comparability because if the linearizations differ, then the comparability essentially moves up the hierarchy to the point where the hierarchies match and because the linearization might expose different levels of detail, for example.

So, I'll just say, in gender and gender transition, you can have 2 or 24 different codes depending on the level of granularity that you want to express. And so, I think there are a variety of options there, but in terms of comparability, it may have to go up to a higher level in the hierarchy. I appreciate your comments also on AI. Thank you. Lenel?

R. Lenel James: Thanks, Jamie. Two comments and then I want your reaction. One, great work, seeing all this summarized really hits home some of the challenges of it. But I think a reminder for all of the group that the implementation of this is going to be a major challenge. The 2,000 payers updating all their systems, all the providers updating their systems, new workflow changes, it will be a real challenge.

So, the sooner we can get started, especially on morbidity, let's not forget that the state public health departments, they need to update their systems, which means those departments have to get approval from their state legislature. So, between our Congress and the state legislatures, the more runway we

can get, it seems like that's going to be a significant part of why this report helps identify the importance of starting sooner rather than later.

Jamie Ferguson: Thank you, I appreciate that. Patrick and then Tammy.

Patrick Romano: Yeah, I just wanted to add to a couple of points that Jamie's made. I think that the analogy that has been used extensively is that there are close to 100,000 clinical concepts in the foundation. And some of those concepts are above the shoreline, so to speak, for the MMS linearization, the morbidity mortality linearization.

So, the concept of an alternative linearization is basically to bring more of those concepts that already exist in the foundation above the shoreline to expose those concepts so that they can be utilized as STEM codes if needed within our particular context for payment, clinical research, so forth.

Now, obviously WHO is concerned, and I've had the pleasure of serving on the Quality and Safety Workgroup for WHO-FIC. So, there is concern about the international compatibility. And what people at WHO have basically told us is, come to us, tell us what you need. Tell us what the U.S. needs are because chances are that other countries probably have some of those same needs. And we've already had some discussions casually with friends, colleagues in Canada, Germany, other countries.

So, there are some shared needs. And if we engage actively with the appropriate governance structure through the U.S. in these international conversations, then it gives us the opportunity to have an influence over the extension codes so that we aren't using U.S.-specific extension codes, but that we do have optional extension codes that multiple countries have the ability to use. So, I think that's the vision that we hope to see.

Also, just to highlight one point, with this cluster coding, we have a STEM code that will be followed by extensions that indicate things about laterality, about pathology, about causal mechanisms, and so forth. And so, instead of having seven-digit codes, we might have a 20-digit code that includes the STEM code with these extensions.

Think of the implications of that for our information systems, which have a fixed width of seven characters for the ICD-10-CM codes. So, this is just part of the implications that have to be worked out with this committee's input and many others.

Jamie Ferguson: Thank you.

Rebecca Hines: Jamie, I also wanted to let you know one of the Workgroup members has her hand up.

Jamie Ferguson: Oh, thank you. I didn't see that.

Rebecca Hines: Vickie Mays.

Jamie Ferguson: Oh, Vickie, please.

Vickie Mays: Thank you, Jamie. And I want to really comment on how well the amount of work that we've done over time, you've been able to present so with such clarity.

I want to talk about the slide that's up in terms of the finding that we're asking people to consider. Because one, I want to make sure people understand that part of why we're asking this is currently the process is, if anyone wants to make a change, they just go straight to WHO and we have all kinds of people in the U.S. then that can do this, and that it would be helpful to have some coordination.

The question I have is about a couple of things in here, which is we talk about this coordination being of morbidity. Would we not want this coordination to be both morbidity and mortality? That's the first one.

And second, what I thought we were thinking about is not that an agency is just a coordinator, but they're coordinator of a council. For those of you who've been around, and you know how data council work is all the agencies come together, there are discussions, there is understanding.

So, rather than it being an agency or a person to an agency, it would be the coordination of a council, I thought, that I think would be more beneficial over time. So that as you begin to suggest, make changes, et cetera, you can see and make sure that it's fitting for everyone. So, those are my two issues that I wanted to raise.

Jamie Ferguson: Vickie, thank you very much. And just so that I can reflect for the Committee members, some more of the discussion in the Workgroup. The Workgroup did discuss in our last couple of meetings that under this lead agency, they would have a coordinating council or a committee that would represent all the different public and private sector stakeholders.

But that it would have to be so that the purpose of the lead office or agency would not be necessarily to do all the work and make all the determinations in an ivory tower in a vacuum or anything like that, but rather to have a body, as Vickie described, a coordinating council or committee for coordination or other various structures that have been used for coordinating other issues in health IT and informatics by the department over time.

So, many of those different structures can work, but some mechanism under the lead office or agency. And I think the input that we got emphasized the need for all the different stakeholders to be involved in the coordination process, but there needs to be somebody in charge who can then be in charge of leading the morbidity negotiations with WHO. And Vickie, regarding your other point on mortality.

Rebecca Hines: I just wanted to say Robert Anderson has an open line. So, I think Robert, you might be best positioned actually to respond to Vickie's question. Vickie, do you want to re-articulate the coordination of the implementation of morbidity and mortality for the U.S.?

Vickie Mays: Sure, Robert, what I was asking is, first of all, to make it mortality and morbidity. And secondly, when we're talking about federal government coordination of a coordinating committee is what I'm asking to be inserted here.

Jamie Ferguson: Yeah, I was just going to respond first that I think we have a coordinator for mortality and that's Bob who's on the line. And that has to follow, I believe, using the MMS linearization, whereas morbidity doesn't. Bob, please, if you could address that?

Robert Anderson: Sure, yeah. Hi, Bob Anderson, National Center for Health Statistics. I think that the problem with putting morbidity and mortality under the same coordinating function is problematic to

some extent because the process is substantially different. The process for implementation is substantially different.

At NCHS, with regard to mortality coding, we're not subject to the regulatory process. So, we don't have to deal with those issues. We can implement when it's practical to implement. There is a certain amount of training of folks in state and local health departments so that they can recognize and ingest the new codes, but NCHS does all of the mortality coding for the United States.

So, I think adding mortality to this oversight function, I think could just encumber the process. And it could encumber the process on both ends, trying to coordinate. That said, I do support the idea of keeping any oversight group on the morbidity side informed of progress with regard to mortality.

Jamie Ferguson: Great, thank you very much. Tammy.

Tammy Banks: I was just going to say, Vickie, what a friendly amendment just at the end in collaboration with ICD-11 mortality makes sense. Because again, we do want silos and we want to make sure that there is efficiency realized across both. But the independent focus of what we have here, I think adequately reflects what this committee has been asking in multiple letters.

And I would put a motion forward if this isn't too early to accept the recommendation as stated with the amendment in coordination with ICD-11 mortality efforts or your department, Bob, whatever you think would make more sense in this recommendation.

Jamie Ferguson: Thank you, Tammy. So, the Workgroup doesn't have a recommendation. It has a finding that it's reporting to the Committee, but now we as the Committee could take this finding of the Workgroup and make a recommendation along the same lines. And we could use this wording or other wording.

One of the things I also wanted to - going back to Vickie's comment - I wanted to emphasize that the idea of a coordinating council or coordinating committee involving all the different public and private sector stakeholders would be, if this were a committee recommendation, then the rationale for that could explain that mechanism for coordination a little more along the lines of what Vickie just laid out.

Rebecca Hines: And then also other Workgroup members with their hands up are Sue Bowman and Geoff Reed.

Jamie Ferguson: Okay, thank you. Sue?

Sue Bowman: Yes, Sue Bowman, American Health Information Management Association. I just wanted to comment that I think that the lead office coordinating implementation issues is not necessarily the same office as the one that could be leading the U.S. linearization work with WHO. They're different issues, different things to address.

And there actually is a team, the ICD-10-CM classification team at the CDC that has been leading the morbidity work from the U.S. perspective with WHO. There has been a bit of a transition with that team with the passing of Donna Pickett, but they are getting back involved in that process. And they have a lot of expertise with regards to requests for U.S.-specific codes and the maintenance of ICD-10-CM.

And so, I think it would make sense for that team to be heavily involved in the U.S. linearization piece, which, as I said, is different than an office that's leading all of the research rulemaking issues around adoption and implementation of ICD-11 in the U.S.

Rebecca Hines: Jamie, can I just make a quick comment and say, given where the Workgroup has been and where your discussions have focused on, I would respectfully encourage you all as you work through this to maybe not work on so much the details of the how. Leave that to the department and more put forward what the need is.

And you can suggest some how's, but I don't think this group is really the best positioned to get into exactly how that would be done, but more here's the goal, here's the need, HHS, this is what we encourage you to get going on, something more along those lines.

Jamie Ferguson: Thank you. Yeah, going back to our expert roundtable and the summary report from that, one of the things that was highlighted there was the fact that there were widely divergent opinions among the experts on which office or agency should be in charge of what.

So, I think that your words are wise, Rebecca, and that's why this finding of the Workgroup doesn't designate any particular office or agency for anything, but basically would be, so if the Committee considers this as a recommendation, then it would be for the department to determine who should be responsible for what exactly. So, as I said, some of the discussion that the Workgroup has had about the need for a coordinating council certainly could be in the supporting rationale for this.

Rebecca Hines: And we have Geoff and Kin-Wah.

Jamie Ferguson: Okay, Geoff and then Michael and then Kin-Wah and then Val. Geoff.

Geoffrey Reed: Hi, I'm Geoffrey Reed. I was appointed to the Workgroup as a subject matter expert subsequent to the August roundtable meeting. So, I'm quite new and I've been trying to get used to the landscape.

I do know WHO quite well because I worked there full time for about 10 years and I was in charge of the development of the mental and behavioral disorders classification for ICD-11 and the accompanying detailed diagnostic manual that was just published by WHO.

And so, I think what I want to emphasize about this is that there is a real vacuum in terms of U.S. leadership at WHO, at WHO-FIC, somebody who can officially represent the U.S. government in those discussions about, do we have a national modification and how does that work and how do we evaluate the foundation layer, et cetera, and there is some real substantive needs.

I think that these decisions about how those topics will be managed are being decided now and they will be decided based on the needs of the people who are participating in the discussion. So, the people that represent Germany and Canada are very good, but they don't have the same needs and they don't have the structure as the United States.

And the United States healthcare system is frankly weird and very specific in the way that the U.S. has decided to apportion the responsibility for developing these segments of the work that's necessary is quite particular.

So, even if it takes a while to set up this council and discuss which agencies should be involved, et cetera, I think it would be really important for you to figure out a way to address, there hasn't really been anybody in that position with regard to the morbidity part of it since Donna Pickett became quite ill, which is now several years ago. So, the U.S. effectively hasn't participated at that level in these discussions for a long time.

I think that should be addressed as a real priority, even if it's by somebody who's temporary, somebody that can be knowledgeable and be there and represent the U.S. perspective in those discussions. Thanks.

Jamie Ferguson: Thank you, Geoff. Michael Hodgkins.

Michael Hodgkins: That's disturbing. That's scary. I'm not sure if I misunderstood your suggestion, so correct me if I'm wrong. But I don't think we want to have two separate tracks where we have an agency with overall responsibility and a council representing stakeholders.

And then over here, a group focused on linearization since the linearization is a central piece of this. So, I'm not sure. But then of course, hearing the comment that was just made, if we don't get in the linearization fight soon, we may have a problem. And how do we manage that so that these things don't get destroyed?

Participant: Hence the urgency of this potential recommendation.

Michael Hodgkins: Well, yeah, but realistically, if countries are at the table today arguing about linearization, realistically, practically speaking, how long is it going to take the U.S. to designate an agency or department for overall coordination?

Can we afford the elapsed time to do that? And then, I don't want this to be mistaken in any way, because I don't know anything about the folks that are involved in managing ICD-10-CM. But is there going to be a bias amongst those same folks to having a CM for the United States that we're going to have to wrestle with as well?

Jamie Ferguson: Okay, thank you. Kin-Wah. Dr. Fung.

Kin-Wah Fung: Hi, this is Kin-Wah Fung from the National Library of Medicine. I'm part of the Workgroup, and I did some of the research about the feasibility of using ICD-11 instead of a U.S. clinical modification. And I just want to echo what Patrick, Geoff, and Jamie, and others said about the urgency of this commitment to really look into the adoption of ICD-11 in the U.S.

Particularly because in our research, ICD-11 probably can replace ICD-10-CM in expressing and covering the contents that we're using now, but that is based on the assumption that we can leverage all the new features, all the powerful functionalities that are new in ICD-11, such as this rich knowledge space called the foundation, and also this post coordination capability.

We found those two that it cannot be done. Just using the STEM codes in MMS, we cannot do without our own clinical modification. And as others have mentioned, it is a lot of advantage in avoiding clinical modification. So, in order to leverage the full capabilities of ICD-11, there are a lot of new things, new pieces that have to be put in place.

Like how do you leverage linearization? how do you leverage the foundation for U.S. linearization? And how do you even implement post-coordination, which is totally new because we have not had anything similar to post-coordination in the past. So, a lot of things have happened like messaging standards, EHR implementation, coding practices.

So, there is no time to waste, basically. If you want to go down that route of not using a clinical modification, we have to act now. Basically, to establish the rules of engagement of using foundation and also doing some basic research to tackle the issues associated with post-coordination. Thank you.

Jamie Ferguson: Okay, thank you very much. I think Val, you were next.

Valerie Watzlaf: Oh, thank you. And thank you, Jamie. This has been wonderful, but I do want to say that I'm just deeply concerned about this because I have been, I think, involved in this since 2018, I think at the first roundtable. And now as a member of the Workgroup, member of our full committee, it is time to really act.

I don't know that we do have to change your recommendation that you have on the slide to include mortality, because I think it has to be the one office or agency that we are designating to do that. So, I would like to make, or maybe adjust Tammy's motion that we, as our committee, that we move forward, that we approve this as written on the slide. Is that okay to do now?

Rebecca Hines: I accept the modification.

Valerie Watzlaf: Okay.

Rebecca Hines: Vickie and Mary Stanfill and Wu, all of whom are members of the Workgroup, have their hands up.

Vickie Mays: Thanks.

Jamie Ferguson: We also have, Deb Strickland had her card up here in the room. Okay, so I think Vickie is next.

Vickie Mays: Thank you. I actually am going in a little different direction than Val was suggesting, which is I think the specificity in this finding is important because it has implications for the public to see that we don't want them going off on their own. We want them coming into this. We want them to know they would be stakeholders sitting at the table.

I think that having something in here about a coordinating council to me is important. And I thought that the friendly amendment that was offered by Tammy would also be useful. And that's because when putting this together, I think that the government needs to have a sense of what it requires, the resources necessary, and the ability to get it going quickly, as opposed to getting it going quickly and leaving some of these out. Thank you.

Jamie Ferguson: Thank you, Vickie. Let me just respond to Vickie, and then I'll call on Wu and Mary. Okay, so Vickie, the idea that we talked about in the Workgroup that I would support for this would be to describe the idea of a coordinating body in the rationale for the recommendation, but not to specify exactly how to do it in the recommendation itself. Would you be okay with that?

Vickie Mays: Yes, as long as it said that that coordinating committee is essential.

Jamie Ferguson: Okay, good. That's great. Thank you. Mary, you're next.

Mary Stanfill: I will be very quick. I want to apologize to the Committee. I spoke to that slide and gave some of the information that the Workgroup had pulled together, but I failed to introduce myself. So, I'm going to do that very quickly just for the record.

I am one of the external expert volunteers that was invited to assist on the ICD-11 Workgroup for this committee. And I also am the official representative of the International Federation of Health Information Management Associations, representing that group on the WHO Family of International Classifications, on the council and a couple of different Workgroups, specific again to morbidity.

So, that's my role, just so that's stated for the record. And then I'll just make one quick comment. When Geoffrey was speaking, I very much agree with Geoffrey's assessment of the urgency for some U.S. official representation for morbidity with the WHO-FIC. And I thought also I would just say that Kin-Wah stated the urgency as well, very clearly, and I agree with him. Thank you.

Jamie Ferguson: Thank you, Mary. Rebecca.

Jacki Monson: Okay. Are we making any modifications to this recommendation? This is for committee only, this group and the two that are on get to vote.

Rebecca Hines: Right. So, just for clarification, Workgroup members, it looks like we're transitioning from Workgroup discussion to just full committee member discussion.

Jamie Ferguson: And so, the recommendation then I would say would be this language. And with the provision that we would develop, after approving this recommendation, that we would use the Committee members and Workgroup members to develop the rationale statement for this that would emphasize the critical importance of having a coordinating body, as well as obviously collaboration with the mortality side. But not to change the recommendation itself in those respects to put those items in the rationale.

Valerie Watzlaf: I just had another question. We will still, as our committee, still be able to have input into this group. We're not going to pull away and not do anything. I just wanted to clarify that.

Tammy Banks: I just want to put on the parking lot because I know we're focused on this recommendation, but I would recommend a second recommendation to discuss after this one in regard to the urgency of an appointing a representative to the appropriate WHO committee. Just to raise that priority and not just assume that it's in that language because of the urgency. I think that was very adequately conveyed today.

Rebecca Hines: And there are some thumbs up coming across. Do we have proposed language for that second recommendation that someone could suggest?

Jamie Ferguson: Well, one way of dealing with the urgency is just to put the word immediately or now into the recommendation rather than having a second one. Just to say it's imperative that HHS designate an officer agency immediately to be responsible. And then I think that's a way of dealing with the urgency question.

Tammy Banks: Well, and maybe you can calm my fears, but bureaucracy runs slow. And so, I was just thinking, the second recommendation, you can easily appoint someone to the WHO a whole lot quicker than creating a coordination entity. And I think it needs to happen now.

That's the only reason for two, not to add complexity. So, I don't know if you want to approve this recommendation first and then go to that language, which I'm happy to offer something.

Jacki Monson: Yeah, let's clarify what the language is going to be here because I'm hearing two different things. So, we modified the first recommendation to include immediately to be responsible for the overall coordination. But I hear a little bit of what you're saying, Tammy, which is more of the urgency around a specific individual to participate.

Tammy Banks: Yeah, so immediately appoint A, and then you'll have to determine if it's representative or federal representative to the WHO, and then whatever department it needs to be to advocate U.S. interest for ICD-11. And then just leave it open because there is a lot of activity that could happen. I don't think we need to say what that is.

Michael Hodgkins: Yeah, I'm wondering if it couldn't be part of the rationale for the first recommendation to say that while an agency is being designated, that consideration should be given to identifying an individual who can represent the U.S. at WHO-FIC for these linearization discussions.

Even though earlier I said that it takes a long time to set up, to make decisions about agencies, I'm also a little concerned though about a disconnect. How do you find the individual that you're going to empower or authorize to represent the U.S. while at the same time you're trying to find an agency to have overall responsibility? So, I'm wondering, rather than having a second recommendation, if it's not part of the rationale for the first.

Jamie Ferguson: So, just to clarify, what you're recommending is to add to the rationale the idea that the U.S. should appoint an individual on a temporary or permanent basis immediately while the agency is being determined. Okay, I saw Cathy and Val and Tammy. So, Cathy.

Catherine Donald: I would just say I support a second recommendation. I'm also concerned about the urgency. And I think we've got to have representation to at least hear what's going on and to be able to bring back that information to this coordinating agency.

And I'm not sure who would appoint this person. I don't know, but I hear that Tammy says she can go ahead and do that much quicker. And I think that's what we need. And I would say being a public health person, there is a big difference between mortality and morbidity.

And I'm also not sure that we need the specificity and the recommendation about mortality because I'm not sure which public Vickie is speaking to. But honestly, I don't believe the public understands the difference between mortality and morbidity. I was just in the morbidity world. No, I'm sorry, I was in the mortality world. And you see, I can get it confused.

And so, I don't think we need to confuse them with the facts. I think we need to get moving. I really do. I'm very concerned that everyone is ahead of us. And so, I would support a second recommendation and we can put it as a part of the finding what we do for this first recommendation, but I still think it needs to be elevated to a recommendation. Thank you.

Jamie Ferguson: Thank you, Cathy. Val.

Valerie Watzlaf: I like them as two separate recommendations. I'm just a little worried that as Tammy said, it's easier to appoint somebody. So, I'm wondering, and this is just a comment, would they just do that and not do the other. That's why I'd like them separated out just for the importance of them both.

Jamie Ferguson: Okay. And so, we're going to need the language for the second recommendation.

Michael Hodgkins: If the second recommendation is the winning proposition, I still think it needs to be made clear that it's on an interim basis and that it would be the responsibility of the agency ultimately responsible for coordinating this to either confirm that individual or appoint someone else as a permanent representative.

Jamie Ferguson: Okay, I see the language of the second recommendation being developed on the screen here. While HHS organizes a coordinating officer agency, it's imperative that the department appoint a federal representative to represent the United States. I would modify the end of that sentence perhaps, represent the United States to WHO for morbidity coding coordination.

Michael Hodgkins: On an interim basis?

Jamie Ferguson: I wouldn't say interim. Okay, and let me see. Tammy.

Tammy Banks: This is just a question because there already was a position that was not refilled. Is it more expeditious to replace the position or is it better just to leave it as a new one? Leave it? Okay, no problem.

Jamie Ferguson: I don't think we want to get into telling the department exactly how to do it, but rather what needs to be done. Is there any other input for any of the Workgroup members on the line?

Rebecca Hines: Is this the language that you want? Does it need any refinement?

Jamie Ferguson: It is imperative that HHS designate one officer agency immediately to be responsible for overall coordination of ICD-11 morbidity coding in the U.S. This office or agency should further be charged with and allocated sufficient resources for federal government coordination of all ICD-11 morbidity coding research, funding, rulemaking, and resources relevant to adoption and implementation and maintenance of ICD-11 as a U.S. regulatory code set.

Second recommendation, while HHS organizes a coordinating officer agency, it is imperative that the department appoint a federal representative to represent the U.S. to WHO for morbidity coding coordination. And I would add the word now at the end of that. Is that language acceptable to the Committee members?

R. Lenel James: Yes.

Jacki Monson: Do I have a motion?

Tammy Banks: You have a motion to approve the two recommendations on the screen. So, I'll amend my previous one to change it to the two. With one addition is under rationale development points that

we say in coordination with mortality efforts or whatever type of word you want to use for collaboration that's appropriate.

Jacki Monson: Okay. Is there a second?

Steve Wagner: Second.

Jacki Monson: Any other discussion? All in favor, put your key cards up. She's not an official member of the Committee. Put your cards up if you're in favor. Online, hand up please.

Rebecca Hines: So, online, Wu and Angela Alton. Everyone else, please take your hand down. We're taking an official committee vote right now. Angela Alton and Wu Xu, if you are in agreement, could you please raise your hand or unmute yourself and say, I approve.

Wu Xu: This is Wu, I approve.

Rebecca Hines: Thank you, Wu.

Angela Alton: This is Angela, I approve.

Rebecca Hines: Okay, so we have two members on Zoom, and we have unanimity in the room. So, that's all 12 members. So, a quorum plus, the motion is approved. Congratulations.

Jamie Ferguson: Okay, thank you everybody.

Jacki Monson: Jamie, anything else before we go to break?

Jamie Ferguson: I want to thank everybody for participating. I want to thank all the Workgroup members. In many cases, we had people who voluntarily took on assignments of reading RFI responses, scoring them, using the spreadsheet, creating that heat map. This actually was a lot of work and people turned it around quickly.

It was a tremendous effort, and we have wonderful experts, a great wealth of expertise. It's an embarrassment of riches, which I'm so pleased with. And I just want to thank all the Workgroup members for getting us to this point and stay tuned for more work assignments.

Rebecca Hines: Thank you for your leadership.

Jacki Monson: Yeah, thank you. I think it's been one of the most effective workgroups we've had, at least in the time that I've been on the Committee. So, thank you for that. Let's take a break. It is 11:23. So, let's come back at 11:35. Thanks, everybody.

(Break)

NCVHS 2024 Report to Congress

Jacki Monson: All right, welcome back, everyone. We're going to get started again and we're pivoting into the report to Congress. So, I thought we could talk a little bit about the history of the report to Congress to get everybody caught up. We've got some new members since we started this journey, which has been a little long, but we're coming close to the end.

We have the report to Congress, and the statute specifically is listed here. I'm not going to read it verbatim. I'll read the highlights, which are generally responsible for advising the Secretary and Congress on the status of the Social Security Act and that provision, assist and advise the Secretary in complying with the requirements imposed by that provision of the Social Security Act, and then studies the issues related to the adoption of the uniform data standards for patient medical record information and the electronic exchange of such information and report that to the Secretary, both recommendations and legislative proposals.

Next, it shall address the following subjects to the extent that the Committee determines appropriate. So, the extent to which a person's required to comply with Part C of the Act, cooperating and implementing the standard adopted, the extent to which such entities are meeting the security standards adopted in such part, and the types of penalties assessed for non-compliance with such standard, and whether the federal and state governments are receiving information of sufficient quality to meet the responsibility of such part.

Any problem that exists with respect to the implementation of such part, and the extent to which timetables under such part are being met. Here's the history of the most recent reports. We did one in 2017 and 2018. It was published in March of 2019. The 2021; that was published in 2021, was a reporting period of 2019 through 2020.

As I mentioned, we're a little behind, so we have a couple of years of reporting. So, we're reporting for 2021 through 2023, and obviously hopefully soon, either today or what our plan is, to get it into a good draft, almost close to final, and then over the next few weeks, get it final. And we'll call this group back for a vote, likely in May or June.

Goals for the day are the same ones that I sent out to you via email, which is we want changes and suggestions in the overall approach, any additions that you have per each section, or suggested deletions, and then specifically line edits. And I've got a couple of questions about grammatical errors that you have corrected.

I don't think we need to get into that degree today. You can provide those to our two helpers. Denise Love, who many of you know, has been with us for a long time as a committee member and now is helping us with this. And then Patricia, who's in the room with us today. These two have really been helping us get this across the finish line.

So, if you have any grammar, I want to spend time today on the substantive pieces and make sure that we're mostly aligned, get your feedback if we have changes in the overall approach, and additions and deletions high level versus grammatical errors, if that makes sense.

I am going to turn it over to Denise, who is going to be editing the document live. I know in the room, it's not that easy to look at the screens around the room. So, if you have to relocate a little bit to be able to see, that might be a good idea. We're going to go section by section, and if we need to go line by line, we will, and just want your collective participation. So, Denise, I'll turn it over to you.

Denise Love: Thank you, Jacki. It's great to see so many familiar faces and thank you for this opportunity. It really was reliving the past, in the past three years, doing this report. And I wanted to give a shout out and thank you to Patricia McTaggart.

We were so lucky. I was so lucky to partner with her in this experience, and her knowledge and experiences were quite helpful in putting this together. And as Jacki said, we have gotten some grammatical and editorial comments, and that's fine. We've got them. So, today I'll go over the structure and then the sections.

Again, Section 1 is just the background of health IT, standards, policies. Section 2, let me remember. We'll skip the executive summary here. Section 1 is an introduction. Section 2 is just the evolving context for the rest of the report. So, what's happening in the broader scheme of things? And then Section 3 is where the meat of what your work is and the progress towards the administrative simplification provisions and the privacy rules.

And then the last is emerging trends for leaders, Congress, and other policymakers to consider. And the structure of it, as we went through the information, is to break it into the interoperability, future considerations, cybersecurity, future considerations, and emerging technologies, including AI. So, that is the outline, and here we go.

Michael Hodgkins: Can I ask a question?

Jacki Monson: Of course.

Michael Hodgkins: This has bothered me as I've gone through this. The emerging technologies seems to only want to focus on artificial intelligence. There are a lot of emerging technologies that can have an impact going forward. So, I'm just asking if we want to limit the discussion to artificial intelligence or if we want to be broader than that.

Jacki Monson: I don't think we have to limit the discussion to artificial intelligence. I think if we see other emerging technologies, we should include that.

Michael Hodgkins: Well, there are sections that deal, for instance, with mobile health type solutions. Those are emerging technologies to my way of thinking, but we're dealing with them separately from the section on emerging technologies. If that's too much of a net, I can overlook it, but -

Denise Love: No.

Michael Hodgkins: And then there are emerging technologies like the blockchain and there are things in cybersecurity that are in reference to your zero-sum algorithms and the like. So, I'm just wondering how far field we want to go.

Jacki Monson: I think we can go as far as the Committee members want to go, from my perspective. And I think that's part of why we wanted your feedback today is the organization of it doesn't make sense to look at different organizations. So, I think we've heard your feedback, and we can look at emerging technology sections.

I think the one thing that I'll comment on and then I'm sure my writers have more comments is, it's hard to organize this. We've organized it, reorganized it a bunch of times to try to make it in a readable fashion, and not everything fits in each section. And then sometimes they were referencing it in multiple places. So, I'll just put that caveat out there and then I'll let Denise and Patricia comment more.

Denise Love: Yes, and Patricia, feel free to weigh in, but I don't think we intend to limit it. And this is why we're having this discussion now. So, as we go through it, feel free to throw in what's missing.

Michael Hodgkins: Well, but since it's an organizational point, and I can see us going different ways. I'm not saying one way, but emerging technologies could be AI, blockchain, FHIR, and FHIR to me is still an emerging technology. And it's certainly in the context of this report, where you're thinking about the impact that it can have on standards going forward, in comparison to X12.

Mobile health is really an evolving emerging technology. What's the best strategy? Is it individual solutions? Is it a platform strategy? But you can also deal with these things separately. It's just when I see a title like emerging technologies and only one thing being identified, it just throws me a little bit.

Patricia MacTaggart: But if you take a look at the table, and we had that concern too, which is why we have two healthcare innovations, transformation. There was a lot of material that you guys worked on that was AI-focused, but there was a whole thing, as you indicated, that was not. So, there is actually in the tables and stuff too.

FHIR, we put under standards, it may need to move if that's where you want to make the emphasis for doing it, but absolutely agree with your comments on emerging technologies are way more than AI. There is, at least in the first table and going through how we framed it, and again, adjusting to how you want to do it is to group the others into one and then AI into another. Does that meet your needs or does that not? I want to make sure I'm not missing the point.

Michael Hodgkins: Yeah, I think you do capture innovations and maybe the more umbrella terminology would be to have a section for innovation that includes innovations and technology and others.

Jacki Monson: Yeah, I think it makes sense to have a section on it that's specifically focused and then we can reference back to the relevant - if we're going to be talking about it in both standards and privacy and security anyway. But I think it makes sense to specifically call it out because we might actually - I think about where are the readers going to go and what their interest is.

So, I like, Michael, what you're saying, and I think it makes sense to have more than AI in the technology section. And then perhaps if they're going to be coming up in the standards section or in the privacy and security section, we just reference it. But I like that idea because I think that people will go to the sections that are most interesting to them as readers of this report.

Michael Hodgkins: Or we could have a section for innovation and under innovation there is things to be covered here, like we're just discussing technologies.

Jacki Monson: Yeah, or you could call it digital innovation and then you cover both.

Patricia MacTaggart: Denise, you're on the executive. If you could just go to the sections that you're just talking about and skipping the executive, maybe it will help because that's what the table does. What I'm hearing.

Denise Love: Right, where the table starts. So, this is the progress made, the introduction. These are the tables coming up. So, emerging information technologies and digital innovations. And the way it's structured is these are the innovations here, but then each of the tables includes potential opportunities and risks and trying to summarize.

And Patricia, who's had way more experience in doing these types of reports than I, it made sense to put it in tables for different staffers and others who are reading it who won't probably read the whole report but will pull out the sections that are relevant to their interest or their focus.

But I want to say that much of this report is embedded into the footnotes. And a lot of information is down here so they can access the references that refer to the tables above. So, what is the pace you want me to go? Here's emerging health information technologies, IT, and digital innovations. And so, just following that through -

Jacki Monson: Before you go there, I'd like to hear any other overall comments. I think Lenel has one, and then my only other - we've got to shorten the executive summary. It's actually got to be an executive summary. It's too long, I think, right now. So, that was mine. Lenel.

R. Lenel James: Yeah, I want to gently push back on Michael because one of the things that the industry is dealing with in 2024 and 2025, the industry is awash in regulations, awash in doing technology. And right now, payers, providers, and vendors are struggling to implement the techs we have. And I'm not sure we - because this is supposed to be a report for the next two years.

Well, in the next two years, most payers and providers, their bandwidth is gone for just what we have. I think it's important to put out these new technologies, but I think we have to be very careful. If this audience is the report for the next two years, from a payer, EMR vendor, provider vendor standpoint, the ability to do much of these new technologies is almost gone in terms of real bandwidth.

I'm seeing in real world discussions with senior leaders about what their staff is available to do, what their budgets are to do. And then of course, with the latest billing mess, some of the providers are struggling to keep their doors open. So, I think we have to be extremely careful and focus on the emerging technologies that are aligned with what we already have to do and aligned with what the states are doing and be very careful of talking about technology that is five years out, that's not going to be very realistic for the feds.

But again, you have to start early with tech if you want to get them. There is a counterpart, get it on the table. But I just worry that if we have a report that has something that our leaders that make decisions are going to go, that's not in my budget, that's not happening for two or three years. And then they stop reading the report because we've gone so far in the future, it's not relevant to their current planning for the next two-year horizon.

Denise Love: Thank you.

Michael Hodgkins: I have a solution. Looking back at the table now, there is a section in the table, I'll find it, it's a more expansive definition. And then it merges. Yeah, so there is a section in the table on emerging health information technologies, health IT, and digital innovations.

So, instead of having the section in the content that simply says emerging technologies, artificial intelligence, why don't we substitute the title in that table and then cover what's being covered in that table and making sure to include AI. Does that work?

Denise Love: So, change the title of the table.

Michael Hodgkins: Go back to the table of contents and under part 3C, use the title that's in the table that talks more broadly about new technologies, IT, digital innovations, I forget the exact wording because I'm not looking at the table again. Make that 3C and then it'll tie to the table.

Jacki Monson: So, expand this. It does, okay. And I'm sure Jamie's comment is about cybersecurity with the technology if I was a betting person. So, let's hear it.

Jamie Ferguson: How did you know? Yes, indeed. So, my general comment is in the cybersecurity section, I would like to see the report emphasize some of the discussions that we've had about ensuring greater compliance with the existing HIPAA security rule. And when we get to that point, I do have a friendly amendment I'll propose for Page 26.

Denise Love: That sounds good. Thank you. Excellent.

Jacki Monson: Denise, before we start perusing, does anybody else have any other overarching structural organization comments? Okay, I don't see any in the room. So, let's go section by section.

Denise Love: Okay, we'll skip the intro part because the executive summary will have to be revised. So, this is the context. And to Lenel's point, I think the context isn't saying what is absolutely going to happen, but it's the context of the larger landscape or the environment by which the - looking forward, and some of the discussion in the middle, will follow.

It's not so much saying this has to be done, but this is what's happening in corners of the healthcare sector as we evolve. So, I just wanted to say the report really in the middle covers what happened over the last three years. And then looking ahead should be the things that maybe the Committee wants to shout out on priorities for policy and considerations for others going forward.

So, we have the section under drivers and dependencies, the - I'm not going to read it, but you can see here the need for transparency, oversight, accountability, digital healthcare, IT, and data standards, including SDOH, USCDI with the references, opportunities, and risks. These are things that are coming down and some of the things to watch for.

Interoperability, the Cures Act, TEFCA, a lot of concerns about HIPAA and non-HIPAA covered entities, and information outside of HIPAA, the last mile, the digital mile, rural and under-resourced communities, cloud computing, and some of the related security and concerns about that. Again, digital health, privacy, DOB, and some of the fallout related to that with the references underneath.

And this comes up, and this is near and dear to my heart, and I think the Committee. De-identification practices come up several times in this report and the need for revisiting that. ICD-10 to 11, just the context. And then the details of what the Committee did is in the next section. The HIPAA transaction process, the need for keeping pace.

Some of the standards are evolving and more expensive data flows. You tried to capture some of those challenges and opportunities related to the work that the Committee's done and looking forward to how the clinical and data are merging and converging.

Cybersecurity, a huge deal. Poor security practices for when breaches are occurring, the consequences, but just basic risk management needs, just applying the current practices and compliance issues. Again,

SDOH is a theme that comes through in several of these categories. Data silos, some of the challenges of capturing and using that data, how COVID impacted that.

The need for a national framework. Again, tribal, state, local come up in several places in this report. It is critical. And some of the risk that as you put these more granular data together and share them with more audiences, the risk factors do increase, but not doing that perpetuates the health inequities. I'm just giving my highlights and what I remember, late night writings.

Then this gets into what you've done over the last few years. So, this is really the meat of the report as I look at it from the standpoint of the requirements. We will go quickly here. This is the CAQH core table from their data that really highlights the trend from 2013. The boxes here are the report periods.

The shaded areas are where there has been a retreat in adoption or stagnation, but really, it's pretty minor. I was impressed that in most cases, except for EFTs, we're really getting the traction that is needed in these last three years with attachments, I think, to take off later.

But this is the CAQH core efficiency index from their report. We felt it was important to highlight what CMS accomplished in the regulatory activities relative to the standards during - there were two HIPAA and two non-HIPAA actions, but I think that adds context to your work that follows. And retooled the table to summarize. We just had originally the table with the link, but then trying to flesh it out to what the rule proposes to do and its potential or actual impact for readers who might not follow this as closely.

It's obvious to all of you, but it may not be obvious to a healthcare staffer. And so, that is this table. Then into the sections of standard transaction, code set standards, operating rules, drivers, and dependencies around interoperability. We need predictability in the standards adoption process and the updated standards need to be current, and future business needs and responsiveness. And some of the challenges and opportunities or risks related to moving this along.

Tammy gave some excellent comments getting at the suite versus unbundled transactions, raising questions of compatibility across multiple versions with the relevant footnotes. So, there is a lot here. I can't really go off on it through the time we have, but that's the structure here.

We hit on beyond HIPAA. The regulatory structures and the commingling of data really challenged HIPAA and getting at the targeting improvements needed in the regulatory framework to support the bidirectional flow of data across agency and industry collaboration is essential. Understanding of maturity and workforce capacity and consensus for new versions and new technologies, possible alternative standards under HIPAA.

Enforcement, I took some of this from CMS, but it seemed to be a section that was important. So, we mentioned the enforcement provisions and the work that CMS is doing on that and tried to distinguish between the privacy and the administrative simplification aspects of enforcement. And that was an important component because we did not want to mix those two up. They're different and different players.

We mentioned the attachment transaction and the voluntary adoption of such really led to low adoption because it's really difficult to have the systems invest in solutions without a mandate or guidance. There is too much uncertainty. Harmonizing the mapping of clinical administrative vocabulary standards and then data dictionaries is essential for robust AI and maybe other technologies. But the

data sets really are combined, will power AI to make informed decisions, good or bad, I guess, drive innovation, and impact healthcare and other domains.

We talk about the cadence again and some of the challenges, and there are many, and I'm well aware of some of these, but I really tried to get the social benefits in here in the evaluation puzzle. Because it's so hard to get a handle on what the actual costs are to the industry for a lot of reasons that we try to list, but also the social benefits need to be embedded in that value equation, workforce limitations, broadband, the need for leadership forums and collaboration to standardize and create uniformity. So, that's just a breeze through.

Jamie may have some things to say, but I took a lot of this out of the Phase 1 report, or was it Phase 2? I can't remember, but this is what you actually did here. This draws on the work from convergence, modernization, and ICD-11 Workgroup.

We hit on the opportunities for burden reduction and modernizing, but the challenges for funding and research and communication and workforce training are not solved. Need for greater coordination with other terminologies. And I think we hit on some of the Workgroup recommendations for leadership and centralized coordination in the next section.

Privacy, security, breach notifications. Again, HIPAA and non-HIPAA privacy issues, better access to - the data we have needs to be streamlined and improved and better data exchange to improve public health and social data. And AI transparency and what's behind the black box of AI is going to be critical. Joint guidance on surveillance and data security, safety and security solutions related to AI.

Cybersecurity. Jamie, you may have some things here, but talk about the massive problems and the less resourced entities. It strengthened the HIPAA security rule. Evaluate in concert with other government agencies' level of compliance with the security rule. And helping those that need it with minimum security requirements, like guidelines for a risk analysis and risk management program.

We touched on the breaches. I think there is a lot of reference for the Seattle and change health and some other - we didn't put this in the reading, it's in the footnote. Mandatory minimum hygiene requirements. Evaluate the level of compliance with HIPAA security rule. Assist healthcare entities with the greatest need.

I think these things recur. So, there may be some redundancy, but I don't think that's bad because you don't know what section someone's ripping out on the table. And so, I don't think that's necessarily a bad thing.

Jacki Monson: Instead of saying things like poor and lack, can we just say they don't meet the minimum cybersecurity hygiene? Cause that's really at the crux of it.

Denise Love: Okay, where? Let's see.

Jacki Monson: I think it's all over in the report now. I've seen it probably two or three times as we're scrolling through.

Denise Love: Let me just make a note. So, lack, replace.

Jacki Monson: I think you have lack somewhere and then -

Denise Love: With minimum.

Jacki Monson: Poor. And I would flip those too. Just, they're not meeting even the minimum cybersecurity hygiene, cyber hygiene. And you could even add the point that Jamie wants to make, which is even what's in the HIPAA security rule today and the opportunity to enforce that actually could help us.

Jamie Ferguson: I'll offer that language in a couple more pages from now.

Denise Love: Okay, I'm just putting that in there in red, so we don't miss that. Again, under privacy, a section on the health equity. And this gets at the important work on the tribal and the public health and local. And it's just the really sad situation during COVID and your work here.

And so, we need to do better, and more timely, and more granular, but really preserving privacy and security, especially during the next PHE, because the last one we didn't do very well. That's my editorial comment, sorry.

DOBs is a big deal and your work on that, the legal environment and some of the risks, we're seeing state laws. We saw one yesterday that shocked me. And so, it introduces uncertainty and burden across the covered entities, the public health uncertainty, elevating the need for de-identification practices, re-disclosure practices, and how HIEs fit in.

And we welcome comments, but that's drawing on the work that, and your letters and everything else that did. And I tried to be careful not to insert any new information here. I tried to really draw on what you all did instead of what might need to be happening too much in the future. But these are things you actually recommended.

Okay, we do list under appendix A and B, all of your letters and I'll go through that, but we referenced that. So, the details are in the appendices. This is strengths and barriers of progress of data privacy and security. Emerging technologies, AI. This may be where we want to add others. I'm just commenting from the comments.

These are some of the strengths and barriers to AI as emerging technology. Lenel and other - or Michael, is this where you would add maybe mobile and some of these other technologies here as another line or?

Michael Hodgkins: No, I think I'm going to go back in the table to the earlier section that talked about technology, IT, innovation, and I'll make some suggested amendments there. I'll be gentle because I don't want -

Denise Love: Well, you don't have to be too gentle, but we want - this is your report. We're just the authors.

Michael Hodgkins: I take Lenel's point seriously. And I think that there is enough being covered. It's just a question more of grouping some things together. So, I will make some suggestions there.

Denise Love: And it's totally welcome.

Jacki Monson: We should make sure on the AI front - I didn't see as highly, probably as much as we should, that it's a benefit and it's a challenge, right? When we have AI now being used for cyber-attacks, it's a pretty serious risk that we haven't faced previously.

And I think that just ups the ante when we already have entities that are not meeting the minimum cyber hygiene requirements. How are they going to defend against the use of these cyber attackers, figuring out how to hack. And even a layperson now could use AI to tell them how to do that.

So, I think it just increases the risk landscape and so balancing the benefits of it with - it's not just risk to the PHI, it's risk to patient safety when you have the ability to use AI to fast-track hackers' ability to get into your systems.

Denise Love: Chilling. And then we hit on, under the strengths and barriers to health privacy, TEFCA is emerging as a data sharing and common agreement and how to monitor that and assess compliance. And there is a lot of work here that I'm not as conversant with, but Patricia is, but it really needs some attention.

We touch on accounting of disclosures here and the burden to the industry, but also the trust issue with patients to know what's happening with their data, monetary penalties, OCR funding to really hammer down compliance, and the considerations of the harms, and the patient rights, and cybersecurity, modifying security, encryption, that's not costly or burdensome if that's possible.

And these are just a laundry list of work that needs to be done or considered. Invest in entities to improve their cybersecurity to comply with and beyond, and guidance provided through OCR documents, emerging technologies on telehealth, not part of that security privacy rule.

I see a missing thing, OCR. This was challenging for me because I didn't know how much leeway we had in taking OCR's reports to Congress and importing them. But I think we decided to just focus on their last two years. 2023 is not out. And just focus on that and in their report, they had many years.

We took their graphs and their data and their report and put them into the table to show the trends. And actually, I was surprised when looking at this, the trends aren't as horrible as I thought, except for hacking, just hacking. But some of the others are stabilizing a little bit or decreasing, but it's just their data, not yours.

And it's only the 500 or more individuals, not the small providers. We didn't go that deep. I don't think you did last time. That's, I guess, an open question, how deep you want to go because they have similar data for less than 500 or smaller providers and entities. So, I just picked out the 500 or more, the big ones.

Jacki Monson: I think the other trend that I have never seen them publicly say they're investigating an entity like they did with Change Healthcare. I've never seen that before. I think that's a new trend.

I actually appreciated it, not because I don't like Change, but because it had such a widespread impact to industry that it really could be a crisis, the next vendor that this happens to. And I think the other trend that we've now seen is that they're calling inappropriate accesses to medical records as insider threats for cyber.

And I actually like that connection a lot because it's not wrong, but I think we should highlight those couple of things because we've seen some changes from OCR that I think are positive and in the right direction of focus when we try to highlight and go down the road of, could they enforce HIPAA security more? I think they're rowing in the right direction.

Denise Love: Okay, duly noted. I didn't type that, but I noted in my notes.

Jacki Monson: And Jamie's got a comment.

Jamie Ferguson: We can find the right language for this, but I would add to that, that there is a lot of recent reporting about the change in the nature of threats and it's really the rise of cybercrime, organized crime over nation state attacks and things like that, as well as the prevalence of ransomware now. It should be mentioned.

Maya Bernstein: I find this format with the numbers not very easy to absorb very quickly. Is that a format that resonates with the Committee? Just me?

Valerie Watzlaf: I like the tables better than the, I think there were pie graphs in our original.

Denise Love: Yeah, we had pie graphs, and they were clunky.

Valerie Watzlaf: I see it as well, so. I like the -

Denise Love: The problem with the pie graphs, Maya, is the healthcare clearinghouses don't even show that slice of 1 percent. And maybe an expert formatter that's not me.

Jacki Monson: I think that's okay though because it still is going to give you the trend data.

Denise Love: Right.

Jacki Monson: And so, I understand Maya, your point, which is if you show the visual, they go straight to where the increase is, which we know where the increase is right now. I tend to agree that people focus on visuals if they're interesting, and if they show a pattern of something, and I think if you did do it as a pie chart, you would see that.

Maya Bernstein: Yeah, this isn't showing a trend over time. We could do that with previous reports and add the latest two years if you wanted.

(Cross-talk)

Jacki Monson: I'm super interested in trends because it paints the picture of what we're trying to say in the writing.

Michael Hodgkins: But this may already be there, but given the recent change to Esco, I know it's outside the scope of the report, but is it worth a footnote for a table like this? Because right now -

Jacki Monson: I think it's outside the scope, honestly. I think.

(Cross-talk))

Michael Hodgkins: When it occurred, so.

Jacki Monson: It's referenced in one of the footnotes, I believe.

Denise Love: Yeah, there is a huge footnote on Change health.

Michael Hodgkins: But this table in particular, the numbers for clearinghouses make it sound like, oh, clearinghouses are doing fine. Well, guess what? Change blew up.

Jacki Monson: Well, right, because they're focused on where the data is, and the data is sitting in the healthcare clearinghouses.

Michael Hodgkins: So, I would just maybe repeat the footnote and attach it to this table as well.

Denise Love: Okay, yeah, I think that's good. I was surprised because they haven't been a target until just recently. Apparently, it's providers that have been the - so, these are the entities. They have a lot of graphs in the OCR report and their visual, their graphics is really - I could not import OCRs. So, I had some clunky graphics of my own, but we made the tables. But Rebecca, I'm not great at formatting these from the tables.

Rebecca Hines: Either staff or contract logistic support, either way, we can get those made. You just point us to which ones you want formatted and we'll take care of it in the next couple of weeks.

Denise Love: Yeah, so as I look at it and looked at their data, I'm happy to see the email is declining and network servers are increasing. There is a lot there. But again, this is the OCR. And we hit home again that just basic enforcement and compliance with the security rule as written would cut down some of these breaches, but also a new look at the sufficiency of the rule going forward.

Jacki Monson: Yeah, I think we can debate that a lot, right? Because I think the HIPAA security rule is pretty outdated too, in the sense that the emerging trends are not being met. And then I think the other big issue is that the margins in healthcare are so small that they're not investing in cyber the way they are in the new emerging technology because they don't have a choice.

So, we've got to find some balance to that, but even patch management is not done well at most organizations. So, I think there is a lot to say about that. We also have a comment in Zoom just sharing that having both text and visual is good for those that might be visually impaired.

Denise Love: Okay, all right. Duly noted. This is just again, at the last report, there was some detail on breaches. These are the breaches from their own portal, from OCRs and just some top ones as an example, because it goes on and on for years and pages.

Jacki Monson: This is where I think trend data would be helpful. Now, instead of doing it like that, could we actually just trend on it?

Denise Love: I'm not sure because these are the individual.

Jacki Monson: Well, yeah, but do we need them if we have trend data? If we're highlighting Change already, we're going to highlight some of the big ones. I'm not sure we do. I guess that was my point.

Denise Love: Okay, so question whether this table is helpful or not. We could do a link and just say, this is where the reports are.

Jacki Monson: Others, feedback on that? Keep or toss?

Jamie Ferguson: I think showing a trend is more useful.

Denise Love: Okay. And the trends that you're talking about, just so I'm clear, is the trend data from up here or -

Jacki Monson: So, trend data on the types of incidents, frequency, impact.

Rebecca Hines: A list of breaches doesn't tell you much. So, I'm just saying, instead of having the breach data like that, the other data that's more compiled, and maybe we'll do tables and pie charts to show trends, that might be the way to go and just let this particular table go.

Denise Love: Yeah, that's fine. But how far on the trend? They have every year to report to Congress, but I just took the most two recent. I can go to last year, last Congress, the 14th report. There is some data there. So, how many years trend?

Jacki Monson: I'd like to see us trend. How many years do we have available in data? Because if we have, I don't know, five years, I might trend on that far.

Denise Love: Yeah, I think it's there. There is a lot of data in their reports for each year. So, I think you can go back, and I can just build the table for those three.

Jacki Monson: I think that would be great, but I'd like to hear what others think.

Michael Hodgkins: I would suggest four- or five-years history.

Jacki Monson: Yeah, I was going to suggest five, no more than five. I think that'll show what we want to show.

Denise Love: And on these three, because there are so many choices. They have graph after graph. These are my picks for the large facilities, not the small. You can just go down a rabbit hole here. We do provide a link to the report and the reports, but I can add years here to these tables. I can go back to 2019 at least.

Jacki Monson: Yeah, well, I think what we're suggesting is we just do some trend data on all of it and then we would remove all the different - I'm happy to work with you offline. I think I know what the intent of the meeting is right now.

Denise Love: Okay, yeah, I'd appreciate some input on that so that we - okay, so we'll take this out. Okay, moving on, any other comments there?

Jacki Monson: Tammy has a comment.

Tammy Banks: Yeah, I just want to make one comment before we go to Section 4. And Denise, I just want to elaborate on why I was making comments regarding Page 18, Digital Health Enforcement.

I'd really encourage the Committee to think about highlighting the enforcement that happens with standards. I realize the federal agency has handcuffed that they can only respond to HIPAA related complaints. We hear at each testimony where people do not feel enforcement happens. They're not sure that operating rules have enforcement happens.

The federal agency has very nice reports on the number and types of actions that they've taken. And while the numbers are small, we have to realize that one corrective action, let's say we take - there are a lot of health plans that have over a million physicians and each of those physicians have thousands, if not 100,000 of transactions. So, this is really big, important work that occurs, but it always gets swiped under the table. And I think it's just as important as the privacy and security. And I think it warrants a chart and a statement to the fact of the impact and the work that's being done in this report. So, I hope the Committee will take that under advisement.

Denise Love: And I had trouble, Tammy, and maybe it's just me. It may be just me. I think I got some input from Lorraine, but I didn't see the data like I did with OCR. I had trouble getting at it.

Tammy Banks: It's the second link on Page 18. It goes right to the data that was - I don't know if it is last year or what, but it's something that I think that we should be able to go back to the federal agency and work with them to see how they would like it highlighted. But I just think there should be a chart or a graph or something to put your eye to that this important work is happening. And it's not something that's not occurring.

Denise Love: Okay. And you had some wording that you wanted to highlight needs to be more transparent or more -

Tammy Banks: We can work on that.

Denise Love: Okay. Okay. These are placeholders. We will be looping back. Okay, moving along. How's our time?

Rebecca Hines: We're supposed to wrap this up in about seven to eight minutes, Denise.

Denise Love: Okay. Then emerging trends for Congress and policy and leaders to consider. And they're grouped into interoperability, future considerations, subcategory of standardization. And again, these are what we pulled out, but it may not be the ones, but this is where we're at right now. We mentioned standards and enforcement and responsiveness and transparency. So, I think we hit on some of that, that Tammy was talking about.

Rebecca Hines: And I'm wondering, given Lenel's comment, it looks like you have B is cybersecurity and then C is emerging technologies, artificial intelligence, future considerations. It almost sounds like your point, Lenel, about just the untenable pace of innovation implementation or something along that point might need to get woven in or even adjust that subtopic emerging technologies.

R. Lenel James: Yeah, I think Michael hit it right. We need to talk about that as innovation, so people don't get a sense that it's an expectation, they're going to do it immediately. But we're just trying to make them aware of the breadth of innovation that's available to healthcare, but not to imply they should run and try to do it tomorrow.

Rebecca Hines: Did you hear that, Denise?

Denise Love: Yes, and I'm going to just type it in here because I don't exactly know where it will fit.

Jamie Ferguson: And before you skip over Section B on cybersecurity, I put in the chat some amended wording that I would suggest for the box that's there for the future-oriented cybersecurity on Page 26.

Rebecca Hines: Denise and I will email you -

Denise Love: Yes, please do because I had trouble with the chat. Okay. Okay, that's fine.

Jamie Ferguson: Basically, my amendment would call for increased enforcement of the HIPAA security rule through reviews, assessments, audits, coupled with additional assistance for smaller or less well-resourced entities.

Denise Love: Okay. I'll plug later. I'll waive them in with Patricia's help.

Jacki Monson: And if we're going there, then maybe we should go there with third parties too because I think there is a tremendous opportunity.

Jamie Ferguson: Yes, so I did put businesses. I said for covered entities and business associates. Because absolutely, the trend is that the vast majority of the big breaches are from third-party risk. And as we heard from OCR, just like many covered entities are not fully embracing the risk assessments, they're not auditing the business associates to their contract terms. And this is something that absolutely should be addressed.

Jacki Monson: They're not managing their own risk, and so it's creating all these breaches. And perhaps another example besides changes in MOVEit because there are so many breaches that came out of the MOVEit, which are on OCR's website as well. That was in May of last year, so that might be another one to footnote. And then the other, we got another -

Denise Love: And it's movement? What's the -

Jacki Monson: MOVEit. May of last year. It was implicated, the breach notification though, and the impact is still happening today. And then I think separate from cyber, there is a question in the chat about whether we should include FHIR here.

Rebecca Hines: In the interoperability section, Section A, Denise, Patricia?

Denise Love: FHIR is here, but what - as a recommendation in a box?

Jacki Monson: Yeah, it says FHIR adoption under interoperability specifically.

Rebecca Hines: What do you all think around the table? Do you think FHIR belongs under Section A?

Jacki Monson: Well, I think Michael already said that.

Michael Hodgkins: I think that's just part of the innovation discussion.

R. Lenel James: Yeah, so no, I think that as long as it's covered in standards, so people understand that is an active standard that's available, because in some cases, it's active because of federal regs. In other cases, it's innovative because it's not required, but it could help in other areas. So, it lives in both worlds.

Michael Hodgkins: That's right, that's right.

Jamie Ferguson: And it's important to mention both the risks and benefits of implementing API-based ecosystems because people frequently can confuse FHIR and APIs. FHIR is a data standard that's used in APIs, so I think both need to be mentioned.

Michael Hodgkins: Yeah, we all know FHIR is going to take the place of X12 anytime now, right?

Denise Love: Okay, and then standardization, deeper assessment of safety security issues related to AI, transparency, interoperability, under cyber implementation of security rule to include predictive modeling as part of a risk analysis framework, around privacy, cybersecurity hygiene requirements. I think Jacki made a comment that I'll have to revisit beyond maybe the security rule as well, right?

Jacki Monson: Well, at least in its current form.

Denise Love: Okay.

Jacki Monson: Are there any other comments? We're right at time, so I wanted to talk about logistics of next steps on this, if that's okay, unless anybody else has any comments.

Tammy Banks: Yes. Just one quick comment. I think that we really have to acknowledge Denise and Patricia and the Herculean work of compiling this together in such a short term when we were working on it for a long time. So, kudos to you guys, and we deeply appreciate your work.

Jacki Monson: Of course, and we'll officially thank them when we get it across the finish line.

Denise Love: Yeah.

Jacki Monson: You can never be thanked enough.

Denise Love: We do appreciate it. And I want to just acknowledge, I really benefited from Patricia's experience with these reports, but also her ONC and policy background has just been huge. And so, it really takes a village to do this.

And so, where are we? You see the report, there is still obviously some refinements, but it sounds like they're not just tearing apart the whole report, so that's good. And then I heard the executive - when we finalize that, then Jacki, I think we revisit the executive summary in a shortened form, and we deal with the Executive Committee.

Jacki Monson: Yeah, I can revisit that with you, and then we'll bring it to the Executive Subcommittee. So, just on logistics, I agree with your summarization of the current state. Tammy agreed to get you some language. I think we need all updates, grammatical language suggestions within the next week.

So, a week from today at the very latest, but would prefer it before. And the reason why is because we're going to try to get this in as close to final form as possible before the next executive Subcommittee.

And then we'll look for a special, hopefully only two-hour session to get approval for this. And we're targeting either May or June at the very latest. Anybody have any concerns or comments on that?

Rebecca Hines: Okay. So, get your comments in seriously so that we can get basically a penultimate draft for polishing, which will be obviously a step that we'll need to do as well with some staff support. But we do need to get the content pretty much wrapped up.

Denise Love: Okay, and I do want to thank so many of you for your input along the way. It's a daunting task, I forgot. So, thank you for the input.

And I look to your continued comments because it is your report.

Jacki Monson: Well, thank you both very much. And I'm sure we'll be talking a lot offline to get this across the finish line. And now we're on break for lunch and we'll return at 1:45. Thank you.

(Luncheon recess.)

Jacki Monson: Good afternoon. I am going to turn it over to Lenel and Jamie to start with the standards on SDOH data elements panel. And I also just want to acknowledge that it's really nice to see an all-female panel.

Standards for SDOH Data Elements: Successful SDOH approaches and challenges to promote health equity

R. Lenel James: Thank you very much, Jacki. Lanel James I'm here with Jamie Ferguson, we'll be moderating the event today. Moderating will be a little bit different than normal because we've got seven people. My understanding is this may be one of the largest groups that NCVHS has ever had. So, I apologize to the audience. We're going to have them go through a lot in probably what would be better done in half a day, but we will make it work in 90 minutes.

In terms of the objective here, a reminder for everybody that the Committee in general is interested in hearing from a variety of parties that specify and use healthcare data, but today, our purpose is to really make sure that our members of the NCVHS can understand some of the drivers and demand for the adoption and use of SDOH for health and human services and make sure we understand how those data elements may affect health equity, public and population health, and leverage technology.

Let me just briefly introduce all of the members on the Panel and describe how we're going to move forward. So, we've got Somava Saha, we've got Meagan Khau, Vanessa Candelora, Prerana Laddha, Rachel Harrington, Julia Skapik, and Gniesha Dinwiddie.

One of the things I want to say is what we're going to do is have each of the presenters go in order so that we'll have a couple of presenters take a break for Jamie and I to ask a question or two, then the next three, then a question or two, and then the final two, and then we'll open it up to the entire committee, but before we get going, there is some history here that Rebecca wanted to share so you understand some of the context of this committee. Rebecca?

Rebecca Hines: Thank you, Lenel. So, I don't think any of the current members were here when I came on board, and there was a population health Subcommittee that met in expert roundtable meetings to talk about all of these various measures on social determinants of health, and they remarked it was like a thousand flowers blooming, and everybody knew they needed to do something, and they were doing it their own way.

So, we kept convening, and eventually the Committee realized what they really needed to do was come up with a framework, not necessarily the actual measures where data were being collected around the U.S. at that time, but let's find a framework that we can all say is more or less the right lake, as our previous chair said. And then as our charter says, the Committee doesn't implement, but we stimulate. We stimulate this kind of work. And Somava stood up and raised her hand when one of the co-chairs of the Population Health Subcommittee said, we need a volunteer. We've stimulated you all, but we can't actually go any further.

If you do go onto our website, you will see this framework from 2017 - I can put the link in the chat for those on Zoom. And Somava has just been an incredible champion. Somava has worked as a physician in the safety net all the way through communities and everything else. I love your way of talking from the grassroots to the grass tops. And she has managed to get federal involvement through Healthy People 2030.

I don't think I need to say any more other than to let all of my colleagues here know that the Committee really helped stimulate this work that Somava in particular is going to talk about. And then everyone else is really going to provide other angles that are equally important. So, you can decide whether there is something here that you would like to actually focus on going forward.

I'm just delighted that I started with Somava and I'm ending my time with the Committee with Somava, and it just feels so perfect. So, over to you, Somava.

Somava Saha: Thank you so much, Rebecca. And I have to say, the joy for us was not just that this committee stimulated the work, but really walked side by side with us over a number of years, as this framework grew and blossomed and penetrated in ways that we would never have imagined when we first launched off on that journey.

Of course, this is that famous framework that was published in January 2017, which was a measurement framework for community health and wellbeing. And after the framework was developed, we were asked to steward a process, a federal-non-federal process for measuring population and community health. At the time, I was leading 100 Million Healthier Lives and our mantra was that equity was our price of admission. And there were many initiatives where communities were given things to measure, or health systems were given things to measure.

In our own health system at Cambridge Health Alliance, there were 542 measures we owed someone. Only two had to do with behavioral health. 540 was physical health indicators and none had to do with the social drivers of health. And we realized that it mattered. If we were going to actually improve health outcomes, we needed to have measures that we could all use and live by and learn with as we went along.

And so, a process to start, not from what we had, but from what was needed, defined by communities to validate that with evidence-based using the NQF decision criteria and a grassroots to grass tops approach of developing those measures using the framework that NCVHS has had was a year and a half long journey that really prioritized what communities knew and valued. Things like our wellbeing mattered.

The resources and assets that other sectors had to offer, from the business sector we learned they'd been measuring wellbeing using these two simple questions called Cantrell's Ladder that was predictive of morbidity, mortality, and cost, but also things that we now know are really important, like the

importance of trust, everyday discrimination on health outcomes, things like loneliness and social connection.

The communities knew this all along. And because we started with what they told us and validated and developed validated measures and identified what was already available that we could give back, we were able to get ahead of the time in giving communities measures that they could use. And I'm saying communities, but in some cases, grassroots communities like farmers and barbers, in some cases, 30 million people serving health systems and hospital systems. And in this case, 47 federal agencies that have adopted the federal plan, which is now baked in the core measures for this.

When I say that you all helped to spark a grassroots to grass tops collaboration, that when we went to release the measures and frameworks bricked the whole network because people basically said, hold it, sister, you sound like you're about this is about to go away. This is the only forum in which communities and major national organizations and federal agencies can be in a shared conversation together.

That has continued on to become the Well-being in the Nation network and continues to be a source of connecting people in ways that create new change. We'll have our annual gathering in two weeks. And at the last one, Paul Reed, who leads the federal plan was there and connected with Richard Joyner, a black pastor in Eastern North Carolina. And their relationship and conversation about food and farming and health and access to wealth for black farmers transformed his understanding of the issue. And so, as he's leading the food is medicine effort, it's not surprising that he has resources to turn to.

This framework has gone from an amazing set of measures that are adopted from groups as diverse as U.S. News and World Report, their healthiest rankings to communities, but it's created a space for conversation and connection to bring the grassroots to the grass tops together in an unprecedented and living collaboration to define, measure, and improve what matters to communities.

The second piece was our commitment as part of equity to make sure communities had access to the data that they need. And through spit and chew, there were no actual resources allocated anywhere for this, but we brought our assets together to identify how we could make data accessible.

In the context of the pandemic, that meant a real-time data pipeline that kept 500 communities safe and well. In the context of the pandemic, improved over a million and a half lives, created 5,000 jobs in communities of color using the sum of the measures to understand which communities were experiencing the greatest inequities using that federal policy lever to help HRSA and CDC and that connective lever to make sure that the resources for the response went to those trusted messengers and that those trusted messengers had the data that they needed to drive the response in a way that built trust, that actually closed equity gaps in vaccine-hesitant areas, and turned them from red to green.

Finally, it's to create the enabling tools and supports to transform ourselves in our world. I'll go through a bunch of other slides super-fast because I'm really committed to staying to my 10-minute limit, but that's the story. If you're interested, there is a lovely Milbank paper that shares about the process. This process is still ongoing. So, we said it was a living library of measures and a very detailed process with stewardship from Healthy People 2030, OMH, and others is ongoing for Delphi.

Right now, we're updating the measures based on stories and dialogue of what measures of racial justice and intergenerational well-being and equity should we include knowing now what we know that we didn't know back in 2017. And so, a process of identifying, prioritizing, community voting first,

technical validation, and filtering, all of that is in place today. There's a voting process happening right now, even as we speak, that's open.

This frame of well-being of people, well-being of places, and equity of our equity systems, and having nine core measures that could connect them as well as a library of measures - not one set of measures to rule them all, but a library of measures that were from across sectors, across environment, and the economy, and food, and agriculture, and health, all of that together that people could use that included measures that moved in the short term, because some people needed that, and measures that moved in the long term, because some people needed that.

It was really a measure set that was developed in that way. And for those of you who have been aware of the Vital Conditions Framework - which came out of another part of our work in the WIN Network, as communities defined what social determinants meant to them in a way that centered things like belonging and civic muscle - this framework has been mapped to that vital condition group and is alive and well with data that's available to communities.

Again, we have now a strategic network that's working to not just have measures, but to move the measures. What does it mean to move outcomes? And as they're doing that in places like North Carolina, people are connecting food and health and wealth to not just change the racial wealth gap and the generational farmer gap, but to take food as medicine to be a restorative investment in black and tribal and other farmers, and to do that in a way that faith communities are engaging their communities to eat better food in a way that's already improved chronic disease outcomes.

This is a springboard for equitable recovery and resilience requested of the WIN Network by CDC and FEMA that then became the subject of the federal plan. You'll notice there is a measurement learning and evaluation piece that really drew from the measurement cooperative that was birthed out of this.

This is an example of data availability that is there in real time for communities. At this point, communities have co-invested in being the largest collection of data. And in the context of the pandemic, we were able to show that resources weren't going in the right direction and build a recovery effort that was brought together an unprecedented collaboration of black, indigenous, Latinx, migrant worker, older adult facing an unprecedented collaboration to move the needle to improve health outcomes in over 500 communities across the country with real time data systems informed by measures that are simple and easy to use.

In the state of Delaware, that meant they could see in real time the increase in the percent of people suffering and struggling, ask why they were struggling and suffering, connect them to resources for people with mental health and addictions. And if you see on the right-hand side, they could actually watch as a percent of people's suffering went down. And I don't know about you, but if you have a measure, like are more people suffering and fewer people struggling, are more people thriving? That's pretty simple and easy. And measures like that, that correlate with morbidity, mortality, cost, and others have now been integrated into some of the other frameworks, thanks to the work of this amazing panel of literally thousands of people that are using this frameworks and tools.

I'm just going to end with this quote that I find really inspiring from Maya Angelou, "My mission in life is not merely to survive, but to thrive and to do so with some passion, some compassion, some humor, and some style".

Our measurement systems have often been deficit focused. And as we've partnered with communities, they've helped us learn how to build measures that are of our thriving, of our connectivity, of our community, and the assets we bring. And I just want to thank Rebecca Hines and the entire NCVHS committee for helping to spark a journey that I could never have imagined would take me here and has been one of the most meaningful.

R. Lenel James: Thank you, Somava. That was fantastic. Meagan?

Meagan Khau: There we go. While we're pulling that up, good afternoon, I'm Meagan Khau. I am the director for the data analytics research group within the CMS Office of Minority Health.

The first several slides here are just for background, but I've heard CMS throughout the whole morning, so you all know who we are. Our office is actually one of the eight offices of minority health across the department. And as you know, we monitor and manage the Medicaid and CHIP, Medicare, and Marketplace programs. So, our office coordinates health equity data collection, especially from a demographic side in SDOH across agencies. So, I'm just going to highlight some of the initiatives that we've been working on that drive our data improvement projects.

We have two frameworks that focus on a variety of initiatives to improve health equity for underserved populations. And each of the frameworks includes a priority on improving the standardization and collection of information. And so, we've been working to achieve the goals that are outlined in the two frameworks.

We also released a white paper, The Path Forward: Improving Data to Advance Health Equity in the fall of 2022, as a guideline for us identifying what are some of the gaps that CMS have on the data collection and what are some of the initiatives we work on to improve it. Because prior to us releasing this paper, everybody else was releasing a paper about CMS data. So, we figure, well, we'll do one on our own.

Then here's the Executive 13985, as a lot of you are aware of, recommending us assessing equity as well as collecting disaggregated data. And so, the different initiatives that CMS has been working on, the first one here, which is now outdated, we were collecting data at the OMB 97 standard, but there is a need to collect disaggregated data. So, we went to collect the 2011 data standards where possible. Unfortunately, we're a little bit all over the place, but in the last few years, we have tried to improve our data collection to collect the data at the disaggregated level as much as possible.

However, the challenge here - and I know as the rest of the Panelists continue the conversation - that we're going towards EHR interoperability. The issue - not really an issue, but something to be aware of is that we are collecting data from senior citizens, from individuals who don't speak English well, low-income families on paper format. So, we can't work with 900 categories that are used in the operability perspective, the EHR, but we want to gather enough information so that we can target interventions for the specific population.

Throughout the years, we have done a couple of initiatives, for example, (inaudible) models starting January 2023 that we are collecting race and ethnicity at the U.S. CDI standards. Where we can align, we definitely will align.

Our post-acute care settings, so four of the settings, we have started to collect data in October of 2022, and the last one implemented October of last year. Race and ethnicity in long-term care and inpatient rehab facilities, home health agency, and skilled nursing facility. Recently, we started to collect race and

ethnicity on our enrollment form for the Part C and D, but these are only individuals who are newly enrolled or switched plans, so they're limited in terms of what our sample size is. And then, of course, we have a number of surveys, instruments that we're collecting data from the participants. Our goal is to collect self-reported data as much as possible.

Here, as we mentioned earlier, the recently revised OMB standards, so just highlighting that now we're going to work towards trying to align our data collection with the new standards, which is more in the disaggregated level. One of the challenges we'll have to work with is the write-in because with write-in, we may run into small sample size. Therefore, we can't release information from a data analytics perspective. And so, will that mask any of the smaller underserved communities? Then, combining into the one question. The good part is we have the Middle Eastern and North African, which we've been getting questions on.

The other initiative for us in collecting demographic data is to collect sexual orientation and gender identity. So, I'm very happy to highlight that our marketplace application was the first to collect the data. And of course, standards continue to evolve, so we'll definitely continue to update this, but we feel it's important for us to collect race, ethnicity, SOGI data.

To Somava's point, we're collecting all these measures, but if you can't stratify the measures and identify the specific groups that are impacted, it's going to be a little more challenging to work towards intervention.

We are also working on a number of initiatives to collect SDOH data as well. So, as of recently, we submitted a new SDOH data to look at, do you need or want an interpreter to communicate with a doctor or healthcare staff? We feel like there is a lack in there, and we actually made it to the draft comment, which is, I think, due April 15th. So, if anyone feels that's an important question, please write in your comment to support us.

Then, on the post-acute care settings that I mentioned earlier, we have started to collect preferred language, need for interpreter, health literacy, social isolation, and transportations. And we'll be adding more as we continue to evaluate. Then, of course, our models have been starting to collect SDOH data based on the U.S. CDI standards as well.

Additionally, from SDOH measures, we also added two measures, screening for social drivers of health, as well as screen positive rate for those social drivers of health that we screen for. So, this went into effect in our fiscal year 2023 rule. So, for 2023 calendar year, it's voluntary, but for this 2024 year, it is mandatory to report. And then, it will be effective for the fiscal year 26 for payment determination. And in this small print at the bottom, this will be applied to ESRD Quality Incentive Program, Inpatient Psychiatric Facility Quality Reporting Program, and the PPS-Exempt Cancer Hospital Quality Reporting.

With all the data we collect - and as you all know, we collect a lot of data - we would also like to offer opportunities for researchers in external parties to use the data in addition to CMS. So, I am aware that there was a GAO report not too long ago, regarding having the tribal epidemiology centers getting access to CMS data. So, last year, we launched a brand new one-year pilot program for the techs to get access to CMS data. We actually pay for them, for the seats, which costs approximately $30,000 to $35,000 per seat per year.

I want to say about 9 of the techs signed up about 12 individuals. This is our first time. We have to go through the DUA, and they have to clear the IRB, so we weren't sure what the outcome was going to be, but I think we have a relatively good sample size.

We're hoping that in addition to getting access, we're also providing them technical assistance, peer learning network, helping them go through the DUA, helping them formulate their research questions to better giving them access and determine whether CMS data will be helpful for them or not. So, we're hoping that this pilot program will be a success to determine what may happen to it in the near future.

Additionally, we have the Health Equity Data Access Program grant, which we launched the first grant last year with three awardees. We are working on the 2024 fiscal year grant. So, hopefully, we'll be able to send out a NOFO in the next several months. And then the third grant we have is the Minority Research Grant Program, which the NOFO is currently open. The deadline will be June 3, 2024. And the grant is focusing on minority-serving institutes. So, here's the list of the institutions that can apply.

We actually increased it from three to five grants, totaling $1.275 million. So, we're very happy that we have an increase in funding for this as well. And folks have been applying. We've got really good research projects, and we post that on our website. We also highlight it. We have a CMS Health Equity Conference at the end of May, currently open for registration May 29th and 30th in Podesta. And so, we'll be highlighting a lot of the equity work. Lastly, here is our website and contact information if you're interested in any of our work. So, thank you very much.

R. Lenel James: Thank you very much, Meagan. And I think I'll turn it over to you, Jamie, to see if you have any questions.

Jamie Ferguson: Thank you. So, I think the first question I wanted to ask, and this is about the WIN Network. Do the measures use only data that already exists or are they available in high quality? Or how do you get additional data that's desired by the measure developers?

Somava Saha: That's a terrific question. So, yes, we definitely looked at where there is availability of standard, well-collected, well-sampled data, and we make sure that communities can easily access those during visualizations but in addition to that, we do two things.

One is we make it easy for people to collect their own data and teach them how to do that and build tools to make it easy. For rural areas, as many of our secondary measures are data deserts. There's just not enough collected in our federal collection systems for that to be available. So, giving them the ability to do that, especially people reported outcome measures that are really powerful, has been really powerful.

The second thing we do is we have a community data equity group. So, they inform what measures matter the most. So, things like Cantrell's Ladder and others, we actually collectively put out a survey collection of that. I think right now the WIN Network has the largest collection of well-being data in the nation. And then, of course, because many of these networks for groups serving migrant workers and others, collected that data through trusted messengers, we probably have some data sets that are really unusual and special because who people respond to and how they respond has a lot to do with whether they trust the asker. And so, this has been a rich resource.

So, we take that data and turn it back to communities to have access to those priority measures like well-being, trust, belonging, social connection, experiences of discrimination, things like that that

they've prioritized and say they need in order to drive their responses, along with what social needs might be creating an issue.

R. Lenel James: Thank you. For the sake of time, we're going to move to our second group, which would be Vanessa, Prerana, and Rachel. So, Vanessa, the floor is yours.

Vanessa Candelora: Great. Thank you, Lenel. Thank you for the honor to present today. I'm happy to be here. I'm Vanessa Candelora. I'm a senior consultant with Point of Care Partners and the program manager for the Gravity Project. So, today, I'll share a little bit about the Gravity Project, including what it is, why it's important, how it's being used, and opportunities and challenges we see in our community.

The Gravity Project is a multi-stakeholder collaborative that develops consensus-based, data-driven standards to support the collection, use, and exchange of data to address social determinants of health. It's hard to talk about our work without talking about who is behind it because of this collaboration.

So, these sponsors, members, and partner organizations have all come together to support the project both financially and with in-kind resources and subject matter experts as industry leaders to really collaborate on solving some of these big problems in health and social care. And so, a special thanks to ONC and CMS for your support as well.

Additionally, we have a diverse community that is public that is close to 3,000 participants over time, and they are experts, implementers, contributors. So, this should look familiar. It comes from the U.S. HHS Strategic Approach to Addressing SDOH to Advance Health Equity, and where Gravity really plays a key role is supporting the goals for that midstream of the picture. So, the leaders and adopters of Gravity work, including many on this panel today, understand and recognize the gap in standards to support health-related social needs.

In the interest of time, I'm not going to go through this timeline in too much detail, but will summarize a few things. So, this is how we're moving the needle, what we're doing now, what's to come. And the Gravity Project is in its seventh year, and on the top of this timeline, you can see Gravity's success having introduced a nationally recognized set of open data standards-based terminologies to support care across 19 social domains, with three more coming this year and a four-year roadmap for more with support from the Regenstreif Institute.

On the bottom, you see that Gravity started as a multi-stakeholder collaborative in 2018. We became an HL7 FHIR accelerator in 2019 and quickly developed a foundational implementation guide leveraging FHIR, where it made sense, across social risk domains for activities such as screening instruments, health concerns or problems, goals that are patient-centric, interventions including a closed-loop referral. We also touch on consent, aggregation for exchange and reporting, patient-client applications, and draft specifications for personal characteristics such as race and ethnicity exchange for SDOH. Now the IG, implementation guide, is a standard for trial use version 2.1, and we're iterating with additional workflows and use cases that are in discovery now by members.

How are we doing this and why is it successful? The short answer is we have a trusted evidence-based process to develop open-source consensus-driven standards that bring subject matter experts and lived experience together across the ecosystem.

We aren't just creating a standard, but we're actually integrating it into existing coding and standards for easier widespread implementation and adoption across EHRs and others. So, as you may hear from

some of the other panelists today, Gravity is recognized and trusted as a well-established leader in part because of this curation process.

Here is a snapshot to illustrate how the coded data concepts are represented in real practice today. So, this is an example of food insecurity, encoding questions and answers for LOINC, leveraging SNOMED for observations and ICD-10 CMZ codes for diagnosis, which we're grateful for the CMS expansion and infographics on, and goal setting from a patient-centered perspective as Somava was pointing out earlier is really important, and the interventions are primarily in SNOMED.

Because of our trusted evidence-based process for value set curation, most national SDOH quality measures, programs, and regulations reference Gravity value sets as a base for compliance. Gravity develops data standards set forth by the CMS framework for health equity. Gravity data elements are incorporated into USCDI starting at version 2. We were named in the White House-U.S. playbook to address social determinants of health last November and in ONC's HTAI-1 final rule. Gravity has created the evidence-based value sets that NCQA references in its social determinants of health equity measurement approach as well.

Adoption is really key to success, so standards, policy, and implementation need to work together while meeting the ecosystem of health and social care where it is. Please continue to support national standards adoption through federal and state incentives and mandates as appropriate while recognizing that this data flow need extends beyond covered entities and credentialed providers and into many organizations that may lack investment in infrastructure or technology with a myriad of reasons why.

Understanding the critical need for equitable and ethical use of this data is really essential to any policy or mandate. In Gravity, we advocate that, the data use principles for equitable health and social care you see here are built into every initiative to promote trust and accountability among care providers, patients, their communities, and the institutions that serve them. So, overarching interdependent concepts include improving personal health outcomes, improving population health equity, ensuring personal control, designing appropriate solutions, ensuring accountability, preventing, reducing, and remediating harm.

Gravity in action, there is where we're meeting the road here. While the open standards process driving industry-leading discussions and change and collaboration is very important, again, it's really great to put those to real-world use. So, we recognize that everyone's in a different place in their journey. We've got a lot of people, phone, fax, paper, very manual processes today, or they may already have a FHIR server and be advanced.

We applied a tiered model approach to pilots over the last two years, meeting organizations where they are in that journey. So, in 2023 and prior, the Gravity Project was given support and partnered to run formal pilot sites. In 2023, we did four of them with Civitas Networks for Health with support from Robert Wood Johnson Foundation, and it included the ones listed here, including Pima County Department of Public Health and a Southwest tribe in Pima County, Arizona, as well as the most extensive one that continues on being New York statewide implementation of the Gravity SGHID and aligned Gravity terminologies with whom we continue technical assistance this year.

The six New York State certified health information exchanges, also known as QEs or qualified entities, are collaborating to implement statewide standards for the ingestion and handling of social risk data, and it's part of their strategy for a now approved Medicaid 1115 waiver that Gravity supports. We hope

this will set the stage for other states to leverage Gravity data terminology and FHIR standards and enable national interoperability as they address health-related social needs through a variety of Medicaid authorities.

Lastly, what's next? So, in 2023, we stepped back and said, hey, members, are we done? What else needs to happen? Where are the challenges? Where are the opportunities? With the strategic goals refresh in addition to a priority to drive awareness and adoption for the use of standards, another key focus was support for our diverse community and community-based organizations. And so, after a targeted effort with partners to solicit information, this visual illustrates that there is a lot more work to be done to support social care and CBOs.

There are opportunities for national standards to be developed or leveraged to effectively address needs at individual and population community levels, as well as tackling challenges in data representation and exchange for families, households, tribal connections, which has been a recent topic, reducing burden and improving sustainability for CBOs, portalitis, and asking for clinical diagnosis to CBOs when they're not really credentialed to give that information, things like that, evaluating inequities to facilitate structural solutions, expanding data support for use cases, as seen here, to center whole person care, and to further the capacity for intelligent social care navigation.

Social care has been around for a long time.

It has its own model. Social care and CBOs need access to the right data to be a part of that care team, and they don't always fit into our existing model. So, it's not really as simple as applying our healthcare model to them.

In summary, there is more work to be done to create a world where health and social care organizations readily share the information needed to effectively meet the social needs of individuals and advance health equity and improve health outcomes in communities. Thank you so much for the opportunity.

R. Lenel James: Thank you, Vanessa. So, Prerana, from EPIC, batter up.

Prerana Laddha: Good afternoon, folks. My name is Prerana Laddha, and today I'm representing the trade association of EHRA. I'm also the Director for Social Care and Behavioral Health at EPIC Systems. EHRA is a trade association that comprises of 29 electronic health record companies nationwide, and they also serve a vast majority of hospitals, post-acute care, ambulatory facilities across the nation. The primary goal of the trade association is to provide quality care to the patients by using safe and confidential technology.

Here are the different members who are part of the EHRA trade association today. And the trade association also has a social determinants of health and health equity task force. And the primary goal of this task force is to identify the barriers to delivering equitable care, helping and aiding the industry in prioritizing it, and also exploring ways in which technology can be used to address these disparities in health care.

In today's discussion, I will cover three main areas, firstly, starting with the documentation standards of social determinants in the electronic health record, and then interoperability, so we can exchange this data with other systems in a meaningful way, and then surfacing the data at the population level to support research and analytics.

Diving into the documentation standards first, in the last decade, we've seen a significant increase in the number of health systems who want to document social determinants for their patients, and they also want to address these needs for their patients. And this heightened search can be attributed to more awareness of the impact of social drivers on health outcomes and also updated policies that are reflecting the same understanding.

In clinical visits today, providers document these social needs assessments and help patients with the interventions that are needed to address these. And this documentation and assessments are not limited to roles like social workers or care managers anymore, it is a shared responsibility across all providers in all care settings, ranging from emergency departments to primary care.

Now, while it is evident that documenting these social determinants in electronic health records is important and meaningful, there are some challenges in implementing these practices within EHRs. The first and foremost, I'd like to talk about the additional time that it takes to document these assessments in the clinical visits.

Now, it's a 15-minute short clinical visit, and health systems are already grappling with provider burnout and staffing shortages, and then requiring them to add additional assessments during these visits can feel burdensome. And this is where technology can help. There are ways in which technology can integrate these assessments within existing clinical workflows, so it doesn't feel like an extra step or an extra burden for those assessments.

We can also make it accessible across different care settings when health and social data is shown to providers together in a meaningful way, and interventions can be prompted within their workflows, then there is value to documenting that data. And when providers can see that value, it encourages them to document the information. And then, like Meagan mentioned, technology can also make resources available to patients and families to self-report social determinants, so this information is readily available for providers during the visits.

Then lastly, I cannot skip AI here. Lots of data stats show that more than 50 percent of social information is already documented in clinical notes. So, we can leverage AI to extract that information so we can save some of that provider time in discreetly documenting the assessments.

Then moving on to the different standards that are available today in informing which domains should the patients be screened for. While there is general consensus that patients should be screened across different domains to get a full picture of their situation, there is a lack of consensus in which domains should be prioritized across the care settings. Now we have lots of standards available across the board, and Gravity has done some work in classifying and encoding these domains. And as you mentioned, there are 19 different domains and three more in the making.

However, this is where standardization of some of those domains and what to screen in individual care settings will be extremely helpful. So, the data that is being captured has uniformity and it can be surfaced at the population level in a more standard way. In addition to that, when newer regulations come in for the screening, providing more time for small and big EHRs to implement these regulations in a consistent way can also go a long way to capture meaningful data.

Then the last one I want to talk about in this section is I've heard many providers tell me, well, I hesitate to screen my patients if I don't know how to help them when they screen positive. And there are a number of interventions available in this space ranging from providing education material, connecting

with community providers, and technology can help in surfacing this list of interventions to the providers easily, promptly. We can also automate some of that.

However, there is a need to standardize some of these initiatives, fund and engage community partners more on an ongoing basis. So, when that referral is made out to the community partner, there is a warm and a trusted handoff.

We're also working with Gravity to have a standard terminology for the interventions that are provided for the patients so this data can be exchanged in a more meaningful way with other systems.

And then finally, closed loop referrals, which means when the health systems and community partners can electronically exchange data, they can talk to each other. That will not only help them stay engaged, but also it will help them understand if the patient actually got the help that they were looking for. And having FHIR standards to have this type of closed loop referrals between the systems can also be very meaningful.

Then moving on to interoperability, a patient and people in the community go to different systems using different EHRs or other software to get care in this space. And as the person moves, we want to be able to move the data with them so there is less need for duplicate documentation and asking the same questions over and over again. And this is where I think we have some standards in the industry today where there are code sets available, USCDI version 2 and beyond have data elements included to exchange this information and Gravity again has helped map some of these code sets to nationally available instruments for assessments.

But having said that, again, there are regulatory programs at national and state level that might use screeners where we don't have those code set mapping readily available. There is verbiage in these assessments that deviate from the LOINC code mappings. And then there is no standard mapping between the screeners and the domains either, which makes it hard when we talk about interoperability to say this particular screener represents this domain.

There is a little bit of mapping happening within individual systems to make that. Now, as EHR developers, there isn't a screener that we endorse or promote, but at the minimum, an EHR should be able to say, indicate which domain was the patient screened for. Maybe use Z codes or LOINC codes to represent the domain that the patient is screened for and also specify if the risk was present or absent in a more standard way.

In addition to that, being able to indicate what the measurement or instrument for assessment was used, and we have some of the national standards for that as well, such as PREPARE. And finally, diving into research and analytics, technology can be really powerful in surfacing all of this data that is documented at the population level and make it available for research and analytics. We've heard a lot of research and analytics attempts that have been made and a lot of meaningful data that comes out of this.

Technology can surface this in many different variations. The data can be used to surface screening rates, positivity rates, understanding geographically if there are trends in specific domains such as housing and transportation, understanding the impact of social determinants on health outcomes. I know there are studies out there for diabetic patients to understand how their A1C changes or how their health outcome changes if they have a lack of access to transportation.

And then augmenting the social determinants of data with public data sets such as area deprivation index and social vulnerability index to identify the most vulnerable population and then have strategic initiatives and targeted interventions. And then finally, stratifying by race, ethnicity, language, and more data that is available to promote health equity in this phase, being able to identify if there is a certain population that needs more targeted interventions. And then finally, I will wrap up by saying that capturing this data in a more standardized and uniform way will amplify the power of analytics and all the initiatives that different stakeholders, not only on this panel but across the board, are taking in this phase.

And it will accelerate all of our efforts to address disparities.

R. Lenel James: Thank you very much. And then next, Rachel, giving us a perspective from NCQA.

Rachel Harrington: Great. Thank you so much, everybody. Hello.

While this is getting up, I'm Rachel Harrington. I'm the Senior Research Scientist for Health Equity at the National Committee for Quality Assurance. And I am in a very enviable position right now because I get to build on the work and the expertise and the insights of the Panelists before me.

NCQA, for those who may be less familiar or haven't come across us, is a national quality organization. We develop measures, standards, implement programs, and also conduct supporting research to really ensure that everybody has access to high-quality care. And for us, high-quality care is equitable care.

You can't have one without the other. You can't call something high-quality if it's not equitable. So, I like to joke a little bit.

I am a health services quality researcher by training. I became an informaticist when I joined NCQA, or at least an armchair informaticist, because none of this work is possible without the data standards, the standardization of data, addressing some of these questions in practice on the ground. As much as organizations and systems want to transform here, their ability to do so is fundamentally limited by the data infrastructures that they're working with.

So, just to start off, and I probably don't need to convince anybody here, but I do find it very telling. This was a study that looked at unmet social needs by payer type. It's from a couple of years ago now.

But the point that I the key takeaway here is not to assume that unmet social needs are limited to any specific population, payer, or policy realm. Individuals who are funded or receive services under commercial payers, 48 percent of overall population reports unmet social needs. 44 percent of members with group commercial insurance report unmet social needs.

So, the structures and the solutions that we have put in place are really at the system level. Targeting in on particular payer populations isn't going to get us where we ideally want to be. And I think our healthcare system is recognizing that, and it's interesting working in the quality space in the policy environment that we're in right now.

You see acknowledgment of our public funders on the screen, but Medicaid, this is a little bit outdated now, but as of 2021, I think 33 states had some SQH-related requirement. 24 states, it's more than that now, require screening for social needs. The only 11 at the time of this review, which is a couple of years old, require the use of a uniform screening tool.

And that's contributing to this environment that was just alluded to around the heterogeneity that's coming in the policy space and how that's feeding into our data environment. This is a very common theme of the 1115 Medicaid waivers, as we just heard for New York and for many others. In Medicare, the Chronic Care Act expanded the ability of Medicare Advantage plans to pay for supplemental benefits addressing unmet social needs.

So, we have actual federal dollars now going to meeting these needs. And plans are picking up on that. As of 2022, Part C plans, 68 percent offered meal benefits, 39 percent offered transportation, 30 percent offered nutrition, 11 percent offered in-home support.

So, resources are flowing here as well. And so, where resources and services flow, we want to make sure that the care that's being delivered is high quality, is equitable, and is actually impacting outcomes, which is where the quality measurement efforts come in. And CMS, acknowledging this, has actually included measures for social needs screening in their universal foundation.

Of the 20-some, I want to say, measures that are in the universal foundation, one of those is reserved for social needs screening. And they acknowledge, when they publish the foundation, that they want to get to not just screening, but intervention as well. So, for me, coming at this as somebody who has spent a large chunk of my life framing research questions and wrangling with research questions vis-a-vis data, it really forces us to reckon with the fact that the priorities that we're setting, which we just saw policy, we just saw payment, what's happening there, that determines the questions we want to ask.

The questions that we actually ask determine the data that we need, and the data that we have determine the questions we can actually answer. And so, when you trace through that, and you think about what we're putting into place in this environment around social needs, we might want to look at, are these needs being met? Were outcomes improved?

But if the data that we have is just on a third-degree artifact of screening occurring at some point in time in the last six months, are we actually able to answer that question? And I think what all of our organizations are trying to do is really evolve that data environment so we can ask the questions that we want to ask, and on our end, we can measure the outcomes that we want to measure. So, what as a quality measurement, quality accountability organization, what are the levers that we see here?

First and foremost, incentivizing the collection and management of data using best practice terminology. We have a couple of ways at NCQA that we see of doing that. One is through accreditation or structural standards.

These are the systems that you have to have in place that you are surveyed as saying, yes, we have this process, we have this interoperability, we have these policies. We can also use quality measures directly to look at that. We have metrics of data completeness or data source or so on, and we can also score organizations on data maturity.

And by that, I mean we frequently think of quality outcomes as your clinical outcomes, right? Your A1C or did you have your colorectal cancer screening? But if we say, our data is integral to quality, we can measure, are you doing the screening?

Are you collecting it in standardized terminology? Are you collecting it through self-report, which is something we've been focusing on demographics around race and ethnicity data. You have this, but do you know it came from the members at high quality data?

The other opportunity that we have here to really promote standardized terminology and data is through how we define our quality targets, our measure numerators, our measure denominators, our targets in our populations. This can be done through how we define our measures of social needs. Are we being specific in terms of the terminology that we're using there?

Are we using the LOINC and the SNOMED codes that Gravity is putting out? Revising our measure population definitions, are we measuring these outcomes in a clinically nuanced way that more standardized data gets us to? For us, this has really been important when looking at gender-affirming care.

If we're measuring cervical cancer screening, are we measuring it in all populations who are recommended for routine cervical cancer screening, not on some variable that may or may not represent sex or gender or some other construct out there in the field? Then, stratification is the other big one. Can we look at differences in outcomes, again, using standardized terminology?

To show a little example of how we've been looking at this at NCQA, and Vanessa alluded to this and others in our measurement space, we have constructed a measure of social needs screening and intervention. You can see the spec on the screen here. I'm not going to go through it all in detail.

It focuses on food, housing, and transportation. It has a set of indicators for screening and a set of indicators for intervention. Critically, it's using clinical data systems for the measurement purposes here.

We've already talked about Gravity. It's really been foundational to our ability to execute on this work. This is an example of the flow from a structured screening tool to the screening question to the positive finding to the related intervention using the Lincoln SNOMED terminology.

How we operationalize this? In our measure, our screening indicator, the numerator, members with one or more documented results, positive or negative, on a screening instrument. The denominator is a broad population denominator, something you would see akin to a population health measure.

All members continuously enrolled who don't meet specific exclusion criteria. We also focus on specific instruments here, and this has pros and cons. The pros are you get very specific measurement.

These instruments have different timeframes associated with them. They ask slightly different nuances, for example, on the food questionnaires. Is it family related?

Is it person related? When you use the standardized terminology, you can really understand exactly what the question was and what need was identified. The problem, of course, comes in that we know for many communities, you might need to tailor that, or a state program might have a screener that takes a couple of things from different instruments and adds another question in specific to them.

How do we keep this goal of precision and standardized terminology, recognizing that the world is neither standardized nor precise in many cases? On the intervention side, this one, I think, has been interesting. As far as I'm aware, we are currently the only measure that has an intervention indicator.

It's been tricky to get traction for this in the field because we've got the standard terminology to do that. We look at who had a positive screen. We can do that off the screeners and responses as the denominator, and then the numerator, who received a corresponding intervention.

Our measure looks within 30 days for the positive screen. There are a set of, here, there are the eight Gravity Project-defined intervention categories. What we frequently hear when we discuss this with stakeholders in the field is, first, the interventions can seem very nonspecific.

Trying to understand, did somebody receive the right intervention, is still quite challenging. Also, until our clinical referral loop processes are in place, understanding if a clinician wants to check, oh, did my patient receive the intervention I referred them to? It's still really tough to do that, and that's a barrier to the action side.

We've been doing a lot of work trying to understand the facilitators and barriers in the field on this. Here, you see a sample that just came from a recent set of qualitative interviews we did with health plan organizations across the country. In many cases, we heard screening was being documented actually in health plans.

We're not talking clinician-clinic level, but by the plans themselves, and they have it in their case management data. Not necessarily in their claims traditional quality, but it's in case management. The follow-up was in many cases being done, but they weren't documenting it, at least not in any of the same systems in which the screening was documented.

A facilitator was the more policy makers, the more states, the more quality organizations that put these measures into place, the more easy it is to build the infrastructure. Barriers, mapping, multiple data sources, trying to map to the LOINC codes, trying to make that work, pulling from EHR, and then the variety of state requirements that we've heard about. In the interest of time, I'm not going to spend too much on the standards piece, but we are working on the structural side to try and build the infrastructure for both standardized data collection and exchange.

I do want to point to some work we recently published around cross-sector partnerships, how healthcare organizations and community-based organizations are partnering in this space. We did a series of interviews and focus groups with both types of organizations independently, and both identified data sharing and interoperability as critical for equitable, sustainable partnerships. That's where I'll wrap up.

This also applies to things like sociodemographic, race, ethnicity, gender, many of the same considerations will apply. With that, I will pass it on.

R. Lenel James: Thank you, Rachel. For the sake of time, I think Jamie and I just have one question each. Vanessa, I'm going to hit a softball to you, and Megan, you may want to weigh in.

Your choice. One of the challenges is I heard about the SDOH. What about disability?

Where does that fit in, in the context of both housing and also mobility to travel to an appointment? Where does disability fit as you've seen it so far in Gravity, if at all?

Vanessa Candelora: Thanks, Linnell. That's a really good question. Actually, Rachel was just pointing out the specificity of the interventions.

If somebody has a transportation need to get to an upcoming medical appointment, but they have a disability, it's going to be a very different intervention. If they are calling an Uber or Lyft, that might not

work. If they need help getting out of their house, getting into the car, and the same thing on the other end to get to their appointment and back.

That level of specificity is something that we talk a lot about in Gravity.

Meagan Khau: It is a perfect question because the last several months, there has been a lot of discussion around disability data. The challenge we have, like the Medicare, we have the OREC, Medicaid, and the marketplaces of the other. We use the 2011 HHS data set or six questions, and then there is the ICD-10 codes, and none of them really map to each other.

We are exploring in terms of how we can do better in recognizing the disability population. It's a one end of the spectrum to the other. We are working on it.

Jamie Ferguson: Thank you. Jamie? Thank you all very much.

I have a question that possibly multiple or any of you might want to address. It's a question about the sources of variation in data requirements versus opportunities to impose some greater consistency. Vanessa, you talked about how Gravity engages with states and state-based programs.

We know from our experience that states can have very different approaches and can specify different detailed data requirements. This is a federal advisory committee, and we have potential opportunities to consider providing advice about federal standardization that might be able to mitigate or overcome some of those sources of variation. I don't want to use the word standardization, but greater consistency in the standards that are required to meet the measures that people want to use.

Vanessa Candelora: Say, that was excellently said. Sorry, you're good at this. Great question.

When we talk about Gravity, we really are focused on national standards. For example, there was a lot of discussion about all the different screening instruments and tools out there. I come from a product private sector world where we think in minimum viable product, what's the lowest common denominator of all those things that can be considered a national standard, recognizing that there is always going to be some variability that's community-specific, state-specific, at those really detailed levels that can be built upon that standard.

Meagan Khau: This may already be in the work, but to the extent where OMB releases their standards, if we can have similar standards as a baseline for the demographic data elements that are included in the executive orders, it'll be great for us to have something to start from. I know disability, that would be fantastic.

Somava Saha: I just add, I think we don't spend a lot of time actually assessing what people are valuing in choosing what we value and put things behind. That means that those who have more access or are really smart in getting away, and just to be clear, everybody who's on this panel is doing amazing work in this area and the ability to make things be in the path is important. But we don't often ask what actually matters first and what are people finding valuable to drive what we choose to measure.

And I think when you think about this committee and the recommendations it makes, our ability to have a measurement system that can learn in real time what's valued and uses that to inform what the federal government measures, there is no feedback loop around that right now. And I think we might need one if we're going to be serious about improving population and community health.

R. Lenel James: Thank you. Well said. And let's move on to our last group, which would be Julia Skapik and Naisha Timidi. So, Julia, you're up.

Julia Skapik: Hi, Julia Skapik. I'm the CMAO at the National Association of Community Health Centers.

I wanted to talk today about the very last step in this process, which is getting standards and content deployed in settings where they're really needed. I do have a disclosure. I'm the volunteer board chair of Health Level Seven International, which is the international standard development body that the Gravity Project sits under.

So, I'm a big fan. So, I wanted to say a few words about community health centers before we get started. The community health center movement was started during the civil rights movement because of chronic problems in disparate health care access for people who are minority and in poor populations, the lack of organizations that provided care in those settings, including rural settings, and ongoing discrimination in both health care professionals and health care organizations and directed towards patients. Health centers have five essential elements. They have to be located in high-need areas.

They provide comprehensive health and wraparound services. And the reason I really want to drive this point home is this term enabling services has been around in the health center space for five plus decades, and enabling services are these social interventions that we're talking about. So, if we think about who's really the sneeze in the health care world, I think it's community health centers.

They've been measuring these things and doing things about them for over 50 years. So, I think it's really important to have their voices in the room when we're having these conversations. And they have learned a great deal, and they're happy to share that information.

Health centers are open to everyone regardless of their ability to pay, so you don't need insurance. They use a sliding scale. They're also patient centered.

They're governed more than 50 percent by members of the community. So, the organization is driven by people who are truly invested and understand what the needs of that community are. They also have performance requirements, which includes reporting to HRSA, the uniform data set.

The uniform data set I'll mention in a minute already includes national reporting of SDOH needs in health centers. Community health centers are in every state, every U.S. territory. They're rural.

They're urban. There's over 1,487 of them now, and they serve people in the most underserved communities. Last year, that was over 31 and a half million patients.

NAC estimates, though, that that need is about three times greater than the volume we currently serve. A high concentration of people with SDOH needs have to seek care at community health centers. So, I wanted to say a few things about this last mile problem, and we can talk a lot about the theoretical way that standards get down to the ground, but in fact, there are a number of barriers to the successful use of standards in the field, and I want to be very clear that I'm not here to say anything bad about all of my colleagues all over the rest of the industry.

They are working hard and doing their best to help support users. That being said, the EHRs we have weren't built on open source standards. They were built on proprietary systems, and that remains the fundamental property of the EHR on the back end.

That means that implementing standards in the EHR is an extra step, and for many organizations, particularly community health centers, I've never met a community health center that has a terminologist, but terminology is not a foundational supported element in electronic health records. There are additional systems you can go, and they can help you to do good terminology work, but functionally, I've seen many health centers just have a person who stumbles through the process without the knowledge or expertise of doing this mapping, and a lot of people have mentioned mapping, and it is super important because poorly mapped data is low quality data. Low quality data doesn't tell us useful things about our practice.

It also doesn't help to support the care team in knowing where care gaps are and to close them, and a lack of harmonization in all of the series of requirements that organizations on the ground have to go through adds no value in my mind to the point of care, right? So, if you take a bunch of resources and have people go and re-enter data into reporting systems and have to spend time picking through and mapping and pulling things out of the system, those are resources we're sucking away from helping the patient and putting into administrative tasks that aren't really adding a lot to us, and every time those standards don't align to Jamie's question, that actually takes away from our focus on the patient. So, I think it's really important that we think about where can we enforce these requirements for standardization, harmonization, and make these things like maps available to the people who are implementing these systems?

I'm going to talk about dashboarding later on, but the last thing I want to really hammer on for a second is despite the massive volume of data that's theoretically being exchanged in healthcare and the massive volume of data that's being stored, virtually none of it is being looked at.

Someone at HITECH this morning said 97 percent of healthcare data is never accessed, but more importantly, if I get that information, it contributes to data overload, and the system does not help me to filter and display the data in a meaningful way. Plus, if I see the data and I want that to become part of my record, I can't write to that information almost uniformly. So, my only option is actually to re-document that information.

Again, that is a very low value activity. So, again, I'm not here to complain entirely, but I just want to give a few examples. So, this is an example from EHR extracted data during the SARS-CoV-2 pandemic.These are structured lab results. My personal favorite is Begative, which was there a lot of times, not like one time, like a lot of times. These are things that were listed as test results, which are not test results.

The one that's highlighted is clearly a piece of PHI. So, this problem can get bad fast. The problem is not better in SDOH.

It is definitely worse. You think how easy it should be to structure lab information and send it. Now we're talking about something that has a lot of richness to which the patient may want to contribute their own voice, and that is going to be an ongoing challenge.

I put this slide up here because the purpose of FHIR, Fast Healthcare Interoperability Resources, I'm glad it's there because no one defined it, I think, is to make information easily able to be broken up into chunks and sorted by machines and sent to and from machines. And now we have the requirement

since December 31st, 2022, to have an open FHIR API available to certified electronic health records. I bring this up because I know a majority of health centers do not have that.

It's been over a year in some since they're supposed to have access to that. I'll point out that the version of this API is not the version of U.S. CDI that requires you to exchange SDOH data. So, the time it takes to actually implement these standards in the field is actually years.

So, the things we're talking about today, we need to have both urgency and also focus on how do we make those implementation barriers go down. So, it's not 2030 when I get the things that we have right now. I don't think anyone presented the U.S. CDI slide, another thumbs up.

So, U.S. Core Data for Interoperability, this is draft version five. There are a bunch of things pointed to as SDOH. I want to call out the fact that SDOH is not a single data class.

It's actually a bunch of pieces of information from multiple data classes, which relate to social and health outcomes. While I appreciate our ONC colleagues' attempt to push this forward, and while I very much appreciate the Gravity's efforts on this, multiple people pointed out how the lack of clarity on what should be implemented, how it should be mapped, and how the information should be exchanged fundamentally creates just a wall that this data runs into. Because if one machine can't say, oh, this ACH thing is the same as this PREPARE thing, then there is not really interoperability.

So, I mentioned PREPARE. PREPARE is a protocol for responding to and assessing patients' assets, risks, and experiences. And it's been around for decades.

It was developed in community health centers with the Asian American Pacific Community Health Alliance, and it's implemented in every EHR. And it's patient-centered and designed to be used all over the industry. I call out PREPARE in part because if we're going to aggregate data at the population health level, we need high-quality patient-level data, and we need to be able to normalize that.

That's been called out several times. So, our use of harmonizing and normalization techniques on SDH data is really important. I'm going to skip over risk stratification.

If you want to look at our story about a health center who did risk stratification with their patients, they identified high-risk patients as seven-plus social needs. That is just a huge number. I want to mention Z-codes.

I heard them mentioned once. So, Z-codes are billing codes. People have been using them to get SDOH data since before you could get paid for it.

But actually, the reason they were doing that is because it's very difficult to extract information from electronic health records, aside really from billing codes. So, people are using these Z-codes as a workaround so that they can pull this data out and identify these patients. It may not be as rich as you need to actually respond.

There was an excellent point about social interventions. While codes theoretically exist, the workflows to put the code into the record do not. So, we're generally relying on people to remember that there is the opportunity to enter these codes, and we're definitely not learning at the population level what things work because the codes are not granular enough.

I'm going to skip for this. So, the last point I want to make is about health equity. So, one thing we have heard repeatedly from health center staff is that asking someone whether or not they have a social need and doing nothing about it is a source of moral injury for both the patient and the care team member.

We have to create systems that address that and make that possible. So, an equity-first approach means that we have to build all of this in as a foundational requirement to these systems, and that includes dashboarding. If you can't see what's going on with your SUH data, if you don't know which of your patients have health-related social needs, then you'll never do that.

And if health equity measures and care gaps are not part of your KPIs, it's not going to drive your business strategy, it's not going to drive your revenue, and it's not going to drive your patient care. I thought this was an interesting slide on intersectionality of SUH and disability. You can see in the dark red that transgender adults have many times more different types of disability categorizations than people who are not transgender.

So, I'm going to skip that one too. So, I think these are the opportunities, right? We've talked heavily about standardization of data elements, but we also need to standardize templates.

We need to create care plans that support SUH and not just have a little piece of information in there saying, yeah, the patient is unhoused. The interoperability challenges continue. I think if we use machine-to-machine reconciliation and do some of this work at scale and look at harmonizing these requirements, it's going to really help.

EHR support for care teams, I'll just say as a primary care physician at a health center, there is nothing else you can ask me to do. I can't even do the things that I'm already supposed to be doing. So, all of this needs to be part of a system built around the care team and the right person for that expertise.

And finally, someone mentioned patient-generated health data. I think there is tons of data I just should not be entering. A patient can tell me that and it should come straight into the record.

Thank you so much.

R. Lenel James: Fantastic.

Gniesha Dinwiddie: Hi, everyone. I'm Dr. Gniesha Dinwiddie. I am a health scientist at the National Institutes of Health and my IC is the NIMHD.

I'm in the office of the director. I just want to thank the Committee for listening to what I have to say in my quick 10 minutes. And I will try to keep it to 10 minutes because I know we've been here a while.

The ask, when I was invited, I was asked to discuss NIH funded research that is using SDOH data. And so, what I want to do is to talk very briefly about some major NIH-wide initiatives that are either using SDOH data and or are encouraging researchers to collect SDOH data. I also want to talk about NIH investments in SDOH research because NIH is considered one of the, or considered the federal agency focused on biomedical research, but we spend quite a bit of our budget on social determinants of health and supporting those types of activities.

So, I'm going to highlight some research programs and projects and initiatives, and then I'll close by what we're doing in the SDOH space in terms of trying to move the needle forward. I'm not going to go

too much into what the National Institutes of Health is, but we are the nation's leading medical research agency, a part of the federal government. There's 27 institutes and centers.

Of the 27, 24 institutes actually fund research activities. We have the largest clinical center dedicated to clinical research in the world. For NIH, about 80 percent of the budget goes to the extramural communities, meaning that we support over 2,500 university and research institutions.

This represents the distribution of research dollars and projects around the social determinants of health that have been supported by the NIH. The left hand, the graph on the left side shows a trajectory from 2021 all the way up to 2023. You can see that we went from investing $3.4 billion in SDOH research to $4.7 billion in 2023. In terms of the projects, you can also see, and this is represented on the graph on the right hand side, that our projects for SDOH have increased as well. We're projecting for fiscal year 2024 and 2025 that these increases will continue in projects and in funding. I want to talk a little bit about a few specific projects and NIH-wide initiatives that exemplify novel advancements in the social determinants of health.

You may have a little bit of knowledge or much knowledge about some of our data. The first is the Oliver Research Program. This is an innovative research effort where they're attempting to collect data from over a million people or more.

The focus of the All of Us data is to inquire that patients actually give consent to have their EHR records released so that it can be a part of a repository. In this repository, there is also data from multiple different sources, such as surveys that ask questions about healthcare access and quality, different behavioral questions, and most of all, social determinants of health, which is a survey that was most recently added to the All of Us. There's also baseline physical measurements, such as height, weight, waist circumference, and biospecimens, such as blood measures and saliva as well.

I want to talk a little bit about the SDOH survey from All of Us. You'll notice that on the right-hand side are the different domains that are included. So, there is 11 subject matter domains out of 81 questions that ask about the social determinants of health.

This was launched in 2021. The good thing about this is that the sample is very diverse. About 80 percent of the sample are from underrepresented persons in biomedical research.

However, some of the pitfalls that we've experienced is that there is missing data on a lot of the measures that are important for measuring health equity in particular, such as race and ethnicity, age, and socioeconomic status. So, to overcome this, All of Us tried to relaunch the survey again at later dates, but then it was found that later surveys sometimes had fewer responses than initial surveys. So, another large NIH-wide initiative is called the PHENIX.

So, this is consensus measures for phenotypes and exposures. And so, this represents a catalog of recommended measurement protocols across many domains that are encouraged for researchers that receive NIH funding. We do actually have a core collection from the PHENX toolkit that was launched in 2020.

And in this SDOH core collection, there is 16 protocols that are recommended for researchers to structure these protocols as they collect their SDOH data. And on the right-hand side, you can see the particular measures that we encourage researchers to collect that relate to the social determinants. Also, with the PhenX Toolkit, there is about 23 different protocols that measure social determinants on

the individual level, such as education, income, and then there is 14 different protocols that measure social determinants of health on the structural level, such as measures of food insecurity, and residential segregation, and others.

The PhenX toolkit has been relevant for advancing minority health and health disparities research. And there has been much support in terms of using these respective core collection of protocols for social determinants of health. And we're also in the process of trying to convert some of the measures from the PhenX Toolkit, particularly the SDOH measures into our CDEs.

We also have the National COVID Cohort Collaborative, the NC3, which is an example of an electronic health record database for patients that have tested positive or tested in general for COVID-19. And to address data sharing needs, N3C has collected data from electronic health records from 45 health systems across the country on about 3.5 million patients, and there is a proportion that have been diagnosed with COVID-19. I want to talk a little bit about a major initiative that received a lot of support at the NIH, and this is addressing the impact of structural racism and discrimination on minority health and health disparities.

There were 38 awards funded by 14 institutes and centers in fiscal year 2022, and NIH pledged $125 million over five years. This initiative is important because for the particular research projects that are collecting data, they're very much focusing on looking at how they're going to impact structural interventions that have implications for health disparities. And so, this has been an instrumental initiative because it's been very relevant for SDOH because it has addressed institutional racism, neighborhood community context, and important domains of influence that are instrumental in the social determinants of health.

I want to speak briefly about COMPASS, and this is a particular program that is underway now. And COMPASS stands for Community Partnerships to Advance Science for Society, and there are a myriad of different NIH institutes that have been involved with COMPASS. COMPASS is supported by the NIH Common Fund, and it has a health equity focus.

And what's so important about COMPASS is that it supports community-led structural interventions that have been funded to what are called CHESIs, and these are community organizations that are receiving the money to perform these structural interventions within communities. So, it's flipped the ideas about funding research projects around because for a normal research R01, normally the money goes to the institution of higher education, but in this sense, the money is going directly to these community-led organizations. And for COMPASS, all of these projects are focused on improving health outcomes, reducing health disparities, and advancing health equity research.

This slide represents just the structure of COMPASS, and the goals of COMPASS are, like I said before, to catalyze, deploy, and evaluate community-led health equity structural interventions, and they're required to develop a new health equity research model in these projects. Now, what's also interesting about COMPASS is that these projects last a duration of 10 years. Normally, a research project, particularly an R01, will last five years, but the whole idea around COMPASS is that if we're going to tackle structural racism and structural inequality in communities, we need enough time to not only implement that structural intervention, but also ensure that intervention is sustained.

COMPASS has three different initiatives. So, there is the community-led health equity structural intervention, which is called the CHESI, and there is 25 awards that have been made in 2023 to these

CHESIs that are represented across the country. There's one award that was made to the COMPASS Coordination Center, and that's Drexel University.

Drexel is actually coordinating all of the training and capacity building that will support these CHESIs in their intervention projects, and then we also have a health equity research hub that will be up to five awards. These awards are expected to be, or the institutions are expected to be chosen in July, and these particular institutions will focus on providing the CHESIs with additional infrastructure and training that will supplement what the COMPASS Coordination Center is doing to help facilitate their structural interventions and the structural factors that are being addressed for not only these community-led interventions, but also the health equity research hubs that will be assisting in the facilitation of these interventions, follow along important social determinant domains.

So, this is just a map of the different CHESIs that have been funded across the United States, and you can see that, sorry about that, and you can see that we tried to spread the funding out so that they're not clustered in certain areas, and this is just a particular graph about the particular populations that are being investigated in these structural interventions. COMPASS is a huge effort where a lot of monies have been devoted from NIH to make sure that it's a success, but in order to also be successful, we have a lot of support from our COMPASS working group, which is co-chaired by many of our division directors, many of our directors, ICO directors at NIH, along with project scientists and program officers, and each and every one of the initiatives, whether they're the CHESI initiative or the COMPASS Coordinating Center or the Health Equity Research Hub. Now, in terms of moving forward, I'm going to go through this really quickly because I'm out of time. We've been spending a lot of time in terms of ensuring that our major NIH-wide and IC initiatives that fund grants require the collection of common data elements, and so the particular initiatives that I talked about briefly, the majority of them do require the collection of common data elements, and so we have an NIH CDE repository that is maintained by NLM.

This was launched in 2015 and it provides access to structured human and machine readable definitions of data elements, and so this is to actually facilitate the interoperability of data. Now, there is three out of 18 different collections that are in our CDE repository at NIH. These are the three main ones that focus on social determinants of health.

So, we have SHARE, which is the Science Collaborative for Health Disparities and Artificial Intelligence Bias Reduction, which is a cloud-based platform for population science that includes many measures of social determinants of health and different data sets designed to accelerate research in health disparities and health equity. We have the Phoenix Toolkit, and I spoke briefly about the Phoenix Toolkit that primarily uses LOINC codes, and we have the RADx-UP, which encourages data collection using CDEs for the RADx Data Hub. So, with that, I thank you for listening and welcome any questions.

R. Lenel James: Oh my, that was extremely informative across the entire panel. I know Michael's had a question for a while, so Michael, you'll be the first batter up, and then we're going to open it up to all the Committee members. Yes, we'll do.

Your turn. But I'll encourage the Panel, if you make a quick answer.

Michael Hodgkins: You've got to have the mic on. I'll turn this on. I want to thank you all very much, and I think it was Rachel who had the slide that basically posed the question if you can't measure it, you can't answer it.

And so, obviously, these data collection efforts are extremely important. I wish in the beginning I heard more about things other than food insecurity and housing insecurity. I wish I'd heard more about environmental factors, social support, literacy, access to care, and those kinds of things, which I appreciate that we heard more of towards the end.

But the thing that has always troubled me about this topic is what I see as a fundamental underlying structural problem in our healthcare system. we spend over 17 percent of GDP on taking care of sick people, and less than one percent, and that's generous, on what I would call more broadly public health functions. I don't just mean state agencies for public health.

That includes things like EPA and other governmental functions that can be lumped under public health. And it just seems like we have an upside-down healthcare system. Structurally, we're not set up to really address the issues that social determined health measurement, it seems to me, are meant to address.

I'm a physician by training, and I think it's generous to even say that about 20 percent of what I do actually matters in terms of patient care. And if I'm being more generous and lump in nurses and other allied health professionals, I'd say about 30 percent of what we do matters. And the rest of it is out of our control.

And by the time the patient gets to me, it's almost too late. And if I measure these things, I'm not sure that I can find someone to intervene that's really going to offset years of neglect. So, what I haven't heard from any of you is just structurally, are we really set up as a nation to do something meaningful with this data collection?

Somava Saha: So, the framework that NCVHS developed and gave was actually designed around all of those structural determinants. And the measure domains are actually include the kinds of measures you're talking about, as well as truly structural measures of how society is set up, how environments are set up, how communities are set up, and policy changes that we can make. And alongside these measures, we were asked to develop a health equity framework with the CDC that would help public health go upstream and address those structural and root causes beyond individual interventions to say what would it take to do that.

And that pathways to population health equity framework, which uses the same domains as the NCVHS, those together have helped drive a lot of structural and policy change to address those upstream pieces, not one person at a time, but what's happening in the environment that would actually drive those outcomes.

Michael Hodgkins: And I appreciate that. But again, if 17 percent of GDP is going to taking care of sick people, by and large, and less than 1 percent to broad public health functions, where I think these interventions really need to occur at the community level. I couldn't agree more.

I just feel stymied. I don't know.

Julia Skapik: I'll just make one quick comment to that. So, I think it goes back to the KPIs, right? If we're not using key performance indicators around equity and understanding unmet needs and volumes and failures of care coordination, then we can't reinvest and restructure our ongoing healthcare investments.

I don't think there is anything special about SDLH that's actually not very similar in the broader healthcare coordination data space. So, we can fix all of those data pieces and data quality challenges at once, but we have to be applying that data and those measurements all the time and refining them and showing everyone, the care team, the people who are in the CFO's office, the people at CMS, everyone has to be looking at that like every day, every week, or else it's not going to make an impact.

Gniesha Dinwiddie: And also to your point, I want to add that we're not only looking at unmet needs, but we have to actually look at how not only we're measuring social determinants of health, but if those measures of social determinants are appropriate for that community, right, or that population understudy. This is why COMPASS is so important, because it looks at, it focuses on these structural interventions that are intervening at the community level. So, we're identifying what are the needs of the community?

Number one, what are the communities saying that they need in terms of dismantling barriers to access to healthcare? Let's just keep it simple, right? So, what are they saying that they need to have more equitable healthcare?

And how are we going to put monies into those communities to ensure that they do have that equitable healthcare? So, I think that it's important that we ensure that what we're trying to measure is appropriate for the communities that are in most need.

Tammy Banks: I think the thing that makes my head spin about the collection of this data is, and it's beautiful, you guys are all coming at it from a different approach. You guys are putting different incentives in play in order to get the data you need, regardless if successful or not, to meet the measures that you, and that's all laudable. And when I look at it, it's where should this data be collected?

Where should the primary source? I saw someone said it should be from the patient or the consumer. And I hear Dr. Hodgkins here we're all trying to get this out of the primary care physician or one of the physicians. So, now a patient gets screened again, every time they go into the hospital. Is that the right place? It may or may not be.

We also have community service organizations. We have caseworkers. We have in-home professionals that go in and do in-home care.

Where is the right place to be the primary data collection within the secondary and the tertiary? So, we put incentives aligned so that we get that quality data. And I'm making this way too simple.

It's not this simple. I understand that. But is there any comments to help me digest?

How do we get that good data and make sure that the research that occurs in the community, the data is collected and they're comparable apples to apples. And it's not just pulling like the COVID data, like a lot of data was not even available. we did a lot of presentations and studies on that, and it was really disheartening, right?

On not getting that data to ensure equitable treatment of patients. So, I'm throwing a lot at you, but is there any ideas on how to take steps forward or am I looking at this wrong? Because I would love that as well.

Julia Skapik: To me, the only primary data point is directly from the patient, but the data should come from everywhere all at once. And we should be using AI and other sophisticated tools in addition to standards to reconcile that information and validate it. The only way to get out of our data quality problem is that.

And then we can use the data for meaningful outcomes.

Prerana Laddha: I would second that. While patient is the primary source, I think there are going to be various touch points. We cannot completely rely on the health system or the community health centers.

The patient's going to just travel through the system. I think the key is consistency. Because every touch point leads to different set of questions today, different set of domains that they're being assessed for.

If it gets more consistent across these touch points, I think that's where we'll have more success in getting this data in a more meaningful way.

R. Lenel James: All right. For the sake of time, we've got Valerie, then Jamie, and - Oh, no.

Sorry. Valerie, then Steve. Thanks.

Valerie Watzlaf: Well, first, I just want to commend you all. My goodness. It's just wonderful, all the work you're doing. And I think one of the things I want to commend, too, is Megan.

I think I heard you say about the pilot program that you're doing with the techs, because we also did a letter of recommendations about that. So, take a look at that. So, hopefully that is in there.

Our committee did that letter. So, I want to commend you for that. And I think I had a bunch of questions, but I think my...

I'll ask them, but my main one is, what can we do? What is the opportunity for this committee? What can we do to help you and to be able to move all of this forward?

And could you elaborate on that a little bit? Where could we move forward from here? It doesn't just have to be Megan.

This could be everybody.

Meagan Khau: I was just going to commend you for your work. Thank you for the offer. I think from my personal perspective, data collection, even though we've been doing it at CMS for ages, right?

It's just until the last several years, especially during the pandemic, where we get all these questions where it got escalated. Like what data do we have? The accuracy, the missingness, equality, and all that becomes important, right?

We realize we're collecting data from multiple sources, but when you put them all together, it's not 100 percent reflective of all of our populations. And then there is a lack of standards, too, right? So, ONC standards is great, but we, like I said earlier, we're collecting data from the individual level on a paper format, senior citizens, right?

So, we have to meet somewhere in between. So, I think if there is guidance, like this is how all the agencies should collect consistently, right? And here's the guidance, here's the baseline to give us all something to start with and not just race, ethnicity, sexual orientation, gender identity, but across the demographic, at least those identified in the executive orders, right?

So, then we can take that and do what is necessary and emphasize the importance. Like one of the challenges, and I think this has been reflective across a different initiative, is hiring data scientists, right? It took me a year to bring in one, and then I hit the hiring phrase, and now I'm stuck.

It is important that we have more data individuals who can actually understand the program, understand the data, and at least for me, understand health equity, and putting all three of them together is very, very difficult. So, a support in that area would definitely be helpful, but I think just emphasizing the importance of self-reported data and how we go about doing that in the most efficient, consistent way.

Rachel Harrington: If I could just build on the theme that's been coming up around the intersection between healthcare and public healthcare, don't design a solution that only meets the healthcare system needs. Design a solution that meets public health needs alongside the healthcare system.

Team-based care models are nothing new, but it's no longer healthcare teams, it's health teams, and it's public health, it's community organizations, and it's promotoras, and it's everybody else that's out there doing this. And so, if we over-design the solution just to suit healthcare systems, we risk missing the boat on bringing all of this together. And it's not to say that public health and healthcare systems work great together in other cases too, but look to where they work better.

Things like immunizations, things like some of the prescription drug programs, not to say they're perfect by any means, but what can we learn from them to set up structures in this space that can facilitate us all working together?

Julia Skapik: And maybe a task force on data governance and harmonization of SDOH that includes people like VA and ACF and some of the payers would be excited.

Somava Saha: I think we underestimate the fact that data is not only one person at a time, but that we exist in a nation with highly predictable health and life outcomes based on place because we have a history of structural racism and segregation. In the UK and other places, for example, they don't do social need screening for everyone. They do, they use small area deprivation index, something that ABIM here has piloted and really demonstrated the value of, to rapidly identify which places have the greatest need.

And then within that, they use equity factors and social needs to help a person, but they also use it to understand what's driving the deprivation and use things like those vital conditions to say, how can we increase jobs here? How can we increase a healthy food environment where food is accessible and affordable? And our problem is because we keep trying to address, as you said, a problem that is just using one set of levers, which is the healthcare system, which as a primary care doctor and a community health center practitioner, I think is so important, but we're leaving 80 percent of the interventions out and that is a miss.

And this committee has actually done a lot of work to elevate what are other kinds of solutions in terms of what data we use and look at that really drives outcomes and the learning around that. And I'd love

to see that continuous commitment to helping us evolve our own framework and understanding of how we measure what matters and what will drive outcomes.

R. Lenel James: You're up.

Steve Wagner: Well, I'll try and be a little quick here since we're already running over. We've been doing work harmonization of standards and data over a significant period of time.

And in this current cycle, we're going to focus more on that. And I heard from multiple people about issues related to standardization of data and getting the data defined correctly and coordinating and collaborating with others and so forth. My perspective from having worked on harmonization of standards for a long time is that there are all kinds of different perspectives about a data element and how it should be defined and what it should be used for or can be used for and so forth.

And that's where it was talked about terminologists and getting someone in, hiring someone to actually be able to help you standardize this. That's what you get down to. So, what I'm interested in, and I'm not going to ask you all to comment right now today, but if you could send us something in an email or something else afterwards, so I won't pick up a whole lot of time.

What we're looking for is input from lots of different perspectives about how we can go about ensuring that all the different areas, public health, providers, patients themselves, et cetera, all those perspectives can be brought together to harmonize this data and define it properly so that it meets all of those needs, not just one perspective or two. And whether or not there are, what you've found that has worked at this point. I don't know that you have large collaborations across lots of areas, but focused on certain areas, definitely.

And if there are organizations right now that exist that are working on this and who actually support harmonization of data, that we could then try and bring multiple ones together so that the providers are represented and the patients are represented and research is represented, et cetera. That's the input we're looking for. So, we're looking to find out how to elevate harmonization and standardization here beyond where we've got it at this point in time.

Vanessa Candelora: I think you just summarized the Gravity Project really well. So, we bring together all of those stakeholder groups you described, patient representatives included, providers in the broadest sense of the word, payers, health technology across the broadest sense of the being, government at different levels come together in an open consensus-based process to build out standards. We identify gaps in existing standards and recommend additional standards.

Steve Wagner: And so, you're looking at developing standards and standardization of data beyond just SAOH.

Vanessa Candelora: Any data? The Gravity Project is focused on the documentation, use, and exchange of SDOH specifically. But there is a lot of work happening across standards development organizations.

I'm most familiar with HL7, of which Julia over here sits on the chair of the board. But there is lots of different workgroups and collaborative accelerator projects that are focused on different areas of standardization of data.

R. Lenel James: Okay. Let me make my wrap-up comment, but I'll put on my HL7. Oh, there is one more.

Oh, I'm sorry. Jamie, you came back.

Jamie Ferguson: Okay. Yeah. I'll talk and then I think Cathy, quickly as well.

So, I'm going to couch this as a question, but it's really a shameless promotional talk. And so, earlier today, this committee spent the better part of two hours talking about the next step towards policy recommendations for implementation and adoption of ICD-11 as a U.S. regulatory code set. And one of the things that the ICD-11 workgroup did about a year ago was to take the ICD-10-CMZ codes for SDOH developed by Gravity, as well as the work in process under Gravity, and map those into ICD-11.

So, they're talking about under 20 data elements that were represented in over 10 times as much detail in ICD-11. Now, some of the particular data elements might only be three or four times more detailed in ICD-11, but some of them might be 20 or 30 times more detailed in ICD-11. And so, the level of granularity and detail that's already in the WHO international code set far exceeds what we have today.

And so, I will coach this as a question. Have any of you yet started to map your data element and measures into ICD-11? And this is without looking at the classification for functioning or things of that nature, but just some of the things that came up here in terms of the sufficiency of social relationships, social insurance and welfare support, problems with imprisonment.

So, the range of detail in ICD-11 is vast. So, have any of you started to look at it yet? Because at some point it will be coming and all of our measures will have to convert to it.

Julia Skapik: So, the one thing I'll say about that is having everyone separately do mappings is not a best practice. So, we should just direct people to auto-map and build intentional value sets so that those definitions live and grow over time. We definitely have a bunch of those data elements you mentioned, but they're not in ICD-anything because they don't exist.

So, we are looking forward to that transition.

Meagan Khau: I can say we haven't mapped it, but we've been looking at C codes at the ICD-10 level for SDOHs to see 55 to 65. And so, if you're saying that can be 10 times more in detail, I would love to see what that increases because we only get about 2 percent of our claims data.

Catherine Donald: Okay. Thank you. I'll be very quick.

Cathy Donald with Public Health in Alabama. And first of all, thank you very much. Great presentation.

Lots of good information. But if I may, I believe there is a model out there for standards and standard setting and how to collect data. And it would be the National Center for Health Statistics with CDC.

That's been in place for decades. And I'm ashamed to say, or maybe proud, I've been in vital records. I was in vital records since 1987.

And we were collecting paper records at that time. So, I have been through the progression. And now where we are, it's not paper anymore.

It has evolved. And please don't get depressed. That's a long time.

But anyway, I would say that I think that's a place where we can look to model and how that organization does it and pushes it out. Standards for collecting the data, how they should be worded. And it did involve stakeholders.

I was on several committees developing that stuff. And it did involve stakeholders, basically from the grassroots level up. How do you collect it?

What do you need to ask? Do you need to be sensitive towards certain cultures or things like that? So, I would just offer that as a suggestion for maybe a place to look for standards setting.

Somava Saha: And I should have said, we partner well with NCHS so that they use us as one of the places to see what measures should be moved. And then it helps because we have the technical part. Helps inform what they do.

Okay. Good, good.

R. Lenel James: All right. As a wrap up, I just want to thank all of you for sharing such a rich amount of information. I know I will be going back to look at the slides and look at the notes because there were things I heard that I didn't know that might affect the payer world and the work of the NCVHS.

So, thank you very much for all that. Sorry you had to squeeze in so much, but you did a great job. Thank you.

Jacki Monson: All right. Thank you so much. So, we're going to try to take, let's take a quick 10 minutes and we're going to try to catch up after this next panel.

Thank you.

(Break)

Jacki Monson: We are going to go ahead and get started just out of respect of everyone's time. And I'm going to turn it over to Deb to kick off this next panel on value-based care models.

Value Based Care Models vs Fee-For-Service: Implications for HIPAA Standards

Debra Strickland: Great. Thank you so much. So, this is a value-based care models versus fee-for-service, the implications of HIPAA standards. This is Panel 2. We have Farzad Mostashari, Todd Couts, Aneesh Chopra, and Erin Weber. Thank you all for joining us. We will be presenting in that order. So, without further ado, Farzad.

Farzad Mostashari: Thank you so much. Thanks for inviting me. It's been over 10 years now since I left the best job I ever had, which was National Coordinator for Health IT. So, in those 10 years, I've completely forgotten everything about having to do with standards. So, I'm not going to go into any of the technical details. I refer all of those questions to my friend, Aneesh Chopra.

No, really, to all of you who've been doing the tireless work in the trenches. But what I will try to do is give you a sense of what it's been like in the past 10 years, building a public benefit corporation focused on value-based care exclusively.

Aledade is the name of the company. We are the nation's largest network of independent primary care practices engaged exclusively focused on value-based care, trying to achieve the triple aim through alignment between payers and providers, in particular, primary care. If we think about fee-for-service, it's simple, it's understandable in some ways.

But it creates misalignment between payers and providers, particularly when we're talking about an increasingly consolidating healthcare system, where what you get paid depends more on how much market leverage you have, not on the quality, not on the outcomes of that care. We colored it black in one way, oftentimes for independent primary care practices. And what we're trying to do is establish a new type of aligned relationship between payers and providers.

And to me, the importance of that alignment is also because data sharing becomes much more understandable, much more relevant if you're sitting on the same side of the table. You're not worried about the other party using the data you share with them against you at the negotiating table.

So, creating that alignment is technical, it's financial, and it's cultural. But fundamentally, we create a new kind of value-based contract between payers and providers, and you need a risk-bearing entity, and we establish those risk-bearing entities, where if and only if we create savings and improved quality, then we earn payments from the payer, whether that's CMS, whether it's private payers.

CMS is by far our biggest payer partner, but we have over 200 health plan contracts with all of the national payers, the regional payers, and many, many local payers. 200, as I said, partnerships, contracts, each of them with their own data relationships. And I wish I could say that there is a standard data transfer that we just plug into, despite the really wonderful work that has been done on the standard side. We are not really seeing those involved in the vast majority of our data relationships.

Let me describe some of what are the data exchanges, what are the use cases, as it were, tied to what is it that we're trying to do? And at Aledade, we've tried to simplify population health, value-based care, accountable care for our practices, and we call it the Core 4. All you've got to do is four things.

This is just four things. The first is access to primary care. In other words, you are accountable now for a population of patients. And you're not just waiting for people to call you. You're not only responsible for someone who calls or shows up and makes an appointment. There is a concept of a population that you're accountable for. And if they don't come to you, you've got to reach out to them.

That's not fee-for-service, right? But what that requires is an attribution file. In other words, what is the list that you, the payer, and we, the provider, agree is our flock, is our population? So, that's population health 101. You need to agree on the population.

There can be a lot of complexity in terms of how that population is defined, where the eligibility criteria, plurality, primary care service, blah, blah, blah, blah, blah. But at the end of the day, there is an exchange of a file that says, here are the human beings who you are accountable for. And that file can be updated monthly, quarterly, annually, whatever, depending on the attribution methodology. That's Piece 1.

Piece 2 is, as I said, we may reach out to patients if they haven't been seen, but we also reach out to patients if they're lacking some quality care gap. So, if they haven't had their blood pressure checked, they haven't had their mammogram, they haven't had their colonoscopy, whatever it is, part of the deal here is we don't just get rewarded for reducing cost, we also have to improve quality.

So, there becomes a partnership between the health plans and the provider - we're on the same side of the table - where they're like, hey, these are the gaps that we see in the data. Do you have those gaps too? We think that the person hasn't had an A1C, but if you can produce the actual A1C value for us, that'd be awesome.

So, there is a pushing of care gaps to the provider from the health plan and a response back to the health plan in terms of filling out those gaps. The third fundamental component is when the patient does show up at the point of care, and when we're really frankly, thinking about all of the financial relationships between payer and provider, and between CMS and the payers, all risk models are risk adjusted.

So, the amount of payment that you expect, the benchmark for the most important question in value-based care, is compared to what? So, we are going to generate savings compared to what? Setting that expectation, setting that benchmark, requires risk adjusting the population.

If you have a population full of healthy young people, you should be paid less. If you have a population full of older, sicker people, you should be paid more. You have a higher benchmark. Health plans are incentivized, whether it's on the exchange side or Medicaid, or in particular on Medicare, to make sure that they have accurate and complete listing of all the diagnoses that the patient has. So, there is a lot of information going back and forth between payer and provider on what are the diagnoses the person has.

Fourth is, in terms of the data exchange, I won't talk about care transitions. There are event notifications that go on there, referrals on the care compass. But in terms of reconciling financially between the payer and provider, we've got to know how much funding are we going to get for this population? And then what are the costs?

It used to be 10 years ago, but there was a lot of debate about, well, will the Blues plan tell us how much they paid for every service? That thankfully now is non-controversial, particularly after the price transparency legislation that took place. So, now, for the vast majority, we actually get paid claims that are coming across.

And those claims are critical for us to be able to understand what are the specialists the patient's seeing? What are the prescriptions they filled or didn't fill? What are any acute events? What is their risk in creating those predictive risk models? But increasingly, there are also non-claims expenses when it comes to Medicare Advantage plans.

There are supplementary benefits, there are vendors that they use, there is transportation that we heard in the social determinants of health panels, there are other costs, there are bundled payments that become implicated.

So, just checking through, and I put this in the slides that will be available to the Committee if you're interested afterwards. I included for each of those five main categories, literally how we are, and you can see on the right, we have the CMS Assignment List Report, ALR that we get from Todd personally, I believe, every month on a million Medicare patients. But also, the Health Plan Attribution wish list that we send to our health plan partners.

And we get our wishes fulfilled about as often as you get your Christmas wishes fulfilled. Not very often, but you can see that there is tremendous variability in terms of - but I thought seeing some of those

data elements might be helpful, and you may not necessarily have expected to see some of those. So, attribution list, including things like race, ethnicity, preferred language, PCP assignment, risk score.

On quality, as I mentioned, the HEDIS Engine Reports or care gaps, the medication adherence list from them, and from us back to them, literally flat files, could be CSV files. And then some of the data elements on the right, risk adjustment, the MAO files from CMS and the MOR files do provide, I think, some more standardization on these, as well as the information we give back to the payers. And then on claims expenses on the right, and then non-claims expenses as examples of data fields that might be implicated there.

So, I'm sure we'll go into more depth on what the challenges are, but for me, I think the heart of the problem is not just what are the standards, and I believe there has been really great work done on this with DaVinci and others, the FHIR standards. The question really is, how do we get to adoption?

And what are the levers, policy levers and otherwise, that we could use to get to the place that is better for everybody, if every payer and every risk-taking provider could simplify, streamline this negotiation that has to take place every single time you want to establish a risk-based contract. And this is revenue funding.

Just in conclusion, when we were asked to present, I said, do I have to worry about who does what, like administrative, clinical, ONC? And the staff were wonderful in saying, no, don't worry about that. And I think that's exactly the right approach. And for some time, there may be - there are areas of overlap. They're administrative and there is clinical, but we do need to get that standards alignment. And there is overlap between the clinical and administrative domains. There just is. And I think it's a greater need now than ever before for that harmonization to be done together.

And then finally, it is going to need, I think, flexibility and having that roadmap, but also appreciating that it's going to take time. And it may be okay for a period to have - we're going to have CPT-2 codes and Z codes, which I don't think that's a great way to communicate clinical information. But we may have to live with it for a while and the clinical data and the FHIR standards.

Just to be realistic. We may have to have support. We may have to figure out how to support both as long as there is a way to get to a transition over time. That's all I had.

Debra Strickland: Great. Thank you very much. Todd?

Todd Couts: Hi, everybody. My name is Todd Couts from the Innovation Center at CMS. I'm the Deputy Director of our Business Services Group. So, I'm an operations guy that pulled out of the weeds and came to talk with you all about this very important topic. And I really appreciate the invitation.

What I'd like to do is to describe what models look like from our perspective. And certainly, you're going to hear a lot of overlap with Farzad. But you're going to see that we've been really, really busy since 2010 putting out quite a few models. And hopefully, you'll have information that will help you with the work plan development.

The Affordable Care Act created the Innovation Center. The marketplace, the Medicaid expansion, that was all about expanding access to care. And since 2010, we've been working on ways to improve the cost and quality of care. That quote that you see is actually from Section 3021 of the law that created the Innovation Center. And it's all about reducing spending and enhancing the quality of care.

And we pursue that vision through model tests. And I like to explain what a model is because everybody uses that word. And so, if you are a data scientist, it's not an AI model. It's not ChatGPT. It's not an IT system. It's a demonstration. It's a pilot of a new policy idea.

And each one of them is putting an intervention into Medicare or Medicaid that changes the way that we pay for care as a payer, communicate with the industry to really incentivize improvements. And most of these models are actually voluntary. This is one of the times where we don't go through rulemaking with a lot of shall statements.

After a model was cleared by OMB, we actually go into a marketing mode. So, today, for example, there was a new bundled care model announced. And there are press releases. We do outreach to really invite people in to join us in the model. And once a model starts, it's impacting a real subset of beneficiaries and providers.

And these models are time delimited. They run typically for 5 years and sometimes up to 10 years. And a model test can expand. It's a term of art for us. It can expand to become a permanent part of Medicare or a permanent part of Medicaid. When I think about how much work we do just to do a model test, I'm like, my goodness, this is just an experiment. But they are.

And we have the actuary and an evaluation group that does a formal study to do a comparison group. If we can create a control and intervention group to see, did this intervention make a difference? And the law gives us three scenarios for success.

One is we can hold cost neutral and incentivize quality improvements. Or if we can keep quality neutral, do no harm and reduce costs, then, of course, the unicorn is if we can do both, improve cost and quality. And if those things are true, a model can expand. And we've had four models so far that have met this expansion criteria.

So, since 2010, we have launched over 50 models. We've been very busy. And the goal of CMS is to have all beneficiaries in traditional Medicare in an accountable relationship by 2030. So, certainly, the patients that we attribute to far side, that's an accountable relationship. And we have other forms of doing that as well.

And in our organization, we have three groups that create these models. And it really represents a portfolio. In one sense, it's like an investment portfolio. Since these are experiments, we anticipate an outcome, but we don't know exactly what's going to happen. And so, we have a seamless care models group. That's the group that puts out the accountable care organization models.

They also have specialty models focused on high-cost conditions. There has been a whole series of kidney-related models and ESRD. And we also do models to try to improve the managed care portion of the program in Medicare Advantage.

Then we have a patient care models group. And they are focused on primary care models. There have been three generations of primary care models. The current one is primary care first. And there is one in development called making care primary. We also have hospital-based models and episode-based payment models, which you heard Farzad mention a few minutes ago. And then we have a series of models that focus on state and population health.

So, these models are where we engage with state Medicaid agencies and with local organizations to try to get out of just Medicare and to affect a broader population. So, there are several unique aspects of the Innovation Center operations that are different than fee-for-service.

We're a small but mighty operation shop. So, we try as hard as we can to use existing systems and existing standards in the agency. But we often have to do things that are pretty unique because Section 3021 gives us a lot of flexibility from an operational point of view. If we need to collect data to measure how a test is doing, we can do that as opposed to other parts of the agency.

So, the first thing that's different is that we interact with entities beyond traditional providers and suppliers. Some of the ACOs are provider-based, for example, and some aren't. And that is very different than other parts of the agency.

And like I mentioned earlier, participants apply to join these voluntary models, even if they are existing Medicare providers. So, I mentioned those primary care models. Those are group practices that already bill Medicare. They've done it for years, but they still review these model opportunities, and they apply and participate above and beyond their normal fee-for-service engagement.

And then there is significant variation in participants. We have some that are extremely sophisticated, and we have others that really are just at the beginning of the concepts behind value-based care. And as you just heard, to begin value-based care, you've got to have a lot of capability - clinical capability, the ability to understand your population of patients, which requires data analytics. And we have a huge variation.

And so, in some cases, we've started to share FHIR-based APIs to share claims data with ACOs. And then for primary care practices, we create dashboards for them and just say, hey, come and click on this because they don't have the time, the capacity, or the resources to engage with an API. And so, we have a wide range of these participants.

The next thing to note is the data. We certainly use administrative data, but we do go beyond that, and I think Farzad explained that very well. So, we are working with quality measures, since quality is a big aspect. Sometimes we're getting snippets of clinical records and certainly social determinants.

And then finally, we make non-claims-based payments. The heart of value-based care is not reimbursing for a claim in an event. Once we attribute a population of patients to one of our participants, we'd want to benchmark where they started, benchmark it from a financial and a quality point of view, measure performance against that benchmark, and then we're making things like population-based payments or capitation payments.

We certainly care about the diagnosis and procedure, especially when it comes to risk adjustment, but the type of payments we make are very unique. And in fact, the rest of the agency, for a while, they were supporting us, and they said, CMMI, you're on your own. So, we actually have our own little, small payment shop to make these payments.

And our data exchanges are very unique compared to the rest of CMS. We haven't made use of the administrative standards so far. We have recently started to introduce FHIR-based exchanges. Aneesh has been one of the proponents of this in helping us get there.

So, for example, several years ago, we had a history of sharing claims files with ACOs, and they were nasty. I mean if you printed out the spec, it would be this big. So, we offer that through a FHIR API for those who can handle it. And we're also working now with a new model that's coming called Enhancing Oncology Model in Oncology Care. And we are building a FHIR-based API so we can get M-code-based cancer data straight from EHRs.

So, we're dipping our toes in this water. However, most of what we do is very, very custom, as you can attest, right? So, I have a couple of slides here just to give you a sense from the beginning, from our perspective, what the data exchanges look like.

And first, entities apply to participate in the model. There is an application that's equivalent to trying to win a new federal contract. So, they're applying to participate in the model. We have an evaluation panel who reviews those applications and makes decisions about who's in.

Second, we certainly share attribution data. We run attribution data based on our historical claims. And then, when we construct that roster of patients that belong to a participant, we're sending that attribution file to our participants.

And we also share benchmark data very early in a model because we have the history, and we've got that claims history, and we use that to construct a financial benchmark. Sometimes, we will compute claims-based quality measures and send a quality benchmark because that's very important in the beginning of a model.

And then, finally, we sign a participation agreement with the entity. Again, even if they are in other parts of Medicare fee-for-service, they sign a unique participation agreement that describes the model, what it's aiming to achieve, and what they're going to aim to do under the model. And this is the equivalent to contracts ACOs might sign with private sector health plans.

And then, entities submit data to us beyond what they might submit if they are already in Medicare fee-for-service. I mentioned how Section 3021 of the Affordable Care Act gives us all kinds of flexibility. And so, we ask for quite a bit of data sometimes in those participant agreements. Sometimes, it might be a provider roster.

So, we might say to an ACO, congratulations, we're happy to work with you. He sends us a roster of all your providers, so we know who is working under you. We also sometimes ask for participant-reported quality measures. Sometimes, we have custom metrics. Sometimes, we want snippets of clinical data. Recently, we started to collect demographics data that aligns with USCDI.

We've done that in ACO REACH, as well as social determinants, and that's been over the past two years. And so, we can request quite a bit of data, and we know this is a burden for our participants. Very rarely does it fit within their natural workflow. So, they're having to do something on the side to give us this data, and we know that.

And then, we send a significant amount of data back to participants. We already talked about claims data for the organizations that can handle that analysis. For some of our smaller primary care-oriented models, we produce dashboards. It's easy. They point. They click. They can drill down and see measures, utilization expenditures.

We also have to share reconciliation reports. You've heard about these benchmarks, and we're measuring against the benchmark, and we've got to reconcile against that benchmark, which drives the payment, and that's a data exchange. And then, we also have been sharing data through health information exchanges. So far, we've done this for two primary care models, and our goal in doing that is to really enable our participants to have the data they need to be successful, and part of that is multi-payer data.

And so, when we're able to share our claims data for attributed patients through an HIE, that enables our participants to have that multi-payer data that they really need, and that's something that we're really looking to do more to facilitate more of that. And so, we have a data aggregation contract that is out there now that we hope to award soon, and our goal is to enable, again, more of that multi-payer data, and we also know that event notification is extremely important because when we attribute a patient to Farzad, he wants to know what that leakage - when they've gone somewhere else. And we want to make sure we can facilitate that happening.

And then, we pay. Sometimes, we are paying adjusted fee-for-service claims, so this certainly rides on top of the 837, 835s, so sometimes we do that, but the real meaningful payments for value-based care, they're not claims-based. We have our own small payment operation, and we're making capitation payments, shared savings payments, and incentive payments. There are all sorts of variations, and these really are not using anybody's standard. These are very custom.

So, in conclusion, we absolutely want to reduce the burden. We know how hard we make you work, and we also know that we're not the only health plan in town with these value-based care models, so I don't know that we are beholden to any. Whether it's X12 or administrative or clinical, we're practical about it, but we certainly want to be aligned with other payers and make it easier for our participants.

And the other factor here is that we treat these models as tests. If you come walk the halls, we call it a model test. And new models pop up all the time, and sometimes they have new concepts, which can introduce new data exchanges, so that's something to really keep in mind as you think about it from a standards point of view, their flexibility.

Debra Strickland: All right, great. Thank you, Todd and Aneesh.

Aneesh Chopra: So, what I thought I might do is to do a little bit of history back, like Farzad described, about 10 years ago we both served. A little bit about the same gaps that Farzad outlined, and Todd referenced. I might share a bit about what's happening in at least a FHIR-based approach to some of these issues, and then maybe leave you with some final thoughts about opportunities.

And so, if you'll indulge, I'll just start with the history. Part of my role as U.S. Chief Technology Officer involved the Strategy for American Innovation, where the President laid out some clear priorities where he wanted an all-hands-on-deck approach to solving those challenges. That could be in healthcare, modernizing electrical grid for more renewable energies.

And I had asked Cass Sunstein at OIRA to help clarify for me, where does standards policy fall when the priorities of the country are not capable of being met with the standards that exist at the time? What do you do if there is a gap?

So, we put out a process that culminated in a revision to OMB Circular A119. And I wanted to highlight a passage in that section, because it gives you a perspective, I hope, of where we're going. Because I think

the message today is there are gaps in value-based care. We want to close those gaps. And so, to some degree, I'm sharing a bias as to how I would recommend or encourage you to think about ways to close them.

And the key message we shared, I think it's still current policy as of 2016, hasn't changed since we left, that where there is a gap, the government can play a very active role and, very specifically, can engage in voluntary consensus standards processes that may or may not necessarily have an existing standards approach to address it.

For lack of a better term, a coalition of the willing can work faster to close gaps, and then those can be identified and scaled through rulemaking. And that's a slightly different perspective, and I think a critical one, when the culmination of this panel is that we have gaps, and we need to find ways to close them.

To give you an example of this in production, I co-chair the CARIN Alliance. The then CMS Administrator Seema Verma gave a speech at HIMSS in 2018 and asked for health plans to standardize how to make data they hold, mostly claims data, available to consumers through an application of the consumer's choice, a standardized way to share payer data, which had not been part of the ONC rulemaking for the Meaningful Use Program. So, basically, a standard that didn't exist.

It was reinforced with a call letter asking the industry to follow up and engage. Our CARIN Alliance then said, does anybody want to work on this? Coalition of the willing. Several health plans raised their hands, and within a year, we had a working draft standard built on the FHIR API foundation, but a coalition reaching consensus, mostly, frankly, Todd, built on a CMS version that went into production later that year, which was called, surprisingly, Blue Button 2.0.

It was called Blue Button 1.0 in the Obama administration, and the Trump administration built on that progress and called it 2.0. And when the final rule was issued by Alex who's sitting over here to the right. It did not require a technical standard. It required a functional working API, and the vast majority of the industry, having already reached consensus, has voluntarily adopted the use of this standard to meet that regulatory requirement.

By the way, you can see some QR codes at the bottom. An obvious point, with no government action in the height of COVID, we didn't have a way of showing proof of vaccination, and the industry voluntarily worked on what is essentially another FHIR-based standard, so we could all carry our vaccination cards on our mobile phones, freely available on Android and iOS devices.

So, having shared that history, let me share a little bit about where Farzad was going, but a little bit of the work that's been taking place, again, in these voluntary industry consortia on five dimensions, related to what Farzad described, but maybe in a slightly different transactional lens.

First and foremost, grateful to this body and to the work that was done over the years, as you've been calling for potentially multiple standards to meet administrative requirements. Very grateful for your letters. Very pleased to see in the final rule that one of those administrative transactions, prior authorization, now has a FHIR-based option and enforcement discretion for the EDI-based option, so we have an industry consensus towards an approach that can drive forward.

Also proud of CMS, not to lean on Todd too much, but some of these transactions do offer chances for standardization, and one of them was how to get doctors to submit quality measures. It's an important part of what you heard Farzad describe. The CMS digital services team built a simple API that allowed

any organization to submit, big or small, their data. And not at the end of the year once ever, but frankly, every day. They can if you wanted - how am I looking today? How am I looking tomorrow? Very lightweight technical specification.

In many ways, it's the heart of the Cures Act, which called for the ability to exchange information, quote, without special effort, the magical words of the Cures Act that we live by. So, I'll just ask the staff. We could do a high-level summary of the five, and then we can have time for Q&A or however you want to handle it, but I'll do my best to go through what I see as the big opportunities.

Let me start with social determinants of health. This is the bedrock of all new value-based care models in CMS. I remember, and Farzad reminded me, when John Glaser was advising us, the godfather in the IT community, CIO at Mass General at the time, while we had - he said, 30 years of electronic health record, he could not generate a list of patients who smoke. And that was a critical part of our goal, so Farzad and the team at ONC made that a requirement in Meaningful Use, so now that's a structured data field. That is something we can do.

Well, a similar challenge for social determinants. How do I get a list of patients who are food insecure? Z code use is 0.01 percent of all claims. It isn't that. So, thankfully, because of the ability for rough consensus and the convening power of the Biden administration, President Biden, on the eve of the White House Conference on Hunger and Nutrition, said, gosh, I would like to have a community of health systems work on universal screening for social needs.

And in response to his call to action, the major EHR vendors, Epic, Cerner, Meditech, and a long list of stakeholders agreed to work in a coalition of the willing through the Sync for Social Needs Collaborative. And what was the first thing we did? Standardized on how to use the existing FHIR observation resource already in USCDI, but to tweak it so that it can communicate that this patient is food insecure. What's called social needs conclusions.

And you can see within a year, Epic, Cerner, all shipped this technology in their existing systems, so we went from no standard to production standard, and here's what it looks like. Patient might be on MyChart, answering survey questions. FindHelp is a community-based organization, has a SMART on FHIR app that works natively in Epic, that's a screenshot of it.

It is authorized to pull those survey data into the app. And so, you can see with no transaction fee process middleman, it's capable of pulling it from the Epic system into the FindHelp system so that the social working staff can take that information to the finish line in terms of getting people the support that they need. All standards-based transactions.

Here's the challenge. CMS just put out a notice to all Medicare Advantage plans, and they noted that all supplemental benefits, a lot of the stuff that we're talking about, non-claims-based encounters, must be shared with CMS, and they basically strongly encouraged it be done this calendar year.

Meals on Wheels are not on EDI systems. The quote is pretty much a laughing one. "MA organizations do not receive information from providers in such a way that an X12 837 Version 5010 record can be populated." Yeah, that's an understatement. So, what do we do? Sync for Social Needs in February announced a year-two agenda.

This is on the agenda. How can we use the foundation of FHIR-based standards to basically do the same thing? Ideally, find an existing service like FHIR Encounter Resource that we can jerry-rig, and if needed,

to find a new mechanism. But it's on the principle of Circular A-119 that allows coalitions of the willing to standardize.

Number two, back to the statement of Enhance the Oncology Model. When Todd noted that CMMI made the announcement that they would allow cancer centers to submit - by the way, it's shocking that cancer stage is not standardized. Sad, frankly. So, when CMMI says we need cancer stage in order to administer payment for the model, Todd is right. CMMI announced its willingness to accept a FHIR-based database entry of cancer stage.

How many EHR systems and health systems or cancer centers are capable of meeting CMMI when that announcement was made? Zero. Didn't exist. It's a concept not in production, but for a few test sites.

Well, again, coalition of the willing. The Biden administration invited EHR vendor leadership to Washington in December, and with very little effort, successfully recruited Epic, Oracle, Cerner, McKesson, Meditech, and Flatiron, who are dominant EHR systems with cancer centers, to voluntarily agree to adopt a minimum data set of the M code. It's 130 data elements in M code. They picked the 15 that are mandated by EOM and agreed to ship it this calendar year. A gap closed by a coalition of the willing.

Now, the big discussion, and probably seven or eight use cases fall under it, we'll use that for discussion after Erin's remarks, is in the area of TEFCA for population health. Now, today, the TEFCA networks only are approved for treatment purpose. So, none of today's VBC, for the most part, qualifies when the payer is involved. The physician networks can do it with themselves, but the payers can't participate because it's a treatment only program.

So, in January, the RCE, the coordinating entity for TEFCA did propose, and it's up for deliberation, the first use case that would invite health plans in for healthcare operations. And if you can read the fine print, it's explicitly for value-based care. TEFCA for population health.

Now, that will hopefully be deliberated, let's say by May or June. And we'll have the same challenge as when Todd introduced the fact that I'm ready for FHIR if you're ready to share, and then no one was on the other side, same thing. Here, the requirement is proposed. Health plans must provide the FHIR API claims data to doctors, which is otherwise not required until 2027 for government-sponsored plans. So, they have to pull that investment forward. And the providers can make available the USCDI in their FHIR formats.

So, it's a bidirectional sharing of FHIR-based data between payers and providers. That is relevant because as you see gaps, gaps in data elements can be addressed faster than gaps in transmission protocols. So, if I'm agreeing to share data with each other, I can add the cancer stage relatively easily. The hard part is understanding the legal governance structures for how a health plan can communicate with a physician or a specialist in the neighborhood.

One pilot project in the coalition of the willing under the leadership of NCQA is called the Bulk FHIR Quality Coalition. Yes, these are fancily named. The idea is to test whether the quality measures can be run, the care gaps that Farzad alluded to, using just the USCDI as regulated by ONC for the provider side and the payer side, the claims data as regulated by the patient access API. Now the provider access API, joining those at the patient level to calculate the measures, that will be another coalition of the willing test.

Last two, in the area of value-based care, but I'm stretching it a bit out of respect to the CMS administrator who noted in a blog post, I think the only blog post she's written about data sharing, that she would like to see price transparency, the advanced estimates or the advanced explanation of benefits to be made available through a FHIR-based approach, but to relate that in value-based care, which is the notion of shadow bundles.

So, if you're a primary care doctor and you're looking to refer a patient to a specialist, you might be able to negotiate a bundled price for that specialist, and you might want to ask what that price is, as you think about where and how you should route the patient to the best quality downstream specialist.

So, today, at the moment, there isn't today a FHIR-based approach to do this, a request for that information, but I am very motivated to work on this, and so our project clarity is spent up to do just that. So, when I ask for a hip replacement price, it should include a bundled open-source definition of all the individual line items that are expected to be in that service.

Last, and I'll stop here. Back to this issue of attribution, we do have a similar challenge as a transaction standard. At the moment, we do not standardize how a consumer can basically name their primary care doctor. If you go onto the CMS, mymedicare.gov website, it's a super painful process.

You have to click a star next to the name of a doctor and then hope that that will find its way into the attribution models for value-based care. I don't know, Farzad, is it 1 percent of your population might use the star? Maybe 0.1 percent, I don't know, it's nothing. But to the extent that we can allow for a simpler process, we can start to educate consumers, do you want to opt into value-based care?

And this has too relevance in the Biden administration. As you know, the Cancer Moonshot announced that 150 million Americans are going to be able to get cancer navigation services if they opt in. Similarly, CMS introduced this voluntary alignment for ACO REACH, which they call it paper-based attribution, although it's digital. Todd, I don't know why it's called paper based. But it allows you to fill out a form.

So, we do have these transactions now that are basically, how does a patient opt in to value-based care? And that could use some coalition of the willing. Okay, thank you for my end.

Debra Strickland: Thank you so much, Erin.

Erin Weber: All right, thank you. So, according to the CAQH index report, last year the industry conducted more than 50 billion HIPAA transactions. So, let's think about that for a moment. Fifty billion transactions in a single year, many of which contain data used to support value-based care operations today.

I think Farzad set the stage for where we are today, and Aneesh always gets us excited about the future. So, I'm going to focus today on how HIPAA, and in particular the parts of HIPAA where NCVHS has authority, can help serve as a bridge between today and what's next. I want to highlight three points.

First, optimizing revenue cycle transactions like those covered under HIPAA to support value-based care is critical. There is an opportunity to improve on the current foundation. Second, embracing the flexibility of APIs, including FHIR, will help take us to that next level. That said, the more aspirational goals of value-based care can only be achieved if industry aligns around common definitions and concepts for exchange, regardless of the format.

Third, the drive towards accountable care is greatly enhanced by an interoperable infrastructure. Industry must come together through coalitions of the willing to ensure technical and data content requirements are moving at the same pace as the uptake of accountable care programs. As many of you know me from our time together, I'm Erin Weber, Chief Policy, and Research Officer at CAQH.

I'll start with a quick refresher on CAQH for those who are less familiar. CAQH brings the healthcare ecosystem together to create a less costly, more connected experience for all, including providers, plans, and most importantly, patients. This is achieved through our continuum, which has three legs. CAQH solutions, our product arm, which focuses on provider and member data, our insights team, which provides thought leadership and tracks industry progress towards automation through the CAQH index report, and our core initiative, which I'll focus on today.

As the HHS-designated operating rule authoring entity, CORE has 10 operating rules mandated under HIPAA addressing the execution of eligibility and benefits, claim status, healthcare payments, agreements. Operating rules are built on industry consensus and ensuring that the rules have the greatest business impact possible.

CORE has over 100 participating organizations, ensuring widespread representation and adoption. The initiative is governed by a multi-stakeholder board that brings clinical, business, and operational perspectives to our value-based care strategy, which originated in 2015.

And I remember these board calls well. Our members were really challenged by the growing administrative burdens associated with value-based care at their organizations, which were slowing the adoption and adding costs to the system, not unlike when we first transitioned to electronic administrative transactions. As a result, streamlining value-based care became a priority for CORE.

Through extensive industry research, we identified seven opportunity areas where a more uniform approach can help streamline value-based care operations. I thought there were a lot of similarities in this list to Farzad's. Data quality and uniformity, enhancing accuracy, completeness, and timeliness of data, interoperability, patient risk stratification and provider attribution, addressing both the exchange of this data and transparency and methodologies, and quality measurement, reducing the burden of collection and variation in measures.

The other two identified more recently include health equity by design and issues related to growing program complexity and administration. These opportunities are interconnected, and addressing one impacts the other. Through this framework, the CORE participants reached consensus on operating rule requirements that simplify the administration of value-based care models.

The CORE value-based rules span topic areas, including identifying attributed members of a value-based contract, exchanging sociodemographic information during member enrollment through a secure infrastructure, and submitting claims that support the use of diagnosis and procedure codes for risk adjustment, quality measurement, and other nonmedical factors. Connectivity requirements in our value-based care operating rules allow for real-time, web-based exchange through APIs enabled by REST and SOAP protocols.

To connect the dots, this committee recommended both the CORE single patient attribution rule and the CORE connectivity rule Version 4 for federal adoption last summer. CORE participants are applying the same rigor to other aspects of VDP, and recently approved the framework for semantic

interoperability, which is an industry reference document to unify specific terminologies and concepts from value-based care.

As we explore the move from fee-for-service into purely value-driven contracts, it's really important to recognize that at present, value-based care models are heavily reliant on revenue cycle transactions, both those that are HIPAA mandated and voluntarily implemented. Just think about the importance of claims data for value-based care.

X12 transactions, such as the currently mandated versions of the 837, support the submission of diagnosis and procedure codes that affect value-based care methodologies. Updated versions of these standards expand the number of available diagnosis codes, directly enhancing this function and allowing for more accurate appraisal of risk and outcomes. Operating rules play a crucial role in maximizing the impact of these revenue cycle transactions by addressing specific levers that can be pulled to support novel and impactful VBC programs.

For example, leveraging the eligibility transaction to notify a provider of a patient's attribution status at the point of care. In addition to maximizing the flexibility in the revenue cycle transactions, leveraging newer standards like HL7 FHIR supports clinical data exchange and new administrative use cases for value-based care.

An example is the great work being done by the DaVinci Project. Their value-based reporting workgroup is focused on strengthening the presentation of provider quality and other value-based metrics using FHIR. So, when activities can be carried out using more than one standard, data alignment is essential to facilitate a common understanding across stakeholders.

So, real-time exchange and aggregation of data empowered by health interoperability standards both in and outside of HIPAA is the ideal structure for the effective management of value-based care programs. But more work must be done, as we've heard, on our current state before this real-time exchange becomes fully achievable.

An example is the CORE participants identified potentially harmful variation in the collection of SOGI information. And because of this, they developed operating rules enhancing data uniformity at the point of member enrollment to align industry around the standard collection and exchange of member language, race and ethnicity, and self-reported gender identity when discretion is exercised for collection. The operating rules empower the secure collection of SOGI information that align with industry-supported vocabulary standards such as the USCDI.

This brings us to another critical step, which is the uniformity of the data content within a standard and how it is used. As you'll see on the next slide, disruption of data quality or content at any touchpoint in the VBC environment can harm care coordination.

So, even when the types of interoperability are in place for data exchange, disparate data fields, data content across entities, whether in the claim or in the EHR, can render the information useless, that whole garbage in, garbage out concept. And this is one of the biggest concerns I hear from our board members. Without consistent definitions and data use, real-time access, data at the point of care, and even AI cannot be successfully leveraged. This is a problem we can solve by working diligently to define the uniform data content that can be applied to both batch and real-time exchange.

So, I just want to reiterate some key points that we've heard, not just in this panel, but throughout the day. Value-based implementations involve many stakeholders, all exchanging data and ingesting data of various types and formats. As we move towards an integrated data-sharing framework such as TEFCA, it is imperative that we work together as an industry to align our data sources and infrastructure requirements to avoid disruption and improve program effectiveness.

Value-based care world is complex. This is not news. Current revenue cycle transactions support the administration of value-based care, and optimal use of all standards will bring us to that next level. To meet the value-based care goals of improved health outcomes and patient care, advancing standards and optimizing data quality exchange are critical. The foundational work being done by industry stakeholders, including CORE, to define technical and data content requirements will simplify a transition to real-time exchange and aggregation of value-based care data.

But more is needed. A faster, more flexible adoption process for standards will help stabilize the context we are operating in. I know that we have spent a lot of time contemplating this regarding HIPAA. More frequent updates to the existing standards that specifically address value-based care requirements can optimize current workflows and act as an accelerant for standardized real-time exchange. The flexibility within HIPAA to adopt new standards also supports future opportunities and use cases.

So, let's take it back. Optimizing those $50 billion annual revenue cycle transactions to support value-based care is critical. There is an opportunity to improve on our foundation. Second, embracing the flexibility of APIs, including FHIR, will help take us to the next level. The more aspirational goals of value-based care can only be achieved if we can align around common definitions and concepts regardless of format.

And third, accountable care will continue to grow - we know they have lofty goals - without waiting for data format and exchange method standardization. So, it's in the best interest of providers, plans, and most importantly, patients, to find solutions now. Thank you.

Debra Strickland: Great. Thank you so much. That was very informative. We heard a lot of information around the value-based models that are working, ways to move forward, ways to grab some willing partners and get things done, and also ways for the industry to promote these new value models and the standards to make those things work. So, I really appreciate all your effort and for coming here and testifying in front of us. Anyone have any questions? Lenel?

R. Lenel James: Yeah, my question is for Todd. When you're talking about the value-based care models, have you gotten any experience in working with specifically SDOH in terms of getting that data in a particular pilot that's doing value-based funding, and who are the key stakeholders involved in that, and how is that pilot going?

Todd Couts: Yes, we have. We have worked with two models and collected SDOH and also expanded demographics data that's USCDI compliant. The first was our primary care first model. So, these were group practices that had a voluntary submission of the data, and that was our first foray into it. And we just finished a collection in ACO REACH, and we had 98 percent of the ACOs submitted, which was really wonderful. And we are in the beginning stages of this. The quality of the data was interesting.

So, for SOGI data, for example, that data was just all over the place, and we really looked at it hard, and we think there is a lot behind it. Some of it was providers not knowing how to submit it to us. We also

know that there were probably issues in the clinical setting. How do they ask the patient? Were the providers trained for the patient?

So, what we got, there were a lot of blank values. We didn't think it was actionable, but we want to keep doing it to encourage our participants to make the investments into training, into improving their methods. So, yes, patient primary care first was the first one. ACO REACH, we just completed a submission period, with more to come.

R. Lenel James: Maybe a quick follow-up, and in all fairness and transparency, I'm the payer advisor to the Gravity Project, so I'm close to this stuff. What has been your experience with the challenge of some of the community groups getting funding through your program so that they can do the infrastructure and do the training of their staff to change the workflows?

Does your funding accommodate that part of the lift to get ready to collect that data? Because I know our payer experience has been you have to ask the questions very carefully to get the answers, and if you don't explain why you're asking, people just assume the worst.

Todd Couts: Right. Well, our models do include funding for infrastructure investments, especially with our state and local models. Those often will have a two-year implementation period with infrastructure funding to make those kinds of investments. And with value-based care models, especially with some of our focus on health equity, we're putting a lot more effort in recruitment to make sure that we have a range of participants, and some of that is coming with either upfront funding or enhanced payments to try to recognize the stat for entities that are serving higher needs patients.

There is funding. Can I say it is sufficient? I guess I would have to ask you, but that is some of the intent behind the models is to try to make those investments.

Debra Strickland: So, I have a question. So, how can a payer identify when an ACO on the 271 response, when there is no qualifier for that to identify an ACO? So, how can that be identified on the 271?

Farzad Mostashari: I'll say this now dates back 10 years. There was a request from the ACO community to be able to gain access to the HETS system for CMS that would provide us with an early warning. This is under NIL, I think. They ran analysis and said, well, eligibility transaction doesn't necessarily result in a visit, so no.

And to this day, we do not have access. ACOs do not have access to - if you are a provider who's seeing the patient, you can submit the 270, 271, but an ACO does not have, I believe, standing to submit that request or to get a record of such requests that have been submitted. So, I think that's a policy gap. I don't think it's a standards gap as much.

Aneesh Chopra: Well, let me just make a friendly amendment to that, Farzad. That's a policy gap on how to get access to the EDI systems. However, and this is relevant, there are efforts under our Sync for Social Needs project right now to make supplemental benefits eligibility an API.

So, if a physician's treating a patient that has shown food insecurity, and the health plan under Lenel's leadership offers a benefit to address it, like a meal voucher, today that doesn't show up on the 270, 271 either. So, the question is, at the moment, the effort is scoped. It's just announced in February, so we have no results.

But to suggest, could there be an API, doesn't have to be FHIR-based or EDI-based, but content-based, that says the payers - payers already have an API that's physician-facing and patient-facing, thanks to Alex's rule. So, how hard is it to add a data element to those existing APIs?

And I think that's the message I wanted to convey. If you want data elements added, it's pretty easy to do that in an API once the connection's been made. So, back to this issue of the cancer data. Just as an example, all those EHR vendors are going to add cancer data elements, but they're going to keep the exact same connection methods. So, CMS can connect to the same EHR. EHR 1 doesn't have cancer data, so it's going to be empty. EHR 2 will have it, it'll flow through. So, the connection is sufficient.

What's missing right now is there is no - maybe it's an idea for your letters to say, what should the standard be to communicate the benefits? And one of those line items could be, are you enrolled in an ACO? And if so, name it. Second is, if you have a qualifying condition, you get access to a benefit. Those two things are missing today. We're hoping to tackle that, and the coalition of the willing would welcome your input and leadership on how to do that better.

Debra Strickland: All right. Great. Any other questions from the Committee? Any online? Rebecca? Okay. All right. Well, thank you very much. Thank you for your time.

(Applause)

Jacki Monson: All right. Let's move to public comment.

Public Comment

Rebecca Hines: Great. So, if there is anyone in the room, we are starting the public comment period. There is a mic. I don't think we have any members of the public who would like to make a public comment in the room. So, I will shift over to Zoom. Please raise your hand, have your audio unmuted, or use the Q&A to request an open audio line. You can also send written comments at any time to NCVHSmail@cdc.gov. So, we'll wait a minute.

We did just get a message. Where can we learn more about the Supplemental Benefits for SDOH Services API that was just mentioned? We'll see if we can get you an answer to that.

Aneesh Chopra: HL7 website or Sync for Social Needs.

Rebecca Hines: HL7 website.

Aneesh Chopra: Or Sync for Social Needs.

Rebecca Hines: Sync for Social Needs. So, anyone on Zoom have a public comment? Thank you very much. Can you please open the line? Stanley, you have three minutes.

Stanley: Thank you very much. I appreciate the opportunity. Jamie and the members of his committee raised quite a number of very important issues and questions and needs for further analysis in order for us to move forward on ICD-11. Given that vast number and their tremendous questions, do we have a sense of how long all of these analysis might take and any idea when the industry might even begin to expect a recommendation and the movement to ICD-11?

Jamie Ferguson: Stanley, thank you for the question. Nice to hear from you. The answer is we don't know yet, really. And as I said, we have started to outline what we might be able to inform the Committee on for this year or for this phase of work, this fiscal year, to inform committee recommendations. But I think a lot of those questions that we're talking about that you just referred to are going to be in Phase 3, which is in the next fiscal year. And so, that's the best I can do in answering your timeline question.

Rebecca Hines: Anyone else have a public comment for the Committee? As you saw in the chat, we're not having an oral public comment period tomorrow, but you are welcome, as always, to send communications to the Committee to our email, which is NCVHSmail@cdc.gov. We'll wait another moment. Okay. Public comment period is done. Thank you.

Jacki Monson: All right. Tammy and Steve, the floor is yours to give the standards update.

Subcommittee on Standards Update

Tammy Banks: First of all, I want to congratulate Steve Wagner, who has volunteered and is very excited to co-chair the Standards Subcommittee with me. Very appreciative. Thank you, Steve.

I'm going to talk in 15 minutes about just an update of communication received, like we did in our last report. But I do want to spend time on the Office of the National Coordinator and the SDO November session report-out. And there are some areas of consideration that we need to discuss as a committee. So, please get some more caffeine. Stay with me for 15 minutes.

Okay. As you recall, last year we received two different sets of X12 transactions to review. And one thing to remember with that is when we take a look at a transaction or a suite of transactions or a bundle of transactions, we're looking at it from a national implementation perspective only.

And I just want to update you on a couple of correspondence that we received that were not included that we received after our last report. I want to appreciate Diana Fuller from the Michigan Medicaid, who wanted to share why the industry moving to X12 version 8020 in the entire suite for all the mandated HIPAA transactions was preferred.

We also received a letter from the SMI, a community of healthcare supply chain organizations, that wanted to reconsider the decision regarding the adoption of X12 standards, specifically in regard to the UDI, DEI, and the claims transaction. Again, just want to reiterate, we have to look at it from a national implementation perspective, but we do appreciate these comments.

Now the ONC SDO November session report-out, we invited the Office of the National Coordinator because of the HIT certification. They review different standards to be put into their ISA, Interoperability Standards Advisory. And we invited the SDOs, the X12, HL7, and NCPDP to really help educate us on what is out there to evaluate and assess the readiness of new and updated standards prior to release for national implementation of certification.

I'm going to go and give you a very high-level overview of what was presented in that session. Obviously, there was a lot of meat. It was a very good, robust discussion. But it's just to remind you of the conversation that we had last year so that we can address five points that were raised.

So, the first question was, does ONC or the SDO assess and report on backward cross-capability or specific anticipated issues with version update? The SDOs, HL7, NCPDP, X12 all check for backwards and cross-compatibility. X12 from individual standards perspective, ONC examines forward compatibility in some cases but really looks at the directionality of the compatibility based on how the standards are referenced.

The second question that we received feedback on was, how does ONC or the SDO assess and report on backward compatibility or specific anticipated issues with version updates? ONC considers the compatibility of standards relative to whether there are breaking changes that would affect the industry efforts to update infrastructure and standard performance as it relates to its HIT certification.

HL7 provides documents related to the backward compatibility, has summaries of changes, and also creates a maturity level framework applied to each of the artifacts in order to help add that clarification. NCPDP provides its members easy to understand and read documents that are crosswalks. So, it has a side-by-side comparison of the transaction message types and transaction guidance crosswalks. And X12 provides a list of changes supported in the implementation guide as a reference.

And then assess whether current systems can support the functionality and the impact. The ONC certification for EHR is voluntary. The testing is completed prior to rollout in the real-world settings. HL7 has testing completed prior to release, and four stages of standards development up through normative is released to help people know where it is in that progression. NCPDP does not require a special level of testing, and neither does X12, even though they did have or have in process a proof of concept for the versions that were released for our review.

Assess cost and value. The HL7, NCPDP, and X12 do not have a peer-to-peer validated study. The HL7 does compile implementer case studies as well as peer-reviewed academic studies in a repository in order to gain that type of information. NCPDP collects cost or harm when a standard is not moved forward. And ONC, the benefits are not either obtained between the peer-reviewed, but they look at cost, like there is a need to purchase a license or otherwise obtain some type of membership to access the standards and report that out on their ISA report.

And this is just an example of the ISA report. I won't go into detail, but this shows how the maturity level is reported, the cost, and the other key data elements that are considered important in the ISA in order to better understand where the standard is, whether it be in production or in draft.

One thing that was brought up in the session was the HL7 Cambia Grove Innovator Fellowship. I just mentioned that because they did come and present their value aid format to us in 2022, and HL7 mentioned that that is something that they're looking at that could be a way to identify value, benefit, and cost. So, it's something that we may or may not want to revisit. And I'm unsure if it's continuing where it is in the game since the fellowship may not be continued at this point.

And the last was risk and impacts across the existing standards plans for ICD-10. ONC defers to the National Standards Group. NCPDP and X12 are looking for education, and HL7 has a contract directly with WHO and also works directly with the developers.

And then the reporting on the testing, ONC real-world testing, again, as new certification rules are published, you can see the very detailed testing that occurs through HL7, NCPDP, and X12 do not have a specific level of testing for their standards before they get brought here.

So, that's just a really quick brush of the key points. But they did bring up some areas for us to consider. And one was when considering different types of standards, examine the industry availability of a testing infrastructure. And we noted that HL7 is the only SDO that presented that they have a testing infrastructure. And some of the questions that the Subcommittee was coming up just to set the stage for our conversation and try and shorten the conversation because I got a deadline.

Are there vendor test tools available in addition to the asset, which are for HIPAA standards only? Is there funding available? So, the question for the group here is, is this something that we should be putting on our work plan in order to identify other avenues for testing tools, basically because the feedback was that just HL7 really had a testing infrastructure.

R. Lenel James: Lenel? I guess I would weigh in and say that we should probably at least try to get an inventory of the testing tools because there are several vendors. I know they've approached payers and some of the health systems offering their services, but their services aren't necessarily inexpensive.

But given the cost of implementing these standards, it's not clear to me that the industry in general is aware of the - not that there are a lot of tools, but there are some tools. And maybe if the industry knew what tools that were there, some enterprising entrepreneurs or venture funders would realize maybe they should create some more tools because they don't know we need tools because we haven't told them how important tools would be to test.

Those of us in this room are very familiar with how long it usually takes to implement standards. Well, part of that's because there are no real good testing tools. We implement it by trying to use it, except in other end cases where we can play with it before. But this is probably an area where at least we could figure out who's in the market and educate people that there is a small but growing marketplace for testing tools as we get more automated.

Tammy Banks: To use Aneesh's word, get a coalition of the willing?

R. Lenel James: Well, we could have a coalition of the willing if the coalition even knew what tools were out there. I think there are only a few of us that are active at HL7, active at Connectathons, trying to play with this new API toy that realize there are tools out there. And I suspect if we asked, we'd find out there are maybe more tools than we knew. And maybe there are tools for other industries that don't realize healthcare might be mature enough to start using tools they use in other industries.

Tammy Banks: Deb.

Debra Strickland: Yeah, I would support that. I do think we need to beat around the bush and figure out what's out there, or even promote a marketing type of approach to say this is an industry that needs testing tools. Maybe even so much as finding those willing partners to vet out what tools would help us without building the entire onslaught of the standards.

I mean, it's a tough thing because no one has the funding to do that. Or maybe there is funding available via grants or something that we can approach as ideas. But we need to vet out solutions because the industry can't keep not moving forward because there is no testing approach.

We also can't not move forward because there are no requirements on what is testing, and what is a pilot, what makes that successful. So, I think some of the brainpower needs to be focused on those

types of questions and topics so that we can get more solidity around what it all means. And maybe there will be partners that will come out and say, hey, I'll build it. Worth asking.

Tammy Banks: Good points. Valerie?

Valerie Watzlaf: I just had a clarifying question. So, could HL7 be used as a best practice since they are doing the testing? Or why are they able to use the tool? It's available for them, why wouldn't it be appropriate for others?

R. Lenel James: Well, the tool was actually built specifically for FHIR in terms of - but again, as Jamie pointed out earlier, FHIR is just the healthcare unique version of APIs. Amazon has been using APIs forever. That's how we can order all this cool stuff. It's just an API. But there was never one for healthcare until FHIR.

But healthcare, because of HIPAA and the privacy of the data, it's not like ordering a book. The data you share on the API for Amazon is not going to be a HIPAA violation. So, healthcare is a different animal. And because of that, some vendors and other industries assume it's just too hard, and they don't want to get involved in something that complex.

But they don't know we're now very eager to get into more high-quality, high-volume data exchange. So, if we don't ask, they won't know we could be interested.

Tammy Banks: Okay, Jamie, last question. And then I think the consensus, unless I don't hear from anybody, is we'll put it on the work plan for further discussion. Jamie?

Jamie Ferguson: Okay, thank you. I think if we're talking about the costs and benefits of different approaches to testing and implementation in the lifecycle of new standards, we have to also look at the licensing costs. And I would point out that with HL7, not only is the testing included, but they're licensed free for use in the United States, which is unlike any of the other standards.

And so, we really should be looking at the total package of the cost of testing and implementation in that lifecycle view. It's just that they have a different business model from the other SDOs.

Tammy Banks: Well, and that's the next bullet, was consider cost of obtaining standard, which included the open-source discussion. So, anybody have any comments on that, or we'll place that on the work plan as well?

Debra Strickland: I do think that should be on the work plan as well for consideration.

Tammy Banks: Okay. And the third one was consider the cost of not moving forward or promulgating a final rule in a timely manner. This information can be provided with the proposals. There is nothing that prevents it from being provided.

Is that something that we need to address or just raise awareness that that is something that if someone's bringing forward a standard for national implementation, that that information could be included? Or is this something that we need to think about or there should be further action? You want it on the work plan for further discussion?

R. Lenel James: Yeah, I think we need to discuss it more.

Tammy Banks: Okay. Seeing more and more comments. And again, I'm not trying to rush anybody. I'm just trying to be time sensitive. So, well, you're just going to have to hold dinner. There are differences as to what backward compatibility means and it needs to be defined. Cross compatibility was raised as a better term to test across different standards with different versions.

Our preliminary conversation is, is there or does there need to be definitions and specific documents to show these types of compatibilities when a new national standard is proposed? Should crosswalks be included? How to vet and test mixed version of standards? These are some of the topics we brought up. Any other comments on this topic?

Debra Strickland: I think that if we do vet out testing and what is needed for testing and those types of things and those global conversations, this might fit right in with those.

Jamie Ferguson: I think that we can't do away with backward compatibility as a strict discipline. I think cross compatibility is a different issue that also needs to be addressed, but backward compatibility within a family of standards from a single SDO is still going to be incredibly important as a discipline to analyze.

Tammy Banks: And are there no standard definitions or is this something like the cost benefit recommendation that we made that it needs to be defined?

Jamie Ferguson: I think there are definitions of backward compatibility that we can adopt.

Tammy Banks: Any other comments on this topic? Okay. And then the last topic that was brought up for us to consider is the benefit cost analysis. Several of the SDOs said they need to know what information is required in detail, then the SDOs will have a better chance of collecting the information. One thing that we referenced is back to our 2022 recommendation where we were asking for specific data elements.

Is this something that we still need to address, or do you feel that that recommendation addresses this question that was raised to us?

Debra Strickland: I think that answers the question that was raised to us.

Tammy Banks: Okay. Any other comments on all five? Okay. Then what we'll do is update the work plan. We're going to be going through the work plan tomorrow and I'll find the places for it in our four areas that we'll be focused on this year.

One is coordination with ONC and NSG, examine mature and emerging standards and how they can coexist to support current and future business needs and their workflows, review relevance of HIPAA in the current healthcare ecosystem in partnership with privacy and security, and harmonization of standards and data. So, this is the abridged report-out of the activity and the questions that we needed to deliberate. So, thank you.

Wrap Up & Adjourn

Jacki Monson: Let's go ahead and wrap for the day. So, I just wanted to comment on a couple things. There were actually over 100 people on Zoom during the ICD conversation. So, go Jamie and team. So, there is lots of interest in that that we were watching.

And I think the other highlight of today other than what Tammy has already discussed is the SDOH conversation. I think we need to have more conversation tomorrow during the work plan discussion about whether we reinvigorate a working group, task force, however we want to describe it to help pull people together.

I think we've been very successful at ICD in doing that. And we made a little attempt to do that with SDOH, but I think there is certainly an opportunity there. So, I want to further discuss that tomorrow during the work plan.

And that's all we have for today. If the members who are in the room can stay for another 60 seconds after we officially close, we would appreciate that for a couple of announcements. And I thank everybody for all their time today. And thank all of our tech support.

Rebecca Hines: I was just going to say bravo to RLA. Well done today, RLA team. Thank you very, very much.

Jacki Monson: And thanks to our team who is just supporting this whole thing. We can't do it without you. And we'll see you all bright and early at 8:00 a.m. tomorrow.

Rebecca Hines: Well, actually, before 8:00 a.m., if you want to get through security.

Jacki Monson: Probably at least 15, 20 minutes before. So, thanks, everybody. And we're adjourned for the day.

(Whereupon the meeting was adjourned at 5:35 p.m.)