National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Nicholas L. Coussoule	**Horizon Blue Cross Blue Shield of New Jersey**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan School of Public Health	Member
Denise E. Love	Individual	Member
Jacki Monson	Sutter Health	Member
Jamie Ferguson	Kaiser Permanente	Member
James J. Cimino	University of Alabama at Birmingham	Member
Tammy Feenstra Banks	Individual	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Richard W. Landen	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
Vickie M. Mays	UCLA	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Rachel Seeger	HHS Office for Civil Rights	Staff
Marietta Squire	NCHS	Staff
Geneva Cashaw	NCHS	Staff

Presenters		
Name	**Organization**	**Role**
Jim Craver	NCHS	Deputy Director for Management and Operations (Acting)
Lisa Mirel	NCHS	Chief, Data Linkage Methodology and Analysis Branch, DRM
Kin-Wah Fung	NIH/NLM	Scientist

Welcome/Call to Order/Roll Call

Rebecca Hines: Good morning and welcome to members of the committee, federal staff, and public attendees. Good to see you all. Hope you are keeping well and you were able to enjoy some time off over the summer. Now, we are all ready for two days of productive committee time. This is the fall meeting of the National Committee on Vital and Health Statistics. My name is Rebecca Hines. I serve as executive secretary and designated federal officer for the committee.

We had hoped and planned to be meeting in person today, which is why the meeting is placed where it is on the calendar. It is not our typical timing. We are hopeful that it will be possible to meet in person next year. Several members have not actually met in person. It has been so long. We are working on that schedule now.

With that, let us move to roll call beginning with our chair.

Nick Coussoule: Good morning. My name is Nick Coussoule. I am the senior vice president with Horizon Blue Cross Blue Shield in New Jersey. I am chair of the Full Committee and I have no conflicts.

Rebecca Hines: Deb Strickland.

Debra Strickland: Good morning. My name is Deb Strickland. I work for Conduent. I am a member of the Full Committee and a member of the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Denise Chrysler.

Denise Chrysler: Good morning. My name is Denise Chrysler. I work for the Network for Public Health Law Mid-States Region, located at the University of Michigan School of Public Health. I am a member of the Full Committee and I serve on the Subcommittee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Thank you, Denise.

The other Denise, Denise Love.

Denise Love: This is Denise Love. I am a member of the Full Committee, co-chair of the Standards Subcommittee, and I have no conflicts.

Rebecca Hines: Jacki Monson.

Jacki Monson: Good morning. Jacki Monson, vice president of Sutter Health, member of the Full Committee, co-chair of the Privacy, Security, and Confidentiality Subcommittee and no conflicts.

Rebecca Hines: Thank you for joining us on Pacific time, Jackie, along with our next member, Jamie. Good morning, Jamie.

Jamie Ferguson: Good morning. My name is Jamie Ferguson. I work for Kaiser Permanente. I am a member of the Full Committee and the Subcommittee on Standards, and I have no conflicts.

Rebecca Hines: Jim Cimino.

Jim Cimino: Hi. Jim Cimino. I am director of the Informatics Institutes, professor of Medicine at the University of Alabama at Birmingham, member of the Full Committee, member of the Subcommittee on Standards and I have no conflicts.

Rebecca Hines: Margaret Skurka.

Margaret Skurka: I am Margaret Skurka. I am Professor Emeritus from Indiana University. I am a member of the Full Committee, and I am a member of the Standards Subcommittee and I also have no conflicts.

Rebecca Hines: Melissa Goldstein.

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

Rebecca Hines: Rich Landen.

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

Rebecca Hines: Tammy Feenstra Banks.

Tammy Feemster Banks: Good morning. I am Tammy Feenstra Banks, independent member of Full Committee, member of the Subcommittee on Standards and I have no conflicts.

Rebecca Hines: Valerie Watzlaf.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I work with the University of Pittsburgh as an associate professor and vice chair of education. I am a member of the Full Committee and I serve on the Subcommittee of Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Vickie Mays.

Vickie Mays: Good morning. I am Vickie Mays. I am a professor at the University of California Los Angeles. I serve on the Subcommittee on Privacy, Confidentiality, and Security and the Full Committee and I have no conflicts.

Rebecca Hines: Wu Xu.

Wu Xu: Good morning. My name is Wu Xu. I am a retired state health informatics director and adjunct faculty with University of Utah. I am a member of the Full Committee and I have no conflicts.

Rebecca Hines: Thank you. I believe that is all of our members. We have several federal staff, one of whom is on with us now, Rachel Seeger. Good morning.

Rachel Seeger: Good morning. I am Rachel Seeger. I am a senior advisor with HHS Office for Civil Rights and I serve as lead staff to the NCVHS Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Thank you. We have several other federal staff who are not quite on with us yet. Sharon Arnold is the executive staff director of the committee. We have Maya Bernstein. Both of them are in ASPE. And Lorraine Doo, who is our lead staff and a senior person with the Centers for Medicare and Medicaid Services and Marietta Squire and Geneva Cashaw behind the scenes, making this all happen.

Kim, can you show the public comment slide? Just take a moment for members of the public. The agenda includes time for public comment both today and tomorrow. Today's public comment period is schedule for 5 p.m. Eastern. Tomorrow, it is on the schedule for 12:45 Eastern. We do try to adhere to the public comment timing. Although we suggest that if you are planning to comment to be aware in case we are running ahead of schedule or behind. Also, for awareness, public comments can be sent by email to the address that you see there on the slide, NCVHSmail@cdc.gov, and we will read them out loud during public comment.

I think that is all the preliminaries. Nick, over to you.

Nick Coussoule: Excellent. Thank you. And I see Maya has joined us as well.

Rebecca Hines: And Sharon Arnold is with us as well.

Welcome Remarks/Agenda Review

Nick Coussoule: Let me welcome everybody and kind of in advance thank the members and the staff for all their hard work and their expertise leading us up to today and actually participating in today. Many of you know there is enormous amount of work that goes in and happens behind the scenes and work that happens by all the committees and the staff. I really want to thank them multiple times. I will try to do that at the end as well. Sometimes I forget so I try to make sure I cover it early enough to thank them for that. We have a very full agenda. I am going to walk through it with you in a bit of detail in just a second. I think we have some pretty exciting and meaningful work underway as a committee. I think that is fun for us that are involved.

But I also want to thank our listeners that are on the call today. In many cases, they are participants in our work and activities as we solicit and seek expertise from across the ecosystem to help us, inform us of our work. Thank you both for your time today as well as your participation and the work that leads up to this and hopefully future work that comes out of this.

Let me walk through the agenda. We are going to start with an update from ASPE. I will thank you, Sharon, in advance also for coming and joining us today. And then we are going to update from NCVHS. A couple of folks are going to talk to us about the Data Modernization Initiative and Data Linkage Activities, which are near and dear to our heart and very tied into a number of the things that are going on at the committee.

And then we will have the first of a couple of different privacy, confidentiality, and security activities. The first will be a report-out from the July 14 hearing that happened a few months back on security and health care.

We will take a break and then we will – when we reconvene this afternoon, we will go through our Report to Congress, the 2021 Report to Congress, which covers the last two calendar years. And the action item ideally where we will finish that up hopefully with a confirmation that this report can be distributed. That will be our objective.

We will take a break and then come back. We will have the first of our Subcommittee on Standards sections where we will go over the updated action on ICD-11. And then we will have a final – final session of the day will be another Subcommittee on Privacy, Confidentiality, and Security. We will get an update on our data collection and use during public health emergency.

This afternoon we will have public comments. I will open it up at roughly 5 p.m. this afternoon. We will wrap up with anything that we need to finish up with and cover and adjourn for the day.

Then we will come back tomorrow, starting at 10 o'clock Eastern Time. We will have a morning session, which will be focused on the Subcommittee on Standards for a bit of an update and review. We have the pleasure of having Steve Posnack, who is the deputy national coordinator at ONC, who will be with us for the first roughly hour and a half of that session. We will get an update from him as well.

And then the Subcommittee on Standards will give us an update on the report out from the August 25 listening session that happened obviously on August 25 and then a little bit of an update on the framing of the Standardization of Information for Burden Reduction and Post-Pandemic America. We will talk a little bit more about that work effort.

And then we will have public comments in the middle of the day. We scheduled that on purpose in the middle of the day to make sure that timing wise we are clear with everybody who wants to make comments of when it would be available just because the afternoon sessions can get a little dicey depending on how much work we have to continue on and follow up with.

We will take a break. And then Sharon Arnold will talk to us about health equity update and the discussion in regard to some potential work that the committee could undertake in regard to that.

And then we have the final working session of the day, talking about our workplan and any follow-up items. We have a little bit of flexibility in there for things that may run past our allotted time, or we need to have follow ups specific to try to close out items that we have been talking about. And then we will finish up roughly 3:45 in the afternoon with some closing remarks and we will adjourn.

Again, that is a very full agenda. We will try to stay as close as we can to the time. I am sure we will have some sessions that finish up early, some that run late, but we will try to be disciplined about managing our time and expectations. Again, we thank you in advance for the participation.

Without further ado, I will turn it over to Sharon Arnold. Sharon, thank you.

ASPE Update

Sharon Arnold: Thank you very much. As usual, HHS continues to be quite busy. I will just provide you a highlight of some of the activities around the Department, and in particular within ASPE, the Office of the Assistant Secretary for Planning and Evaluation.

As you may know, the vast majority of the department's workforce continues to telework due to the pandemic. We do not know exactly when we will be asked to come back physically into the office, we are fortunate to be able to operate relatively seamlessly on a remote basis. And in the interim, the Office of Personal Management, the Office of Management and Budget, and the General Services Administration is working with all government agencies to build together a plan for return to workplace. This team continues to rely on science and best available information, including guidance from CDC and Safer Federal Workforce Task Force.

Federal employees and on-site contractors will have to attest to their vaccination status or be subject to masking, social distancing, and COVID-19 testing requirements. HHS will require more than 25,000 members with its health care workforce to be vaccinated against COVID. Since our last meeting in March, we continue to become familiar with the new administration's priorities and vision for the department.

We have had a number of new HHS appointees since our last meeting. Chiquita Brooks-LaSure is the Administrator for the Centers for Medicare and Medicaid Services. Dawn O'Connell has been confirmed as the Assistant Secretary for Preparedness and Response. Cheryl Campbell is the new Assistant Secretary for Administration and Miriam Delphin-Rittmon is the Assistant Secretary for Mental Health and Substance Use and Administrator of SAMHSA.

HHS has continued to work to support the Biden Administration Executive Orders. There are quite a number of executive orders, identifying priorities for this Administration. Groups across HHS have been working to support the Executive Order to advance racial equity and support for underserved communities for research grants and other work to develop new standards for HHS.

There is a workgroup to restore trust in government through scientific integrity and evidence-based policymaking that ASPE has been leading. We will be developing a report, which will cover issues, including fraud in science and evidence-based policymaking.

Just a couple of weeks ago, HHS announced the establishment of a new Office of Climate Change and Health Equity in response to the President's Executive Order tackling the climate crisis at home and abroad. This is the first office of its kind at the national level to address climate change and health equity and the Office of Submission is to protect vulnerable communities who disproportionately bear the brunt of pollution and climate-driven disasters such as drought and wildfires at the expense of public health.

HHS continues to devote a lot of resources and energy to support the COVID-19 response. On August 23, the FDA formally approved the first COVID-19 vaccine. The vaccine had been known as the Pfizer-BioNTech COVID-19 vaccine and will now be marketed as COMIRNATY. I am probably getting that pronunciation wrong. This is approved for the prevention of COVID-19 disease in individuals 16 and

older. CDC regularly provides and updates COVID-19 guidance based on current science and the best available information. There has been recent guidance that has addressed the spread of the Delta Variant, return to school guidance, and issues concerning the increase of COVID-19 among youth and more.

On August 30, the Biden-Harris Administration released Medicaid and CHIP guidance, targeting vaccination and testing for COVID-19. On June 9, Secretary Becerra sent a letter to insurers and providers following recent reports of ongoing concerns about Americans facing costs associated with COVID-19 vaccinations or testing, reaffirming that vaccines and testing must be free for patients.

On July 15, the Surgeon General issued an advisory warning to the American public about a threat of health misinformation, including disinformation has threatened the US response to COVID and continues to prevent Americans from getting vaccinated, prolonging the pandemic and putting lives at risk. The advisory encourages technology and social media companies to take more responsibility to stop online spread of health misinformation.

On August 18, HHS public health and medical experts released a joint statement on COVID-19 booster shots. The statement reaffirmed the effectiveness of the vaccine, authorized in the US, and concludes that once approved, a booster shot will likely be needed to maximize protection and prolong durability of vaccines.

Since the American Rescue Plan passed on March 11, HHS has worked to mobilize funding provided in the Act. This funding includes $424.7 million to rural health clinics for COVID testing and mitigation in rural communities, $125 million in workforce grants for community-based efforts to bolster COVID-19 vaccinations in underserved communities, $80 million to strengthen US public health IT and improve COVID-19 data collection and bolster representation of underrepresented communities in the public health IT workforce, $3 billion as part of COVID-19 anti-viral development strategy to accelerate the discovery, development, and manufacture of antiviral medications to treat COVID-19, $1.6 billion to support COVID-19 testing and mitigation in vulnerable communities, and $121 million in American Rescue Plan funds to support local community-based efforts to increase COVID-19 vaccinations in underserved communities.

The response to the pandemic continues to support the principles laid out in a number of executive orders, including organizing and mobilizing the United States Government to provide a unified and effective response to combat COVID-19 and provide US leadership on global health and security, ensuring a data-driven response to COVID-19 and future public health threats and ensuring an equitable pandemic response and recovery.

In other news, we have just marked the 25th anniversary of HIPAA on August 21, a notable anniversary. HHS continues to support the placement of large numbers of refugees, resulting from both the border crisis as well as Afghan refugees evacuated from Kabul. On August 30, following President Biden's lead in declaring an emergency for the states of Louisiana and Mississippi, Secretary Becerra declared public health emergencies for both states. These declarations along with waivers that Secretary Becerra authorized under the Social Security Act gave CMS beneficiaries and their health care providers and suppliers greater flexibility in meeting emergency health needs and disasters. And additional states

affected by the flooding include Pennsylvania, Maryland, Virginia, New Jersey, and New York. And the federal response includes not only support form HHS, but FEMA, HUD, SBA, the Coast Guard, DoD, among others.

Just a few days ago on September 1, Secretary Becerra made the following statement on Texas Law SB8, and he said every American no matter who or where they live deserves access to quality, affordable health care, including safe and legal abortion. Texas Law SB8 is dangerous and dubious. The burdens of this law descend disproportionately upon low-income families and communities of color. The 21st century must be about protecting and expanding Americans' health care, not illegally and discriminatorily denying it.

The Office of Minority Health and the COVID-19 Health Equity Task Force have been hard at work, supporting an equitable pandemic response. On August 23, they released a blog titled using mandatory health, social vulnerability index to drive equitable public health efforts. A lot going on in the department.

Within ASPE, there is also a lot going on. First and foremost, ASPE takes the lead across the department in developing the HHS strategic plan. We are hard at work, developing the next strategic plan for 2022 and 2026. A draft plan will be posted for public consultation later this month.

We continue to work on implementation of the Evidence Act. There are three Title I deliverables that will be delivered to OMB shortly: the HHS Evidence-Building Plan, the 2023 Evaluation Plan, and the Capacity Assessment. These are the first full drafts of these documents, and they are due to OMB on September 24.

We have not yet received final guidance from OMB on Titles II and III Implementation of the Evidence Act, which cover open data and CIPSEA reauthorization. However, we continue to meet regularly within HHS with the Office of the Chief Data Officer to coordinate work on the implementation of Title II. And we work closely with the HHS Statistical Officer and including HHS Data Council to implement Title III.

The Secretary has the authority to waive the requirement of the Paperwork Reduction Act for voluntary collection of information during a public health emergency as declared by the Secretary or when a disease or disorder is significantly likely to become a public health emergency. ASPE is responsible for managing this process and making a recommendation. The authority allows information to be collected for the specific preparation for and response to a public health emergency and avoids the otherwise lengthy public comment and review process associated with obtaining OMB approval. Since our last meeting in March, there have bene ten PRA waivers that have been approved by the Secretary. That is it.

I wanted to also highlight that ASPE has just released several new reports and briefs over the last few months with an emphasis on COVID-19 and supporting agency efforts to combat the pandemic. The research that ASPE conducts includes work on vaccine hesitancy, regulatory impact analyses for regulations, and other policies that combat the COVID-19 epidemic.

I want to highlight four briefs that were just posted. The first is an overview of barriers and facilitators in COVID-19 vaccine outreach. The second is titled unvaccinated for COVID-19, but willing, demographic

factors, geographic patterns, and changes over time. The third is evaluating COVID-19 mortality and morbidity and risk reductions in the Department of Health and Human Services Regulatory Impact Analyses. And the last one is an analysis on the impact of COVID-19 pandemic on major HHS data systems. I encourage you to go to the ASPE website to find copies of these and other research briefs and policy briefs. Thank you very much.

I am happy to take any questions if anybody has any.

Nick Coussoule: Thank you, Sharon. It is good to know that there is not too much going on at HHS today. I will open it up to committee members. If you can raise your hand, it would be easier for us to see and we can have questions.

I will actually start first and then – Sharon, you mentioned that the start of the new Office of Climate Change and Health Equity. How will that interplay with the other organizations within HHS? Do you have a feel for that? I am curious as to how that would be interspersed between the rest of the work that goes on across the other organizations.

Sharon Arnold: It is really just established, and I think that it will primarily be a coordinating policy development activity. It will work with other offices and agencies across the department to try and coordinate and lift up the topic of climate change and equity. I know that we have been in touch and ASPE has been in touch with folks from their office and will be providing I think coordination support and policy analytic kind of policy research support to inform their activities. It just started up. It is a bit of a work in progress.

Nick Coussoule: Vickie.

Vickie Mays: Thanks. Thanks for the update, Sharon. As usual, it is always so informative. As Nick says, not a lot going on.

(Laughter)

My question really has to do with – from Biden on restoring trust in government through scientific integrity and evidence-based policymaking. If I understand correctly, that went to the Office of Science and Technology Policy. If you read the memorandum, it has a big data component in it. I am wondering if you have any sense of what they are looking at or if the report is out.

And then the second thing they also were going to look at is whether or not advisory committee boards, the role that they were playing and making sure that data was going to be inclusive for underrepresented populations. Does that have any implication for us in the work we are doing?

Sharon Arnold: First, I want to say that the Office of Science and Technology Policy at OMB at the White House is developing a report. That report has not yet been released. It is still under development. I think that report is going to provide a lot of guidance to departments in how to implement the law. We are waiting for that.

But while we wait for that, we have been taking a look at the existing advisory boards and policies around the department relating to science and data and making sure that everybody is aware of the need for scientific integrity and for politics not to play a role in the development of results and findings. We have been working towards that.

There are some agencies within HHS that have well-formed scientific integrity policies. We are taking a look at those and trying to use those to inform a department-wide approach. We have started on this work and getting ready. But again, we are getting ready for the guidance from the White House.

Nick Coussoule: Rich.

Rich Landen: Sharon, much appreciate the update. Always impressive as how much work is going on and how many different areas.

I would like to go back and follow on to Nick's question about the Office of Climate Change and Health Equity. Two points quickly. One is I heard you say it is a work in progress. But one assumes that there is going to be data and data flows associated with that. I am wondering how that might impact on the NCVHS charter. I am not looking for an answer to the question, but assuming as things developed, we will be kept apprised of how it may impact our duties and obligations and our opportunities.

My second point is a little bit more specific as we will talk about mostly tomorrow. The Subcommittee on Standards held a listening session about data convergence and other things. I am wondering if we need to look at this new office to kind of build it, begin to build it into our landscape assessment. Since this assumes I believe from what you described, there will be some tie-ins between climate change and health equity and that is not an area that we looked at in our listening session last week. I am wondering if that is now a new gap that we need to – the Subcommittee needs to take a look at in terms of what the scope of our two-year project is and just kind of mapping all the different flows between the shall we say less traditional players in the health and wellness data exchange. This may be a new player.

Sharon Arnold: I think some of your questions tee up my discussion for tomorrow where I am going to provide an overview of the efforts around collection of data on health equity tomorrow and identify some potential work for the committee. I think the first order of business is making sure we have the appropriate data and level of data to assess the impact of anything on health equity. If we do not have the health equity data, we cannot really assess the impact of that. And then the second order at a later point might be to assess the impact climate data. But at this point, I suspect that a lot of that data will be received from other departments and will be at a geographic level potentially. But we have not gotten to a point where we have identified new data collections relating to that. But I think focusing on what kind of data we do collect on health equity and how that can be improved is a huge focus of so much of what we are trying to do in the department that I am very hopeful that the committee can get engaged in that.

Nick Coussoule: Excellent. Denise.

Denise Love: Thanks Sharon for the update and I look forward to tomorrow's discussion on health equity because we heard a lot about that in our listening session and a lot of the data that come from nontraditional streams.

As you are talking about climate and environmental data, I am assuming that the CDC public health environmental tracking network is a big player in this because I was involved with that for 20 years. They have merged data sources from everything from public health data sources to NOAA and NASA. I am assuming that that is a big component of this. Okay. Thank you.

Nick Coussoule: Any other members? Questions? Thank you again, Sharon. Much appreciate your time. It is exciting stuff. We look forward to the discussion tomorrow afternoon as well.

Sharon Arnold: Thank you very much.

NCHS Update

Nick Coussoule: We can proceed to the next item on our agenda, which is an update from a couple of folks at NCHS. Let me update or at least introduce them very briefly and they can tell us about themselves as they go. We will start with Jim Craver, who is the Deputy Director for Management and Operations, Acting Deputy Director for Management and Operations at NCHS at CDC. And then we will move on to Lisa Mirel, who is the Chief of Data Linkage Methodology and Analysis Branch at NCHS, also at CDC. We will start with Jim. Thank you again both of you for being here with us today.

James Craver: Absolutely. Thank you, Nick. A pleasure to be able to present with you. I am going to give you a quick overview of the Data Modernization Initiative at CDC and then dive into what that looks like at NCHS.

The Data Modernization Initiative. It really is a way of trying to shape a new paradigm for sharing and using data across the entire public health ecosystem, starting within CDC and then moving outward. It really is intended to be transformational to how we do business, and we are looking to capitalize on the investments that are being made, which I think you will agree are quite substantial.

Ultimately, the vision of CDC's DMI is to move from siloed and brittle systems that are in some ways fragile to an interconnected and very much a response-ready system at every level of public health. I think the ongoing pandemic has revealed some of the aspects that we really do need to improve on and be able to use what we are learning now so that once this pandemic starts to cool off that we will be more prepared for the next public health crisis.

What are some of those longstanding problems? What are some of the issues that put us at risk? The information that we have often is quite siloed and often there are disease-specific budget lines and there has been decades frankly of what some might say panic and neglect funding cycles that have resulted in many one-off proprietary systems that are tracking multiple, but individual diseases. This presents us from developing really a shared common operating picture of the state of public health and how to intercede in some cases.

We have outdated skills frankly again from longstanding neglect of our workforce and looking for opportunities to up-skill that workforce is now more than ever apparent.

We have many point-to-point data sharing relationships. However, we believe that an architecture more akin to a spoken hub model might increase the ability for data sharing and also visibility of what is

happening in the world. We believe that the point-to-point data sharing model actually creates additional and unnecessary burden on those who are providing data within the public health sphere.

There are many outdated technologies at the local departments of public health. These in some ways are not flexible as they need to be. They are not as agile as they could be. They do not take advantage of new technologies and new IT infrastructure such as a cloud-based system, which means that they are not as scalable as we might need, as this and other pandemics emerge.

Finally, the federal incentives for modernizing health care records and the EHR system. They do not necessarily address the public health needs. They are often left outside of the broad data ecosystem.

With these technological funding policy and workforce challenges, we are trying to tackle each of these in a holistic fashion through the Data Modernization Initiative.

We have in our efforts to revision what the future state might be. We have created an interoperable set of core data pillars or lanes, if you will. These, we are hopeful, will benefit all of public health. Often, we find detection of public health threats has meant waiting for enough people to come down with the same illness or the same injuries for public health authorities to notice. We are hoping to address that to have sooner access to emerging threats to public health.

DMI seeks to strengthen the core surveillance systems that are used by nearly every part of public health to serve as early warning signals for our biggest threats. Systems that handle emergency room visits, case reporting, notifiable disease, lab results, and death data. You will notice at the bottom of the slide, vital records, which is pat of NCVHS' core data system, is a part of these five pillars.

How is this expressed? How is DMI expressed within the National Center for Health Statistics? One way to think of our portfolio of projects is to separate the efforts, focused primarily on improving data sourcing and production and efforts focused on improving access. These categories are admittedly imprecise. There is wide, gray boundary between the two of them. But for our purposes, this is how I like to separate up our different projects that we are working on.

I am going to highlight just a few of these in the next few slides, being mindful of my time. Lisa Mirel will be following my presentation to focus on the linkage activities at NCHS that have a long history but have recently had an infusion of data modernization investments and she will discuss that program.

First, let me go to the next slide and focus on the National Vital Statistics System. As many of you know, NVSS has a very strong presence at the National Center for Health Statistics, but it is also – NVSS also describes the broad ecosystem of mortality and birth records coming from the 57 jurisdictions that we interact with and those are all the states, the territories, and some of the larger cities. Together, the NVSS – we are continuing to reinforce standards development and testing of those standards. We are creating tools and providing technical assistance directly to jurisdictions. And we are engaging with a community of practice where we are hopeful that there will be exchanges of lessons learned and new ways of doing things, both vertically and horizontally across this space.

Progress has been made in the area of improving the quality and timeliness of national mortality data, in particular. We are approaching our target of 80 percent of death records being received within 10 days

of the date of event. These gains have contributed to the COVID-19 response efforts, and they grow directly from our realization of the need for this type of near real-time mortality data during the opioid epidemic. We are currently at about 67 percent of all death records being received within 10 days. As I said, our target is 80 percent, and we are moving in the right direction at a reasonable pace.

Another very exciting area. I mentioned electronic health records before and how often they are left out of the public health picture. We are exploring ways to correct that. We are collaborating with several of the other CIOs within CDC to increase the efficiency of our acquisition and use of these data.

One part of this project is to develop a cloud-based system. We call it HEHR or the Healthcare Electronic Record Cloud Migration project. And that is to increase the efficiencies of the receipt of the processing, the storage, and the analysis of electronic health records, using a cloud-based architecture.

That should also increase the ability of other parts of CDC outside of the National Center for Health Statistics to have access to the same data for their separate programmatic purposes.

We are also exploring the possibilities and have made early efforts to acquire non-sampled EHR data. By merging records from sampled and non-sampled hospitals as well as providers and physicians, we will be able to enrich the understanding of the entire health care system.

Another exciting area is a model-based estimates project. Typically, the National Center for Health Statistics has created estimates based on sampled or administrative records or our vital statistics records. This project starts to develop our abilities to model what might be seen in situations where we have maybe less coverage or less accessibility to certain kinds of data. We are seeking to develop new programming and data management methods to produce statistical estimates based on the modeling techniques from challenging data sets. The result will be new methods that can be adopted by various NCHS and other CDC data systems. We are confident that these methods will allow us to accurately and reliably fill in data gaps for small area analyses and where data is underrepresented for some demographic groups.

Now, this slide gathers the other side of our portfolio, the data accessibility and the efforts to increase the visibility and the ability for folks to know what we have and know how to get it. We have embarked on a data query system that is a companion project to full redesign of our website that will allow people to enter the National Center for Health Statistics without needing to know what data system they want data from. Rather it will be topic-based discovery process. And over time, we are hopeful that this will grow into an enterprise-wide, a CDC-wide solution so that data from outside of NCHS will be available and linked through the data query system and made accessible to all users.

We have begun efforts to standardize our meta-data. This is a critical and necessary component of increasing the visibility. We are developing APIs and we are requiring document object identifiers or DOIs for all of our publications. We are pursuing other data science advancements such as machine learning and natural language processing.

And last, we have initiated efforts to create a virtual data enclave. This system will create a virtual machine at the user's end for remote access and processing of data housed at our research data center. This, you can imagine, was the prompting for this was accelerated by our own researchers having to

work from home and the gains from lessons learned by that can be applied to other CDC researchers, other federal partners, and we are on path to a goal of providing access to non-federal partners by September 2022.

It begs the question, how can we afford all of these changes. We are quite thankful for the various funding support that has been made available to CDC and then ultimately to NCHS.

Prior to COVID, DMI had received the first congressional or base funding of $50 million to put to this work. After COVID began, there was an additional release of funds through CARES and now through the American Rescue Plan. We have gone from essentially nothing to support these activities to suddenly having resources that will help us take us through the concrete steps and make substantial changes.

Again, to reinforce that, all of these efforts are aligning to breakdown information silos, reduce burdens on our partners who provide our data, updating outdated systems, and modernizing data science and skills across the workforce.

One very recent example of release of funds has to do with a collaboration across CDC including NCHS to use the ELC program or the Epidemiological and Laboratory Capacity for Prevention and Control. This is a mechanism for funneling funds from CDC to the various jurisdictions. There are three tiers of these funds. The first tier focuses on implementing health information systems improvement and workforce enhancements. That is across the entire set of jurisdictions. There is about 64 ELC recipients who received funds to work in this area.

The second tier focuses on increasing the national implementation of the electronic case reporting system. This improves surveillance by seamlessly moving data from EHRs into the health care facilities to state and local health departments.

The third tier near and dear to our NCHS heart focuses on increasing interoperability of the NVSS and NCHS through implementation of a FHIR-based solution or Fast Health Interoperability Resources. The recipients' expertise and system readiness for FHIR-based interoperability is quite varied. There are some early adopters who are well ahead of the pack and there are other jurisdictions who are not quite ready yet. We will be using these funds to support the entire NVSS system to come to adopt this FHIR-based, two-way, real-time communication of vital records. It will allow us to increase our efficiencies of pre-coding and correct any cause of death coding errors or inconsistencies in the records and it should ultimately reduce the burden at the jurisdiction level.

This last slide talks about the future state and what we think will be the end result. What are some of the things that this investment should realize at the end of the day? We hope to imagine a future state where hotspot analyses can happen quite quickly. That whatever the variable driving a hotspot can be identified quickly and then the visualization and the reaction to that visualization can be streamlined.

The identification of vaccine deserts would be possible and facilitate the ability to drop into those deserts and make some real changes. The future state will have a more granular county or better level data to track disease down to a neighborhood, for example. Integration of climate information to the effect on disease over health conditions.

What we have been able to prove during the COVID response is that many of these things are quite possible. That we can see the capabilities in the not too far distant future and importantly, we are learning more and more and understanding better and better how to get there.

The last year and a half have been an incredible challenge. But frankly, we have done some pretty incredible things and we are realizing the gains as we speak. Overall, DMI is preparing us to face the next pandemic or outbreak in very tangible ways.

I am going to end there, and we can either go to questions or if we would like to move into Lisa's presentation. I will leave that up to you, Nick.

Nick Coussoule: Thank you, Jim. I think we should probably move to Lisa's presentation because my guess is once the questions start, we will run out of time for Lisa to talk. If we could do that, that would be great. Lisa.

Lisa Mirel: Excellent. Thank you, everybody. I am really happy to be here today to tell you a bit about our Data Linkage Program at NCHS.

As many of you know and this is just to kind of set the stage, but NCHS or the National Center for Health Statistics is the nation's principal health statistics agency. We are 1 of 13 federal statistical agencies in the US Government. And our mission is to provide statistical information that will guide actions and policies to improve the health of the American people.

What I wanted to talk about today is how our data linkage program can really help answer some key policy questions. There are many different pressing policy questions that would require complex and detailed data to be able to answer. A few examples that have actually been asked and used the linked data to address include questions like do Social Security Disability Insurance beneficiaries have access to care during their waiting period before they receive Medicare entitlements. People have used the linked data to look if there are adverse health effects associated with mandatory folic acid fortification policy for grain products and also looking at how effective are health and housing policies in reducing lead exposure.

Being able to link data can be used to answer policy questions as I noted on the previous slide. Linking data is an incredibly powerful mechanism that can provide policy relevant information in an efficient way.

For example, at NCHS, I think most of you are aware that we have many different health surveys. And the health survey data can collect information that monitors health status, health behaviors, and health care access. And then on the other hand, there is administrative data, which as we know, they are collected for programmatic purposes. But when we combine these two types of data, it can efficiently create an opportunity to answer key health and policy-relevant questions.

On the right-hand side here, I have a bubble chart that we put up often when we talk about the linkage program at NCHS that we have these different surveys and then we link to the different sources of data that are noted on the bubble surrounding – the National Death Index, to Medicare and Medicaid, and Housing and Urban Development. In the past, we have linked to Social Security Administration data.

The surveys that we include from NCHS in our linkage program include the National Health Interview Survey or NHIS, the National Health and Nutrition Examination Survey or NHANES. And we include also some of the National Health Care Surveys.

Just to give quick descriptions of the different sources just to get a handle on what is being collected at the survey level, with NHIS, it is a nationally representative, cross-sectional household interview that serves as an important source of information on the health of the civilian non-institutionalized population in the US.

And then there is also NHANEs, which is similar to NHIS. It is a nationally representative, cross-sectional sample of the US civilian non-institutionalized population. It is like HIS. It also has a household component, but it also has an examination component. That means that the participants of the survey actually receive a physical exam in a mobile examination center. That is where we get information about blood pressure, height, weight, and all those sorts of things.

We also include the National Health Care Surveys and their data linkage program. Those are a family of data collection efforts that gather information about providers of health care services and the patients that they serve across the spectrum of health care settings. This can be ambulatory and hospital care to long-term care settings.

As I mentioned, the different surveys collect different information. This slide kind of highlights what some of the we call household-based surveys or NHIS and NHANES collect. Within those surveys, we get information on health behaviors. That could be physical activity, dietary, the amount of alcohol people drinks or smoking. We also get information on health conditions. Participants are asked questions like has a doctor ever told you that you have a certain condition.

We get information on socioeconomic status. That could be income, education, and other demographic type variables. And we also have questions that ask about health care access and utilization.

We can take that information from our survey participants. I noticed actually in the agenda that there is quite a bit about privacy and security. I wanted to touch on that. We have the survey participants. We have their data. But we only include survey participants who are what we call linkage eligible in the linkage activities. These are survey participants who provided consent as well as the necessary personally identifiable information that we could use in the linkage process, and we call those participants linkage eligible.

They found out about our intent to conduct data linkage activities through a variety of informed consent procedures. This can be an advance letter prior to the survey. It can be part of the participant brochure or signed consent form. And then there is also in the NHIS, it is asked about actually within the questionnaire. We take these very seriously in terms of who is eligible, and we only include people who have consented to be part of our linkage studies.

You can see on this slide the percentage of participants who are considered linkage eligible just to give you a sense of who is included in our linkage when we link to the different sources. This is an example using the National Health Interview Survey. You can see around the mid-2000s the percent of

participants who are linkage eligible – it started to dip. It was around 50 percent and then went a little bit lower.

And then in 2007, we had been doing a bunch of research right around this time between 2005 and 2006 as a way to figure out how can we increase participants who would consent to the linkage process. Prior to 2007, participants were considered linkage eligible if they have provided their full nine digits of a Social Security Number when they were asked for that as part of the survey. We really started to notice a reluctance of participants to give that. As you can see, this rate really started to drop and that had an impact on the linkage program because it really changed what could be inferred from those participants who consented to link and then they actually linked. The numbers were getting smaller and smaller.

Starting in 2007, we implemented a change in the NHIS questionnaire where instead of asking for all nine digits of the Social Security Number, we started asking only for the last four. And then if people refused to give that then we asked do you consent to link without providing your Social Security Number. You can see this really dramatically increased the linkage eligibility participation rates. Now, you can see that it is close to 90 percent. This graph only goes up to 2015. Even in the more recent years, I think the linkage we did was with HIS through 2018. And the linkage rate has stayed quite high.

What this has done though is it has caused a bit of change in the methodology in how we conduct the linkages. Previously, we had relied just on deterministic linkages, using nine digits of Social Security Number and then finding that similar nine-digit Social Security Number in the administrative records. Even implementing – this kind of speaks to some of what Jim was getting to in terms of data modernization and really being able to hone in on our linkage efforts and really improve quality while working through some of these changes of having more limited PII. I can get into that more later, but I will not bore you with all of those methodologic examples right now.

Once we determined who is linkage eligible then we run through our linkage algorithm, and we link to the different sources that I noted earlier. We link both our population-based household surveys. That would NHIS and NHANES. And then we link information from our national health care surveys, particularly those that have patient-level data. We actually link the patient information to these other sources. We link the survey data to housing and urban development data to get information on health and housing. We get information about the timing of the housing assistance and the type and the receipt that the participant may have been getting.

We also link to Medicare and Medicaid from CMS. That gets us information on heath care utilization and expenditures. I would say probably our most utilized link data file is the linked mortality file where we link to the National Death Index. We get follow-up information. It is a passive follow up by people who are part of our survey and then those that have died, we find information out about the timing of their death and their cause of death.

With all of this, we have these – as I mentioned, it is almost like a passive follow up of our survey participants. It would be very expensive to go out and find the participants again and be able to do these longitudinal follow-up studies. We have this linkage program. I think Jim had mentioned that it has been around for quite a while. I think it has been over 30 years. We have been linking the survey data to these

different sources. I just wanted to give you a sense of the amount of follow-up data that we have in this graph.

We have NHIS and NHANES. We just released our updated linked mortality file that has death data through 2019. What that means is for some of our survey participants, we do have follow-up information of over 30 years for NHIS and close to 30 years for NHANES. This means if they were in the surveys in the 1990s and then we followed them up now, we can look at their cause of death. And then that can be related to different survey collected variables at the time of their survey.

We have Medicare data. We just actually like earlier this year released our updated Medicare file and that has data with Medicare through 2018. Again, for some of our survey participants, we have up to 20 to 25 years of follow up.

We are in the process of linking to Medicaid. We are going to be one of the first federal agencies linking to the updated T-MSIS data. And we are really eager to do that and learn more and share how that linkage process goes. We have linked to Medicaid in the past. We have used the MAX files for that for those who are familiar with it. We do that all within CMS. We use the files at CMS. We are in the process right now also of updating our HUD linkage to have HUD administration data through 2019.

In addition to the household surveys, we have in recent years spent a lot of time linking the National Hospital Care Survey data with the NDI, with CMS Medicare data, and also with HUD. What has been really exciting, and I think again kind of building on some of that data modernization stuff that Jim was talking about is that we have been able to link electronic health records that are collected as part of the National Hospital Care Survey so this gets patient-level electronic health records. We have been able to link that with other sources.

We have received funding through the department, through the Patient-Centered Outcomes Research Trust Fund to do a lot of these linkages and really document the linkage methodology so that others could implement similar strategies as well.

I put up here a recent publication that came out, looking at opioid-involved emergency department visits with hospitalizations and subsequent deaths. That is from our linkage with the National Death Index.

One of the primary reasons to do that was to really assess what 30 and 60 and 90-day post-hospitalization mortality might look like for some of these patients coming into the hospital care survey.

In addition to these administrative sources, one of the other things that we do with the NCHS data linkage program is coordinate geocoding of all of the survey data that we get, and we have also worked with the Division of Vital Statistics to geocode death certificate data.

What is very exciting about bringing the geocode data is that you get this additional auxiliary information that you can bring in at that geocoded level. You can bring in information maybe from the area resource file or different places to augment the survey data or augment the death certificate data.

One example using the survey data was looking at air pollution exposure and then subsequent heart disease mortality from our linkage with NDI and race ethnicity, which was collected as part of the survey. This is an example of using many different sources to answer some key health-related questions.

In terms of the death certificate data, our group coordinated getting the geocodes, but then the Division of Vital Statistics and I believe they partnered with the Robert Wood Johnson Foundation and put out the US Small-Area Life Expectancy Estimates Project or USALEEP.

Again, just to keep highlighting ways that our linked data could be used to answer some key questions, they have been used to answer key policy questions, key epidemiologic questions. There have been over 1000 publications using our linked data files. We keep track of these on a bibliography on our website so that researchers or users can see what different types of publications have come out using these data.

Just some examples that I put on here with the respective journals are looking at deaths associated with underweight, overweight, and obesity, looking at diet quality and all-cause mortality, looking at education differentials in the US about mortality. And then people have used the linked Medicare data and Medicaid data to look at maybe some health characteristics of those who enroll in Medicare Advantage compared to fee for service when they enroll in Medicare, looking at health service use among those who were previously uninsured.

People have used it to look at reporting childhood asthma in the survey data compared to what is actually in the Medicaid files. And then there has been some really exciting work using the HUD data to look at housing assistance and blood lead levels, comparing those who are in assisted housing to those who are not when they have comparable socioeconomic conditions, looking at cigarette smoking and adverse health outcomes among those receiving federal-assisted housing and looking at housing assistance and its association with insurance rates and unmet need. Again, this is just a small sample of some of the work that has been done using the NCHS linked data. I did want to highlight that.

We have been spending a lot of time – it actually has been such an exciting time to be here. But I think more than anything we are really trying to create resources that support evidence building. We are linking our survey data with health-related administrative data. We spend a lot of time on our documentation and our linkage methodology, really honing in on trying to get very low linkage error rates and really improving our linkage quality methods. We provide analytic guidelines to all of the researchers too. We have a data linkage in-box where people email questions and we really do try to work with researchers because working with the linked files can be somewhat complicated and we try to make as easy as possible for people.

And one of the big things that we do is release curated data files for multiple research projects that could be used to replicate findings of other researchers or just to have them over time.

I do want to be mindful – I want to just talk about these files. But I just wanted to note about how people can access the files. Most of the linked data files are restricted use files and they can be accessed through the NCHS or Federal Statistical Research Data Centers. Again, this somewhat builds on what Jim was talking about with some of the data modernization initiatives and the virtual data enclave. I think

there might be some improvements to access with that where you might not physically have to go to an RDC, but you are still going to be able to access some of the restricted files.

But we really do try to be mindful that people want to get some public use data. We do put out a very limited number of public use files. The most utilized is our public use linked mortality file. Right now, we have through 2015 even though the restricted use data, we have death data through 2019. We are in the process of working to update that public use linked mortality file and we are hoping that we will release an updated file in early 2020.

We also put out what we call feasibility files for the Medicare and Medicaid data. This allows researchers to assess if a survey participant matched and they can assess sample sizes before they put in a research data center proposal.

I wanted to note just some really exciting upcoming data linkage activities. The Veterans Affairs linkage is actually funded in part through the Data Modernization Initiative, and we are really excited to get that off the ground.

We are hoping to have the files with the NCHS survey data linked with the VA data coming out in early 2020. Some questions that could be answered with those data would be what are the health characteristics, health outcomes, and health care utilization for veterans within and outside the VA health system?

As I mentioned, we are going to be linking to the Medicaid T-MSIS data and we are hoping with that one as well to have those files available in early 2022. People would be able to use those files to look at changes in health care policy and how they might affect the health status for Medicaid recipients.

And coming up actually I am hoping by the end of this month, I am being pretty optimistic, but we are going to be releasing an updated file that will include survey participants linked to end-stage renal disease database. What this will tell us of our survey participants how many have end-stage renal stage. It is a very small percentage of the population, but it is actually a very large cost for Medicare. I think it is a very important group to understand and be able to do additional research on.

And then just to touch on some data linkage program future directions and I think this builds off of what Jim was talking about in some of the Data Modernization Initiatives. We have been working to incorporate machine learning algorithms to improve our linkage accuracy and efficiency. We have been assessing privacy preserving record linkage algorithms as a way to increase our linkage activities across the health care spectrum without having to share identifiers.

And we have a very exciting pilot going on to create methods for public-use linked data files so not just focusing on the linked mortality files, but focusing more on all of the linkages and I think kind of speaking to maybe some health equity and social determinants of health and be able to get additional variables on our linked files out there by creating synthetic data, which will improve accessibility while we are still reducing disclosure risk.

We have a lot of exciting projects going on and we are really excited to embark on these and others. That really is it. I just included a bit of information about our program. It has the website, my email, and

our data linkage inbox email. Again, thank you all for having us here today. It is really exciting to talk with you all. Please let me know if you have any questions. Thank you.

Nick Coussoule: Lisa, thank you very much and Jim, thank you as well. I would like to open it up now to the committee members for questions for Jim and/or Lisa. Please raise your hands.

Wu Xu: Thanks, Nick. Thank you, Jim and Lisa, for your very comprehensive introduction. My background is a state health data and informatic director. I have a question, a very specific question for Lisa. It is very good to see your survey data linked with different population-based data. You also mentioned the link to the survey data. My question is have you been thinking about reaching out to the states. They have a population base that this charge database, emergency, inpatient, outpatient, you name it. I just want to ask this. Is this in the plan?

Lisa Mirel: That is a terrific question. We actually have done some pilot projects of working linkages directly with states. We actually did a one-state pilot project, linking the survey data with food stamp or SNAP benefits. I think it was in Texas. It was fascinating. We were very excited to do it. But I think the hard part was really being able to negotiate with all of the different states and being able to get those agreements in place that we would be able to have it in efficient linkage process.

I think one of the barriers there was really working on agreements and data sharing, doing it state by state. That is where we focused more on the federal databases where we have been able to do the agreements at the federal level.

Wu Xu: I have a follow up question for Jim. I am so happy you talked about the data accessibility section. You mentioned data sharing will cross all levels. And you have a database building up. But I think in the meta database maybe need a state of data sharing policy inventory. That way it is easy for shared data across states under different policies so it is easy for nationwide linkage and sharing. Just a thought.

Jim Craver: Thank you for that. As part of the Evidence-Based Act, there is a requirement to develop an inventory of data assets. That work is ongoing and underway out of the HHS chief data office. Sharon and Maya and others at ASPE were very instrumental in getting that work off the ground. There is data.gov, but I think the next generation of the inventory of data assets across HHS will meet some of the need that I think you are pointing to.

Nick Coussoule: Denise Love.

Denise Love: Thank you very much for the presentations. I am going to follow up a little bit from Wu Xu because I also was thinking about state data assets. As Jim talked, I was thinking what is the scope of public health? It looks like you are zeroing in on the core traditional data sets. I thought about the states who are really expanding beyond that core to novel data sources like all-payer claims databases that could also be early warning indicators because mortality data is such a lagging indicator. Opioids is one example where the states are really looking at prescribing patterns of the APCDs to look at early warning that you are seeing huge variation in certain areas that precede the mortality data. I really think you can be looking at the states now to get a pretty good sample of data or the insured, the privately insured.

For Lisa, I have a question of the hospitalization data at the states because every state has a statewide data set. But I see the problematic of negotiating individually with states. I do not think it is as hard as it has traditionally been. Have you thought about the HCUP, or do you work intramurally with AHRQ and the Healthcare Cost and Utilization Project, which has the population databases for emergency department and ambulatory surgery and inpatient?

Lisa Mirel: Another great question. I think it has definitely come up with HCUP in the past. I think in terms of the way that we conduct the linkages using personally identifiable information, I do not know that is captured within HCUP that we would be able to do those entity-to-entity linkages.

Denise Love: It probably is in their intermural. It would have to really be negotiated probably secondary release -

But the other thing I wanted to say is the associations. When you are doing your inventory through – I do not know if there is a data council of the state databases. The associations such as NADO have done extensive inventories down to the data element level of what states are capturing. That sometimes takes two years to compile. I am just pointing you and I would be happy to follow up if you need to with some of these associations who very much track what their members collect. The statutes, the regulations, and the data manuals are all compiled.

Lisa Mirel: Great. Thank you.

Nick Coussoule: Vickie Mays.

Vickie Mays: Thank you both for your presentations. Most of my questions are actually for Jim because they have to do with the Modernization Act. One of the things I am well aware of is that part of particularly the CARES money in COVID was pushed by the Congressional Black Caucus to really change where we are with those statistics on race and ethnicity. I really did not see a lot about that. It kind of got to your last slide where it seemed to be more of an aspirational activity.

Let me ask some specific questions. For example, in the beginning when you talked about these data techniques that you wanted to work on, one of the things we know that is a problem to be solved is the development of small population statistics. I heard you talk about small area. But given where we are in terms of issues of privacy and confidentiality and security with the Census, how, for example, are you all thinking that through?

The other think is that lots of the resources seem to be going into CDC. I think CDC at the federal level can have lots of bells and whistles. But what we are seeing is if the states do not give you the data, if the states do not have the capacity to produce the data for you, the advisories that we are getting from the federal level are actually problematic.

A great example is – Denise kind of alluded to this. If states are not – have the capacity to respond quickly, if states do not have the modernization in their data set to have expanded race and ethnicity data then either you get it way late in the epidemic, you do not get it and it takes weeks for you to go back and find it, or what happens is there is no enforcement policy. Right now, for example, CDC does not give great child data in terms of COVID. We had a presentation on that in our meeting last April

where you can see states are just almost absent. And then when a national policy is made and you have not race and ethnicity nor all the states, the policy has differential impact by race or ethnic groups.

Could you talk about some of this because this is my understanding of what a lot of the CARES money was designed to do? I am trying to understand how the states are going to get the data to you if the modernization is just within mainly CDC.

Jim Craver: Thanks Vickie. I appreciate all your points. I think I agree with where you are coming from on this. It allows me to point back to one of my last slides, which has to do with using the ELC program. I mentioned that that is a 200-million-dollar program. I can let you know that 100 percent of that $200 million will go through CDC to the jurisdictions. That is not $200 million for CDC. CDC will administer that and that is – you take $200 million and you divide that by 57 or 64 depending on how many jurisdictions. It starts to pare down pretty quickly.

But it is a specific effort to up-skill both the workforce, the infrastructure, and the data exchange between the local jurisdictions and CDC. That is one very concrete example to your point. These data are to – or this funding is to increase the ability for the local jurisdictions to be able to also modernize their systems and their abilities.

The model-based estimates program I mentioned – you correctly noted that it is for small area estimates, but it is also for looking at underrepresented parts of the demographics – and trying to do our best to guard against those sorts of things.

I am not sure if I answered all of your questions. But hopefully, that will give you a sense of where we are.

Vickie Mays: I guess the question is the priority, where you are going to prioritize fixing a system or prioritize making sure that the system collects the race ethnicity data. What we are seeing as people are modernizing a method of collection and then the money is running out for the actual collection.

And then I think my other question has to do with I did not hear anything about NDI and NVDRS. Again, to Denise's point, NVDRS is the source of suicides/homicides. We are looking at opioids. That is a data set that I and others have written quite a bit about its need for modernization, the ability to be able to better use it, its lack because of how it is set up. Sometimes the collection of some of these social determinant variables that in a surveillance of deaths you really want.

And with NDI, I think it is the issue of researchers have always complained about the costs and the cumbersomeness of being able to use NDI. I think here those are on the table for modernization.

Jim Craver: I would say that some of our efforts in the tier 3 of the ELC program have to do with increasing the education of medical examiners and coroners. As you probably are quite aware, there are issues related to third-party designation of race ethnicity on death certificates. That is quite problematic, and the program is to get a proxy first and foremost, but you know that that is not always the case and even proxy designation of race ethnicity is sometimes problematic.

Up-skilling, training, guidance to the medical examiners and coroners is definitely part of the process of improving the National Vital Statistics system.

NDI just real briefly, that is a well-known critique. The cost and difficulty of using that data. It does not mean that we are ignoring that. We have regular conversations with NAPHSIS and with them the jurisdictions. As you may know, the data that we receive, the mortality data is governed by 57 separate contracts. Those relationships are negotiated on an individual level with consistency coming from above and the associations that are around the space. It is like a large oil tanker that does not move fast on the ocean, or it does not turn quickly on the ocean. It does not mean that we are not mindful of these questions and concerns and are trying to attend to it.

I appreciate your questions and we are endeavoring to improve the quality and coverage and accuracy of those data.

Lisa Mirel: And if I can just jump in really quickly, I know we are tight on time, but I think, Vickie, I did want to mention that one of the things that we are – it has kind of been – it is an initiative we put forward for the next year, using the linked data as ways of taking a self-report from the survey and then comparing that with what is in the administrative data and maybe working to develop methods that are there ways to impute. Is it bringing in some of that geocoded information and trying to develop something where we might be able to address some of that health equity and race ethnicity through the linkage program? It is on our radar as well.

Nick Coussoule: We are running a little short on time. We have two more members with their hands up. If we could try to get through those and then we will try to move on. Rich first and then Melissa.

Rich Landen: For Jim Craver, thanks for the presentation. It looks like it responds well to some of the recommendations that NCVHS sent to the secretary back in 2018. Glad to see it is from federal leadership and glad – the monies.

My question is one of your slides earlier on talked about CDC developing some standards and the question is is CDC developing standards on its own or is it working through one of the accredited standards development organizations such as but certainly not limited to health level 7, HL7.

Jim Craver: The simple answer is yes, very much so. HL7 is – we are very connected with them and the FHIR standard is also something that we adopted through conversations. The short answer is really yes.

Rich Landen: Good. I think that goes along with the statement you made that one of the objectives of the program is to reduce the silos. Good answer from my perspective. Thank you.

Melissa Goldstein: Thank you both for such interesting presentations. We really appreciate you helping us through these issues.

I think my question is primarily for Lisa. Although, Jim, it might be appropriate for you as well. I am trying to think through the linkage ideas with respect to the larger linkage goals of the Evidence Act and how they might be interrelated and how what you were doing is going to affect what happens with other agencies and what HHS shares with other agencies or how you integrated information from other

agencies. Honestly, I do not know enough about the topic. I was hoping you could give us a little bit more info on that.

Lisa Mirel: I think that is a great question and I know – we were very excited when the Evidence Act came out. I think exactly what you are saying. How will the linkage program fit within that?

One of the things that we really thought about – we are eager to partake and be part of facilitating linkages working with different groups. But I think that we saw that both ways could coexist. And that our linkage program – it is kind of what I was alluding to where we have data sets that they are not just put together to answer one question. That is somewhat what I was reading – kind of understanding with the Evidence Act. You come in. You have a policy question. You put these sources together whether it be in the NSDS or some other location, answer the question and then it is gone.

But I think with our program it is that we are putting the sources together. We are taking the survey data with this administrative data. It could be used to answer a variety of questions. We update it over time as new data come in, as new survey data. I think thinking about that graphic. You have this follow-up period. You have these outcomes for our participants. I think it really can go both ways.

There is this curated file that we have that could be used, multiple questions, looked at over time and that kind of thing. And then you have – where maybe with the Evidence Act, it is like let us put these together and let us see what question.

I think one of the things we really are hoping that our group will be able to really help with as the Evidence Act comes into fruition and we have these linkage capabilities sort of the methodology that we have been working on over time and really putting sources together, depending on if there is limited PII or not and the different methodologies we have used to really improve linkage accuracy and quality. I hope that answers.

Melissa Goldstein: It does. One follow-up question. Do you think that a combination of the two – I am just going to call them programs for lack of a better word – will affect how you seek the consent of your participants who gave you the four digits of their Social Security Number and the people that give more information. Do you think you will have to rework that, change the consent, and include things like sharing it with other agencies or do you think that your current methods actually cover that idea?

Lisa Mirel: That is a really great question. We do have an ethics review board that does – that we do put a protocol in to approve all the linkage activities. It is a great question about the consent because right now it does say consent for linking to health-related administrative data. I think that becomes broader and broader like when we incorporated HUD and really thinking about health and housing and SDOH. It might be something we would have to consider. That is a great point for us to put on the table.

Melissa Goldstein: Thank you. I appreciate your help. It is a lot to think about.

Nick Coussoule: Lisa and Jim, thank you again very much for your time and attention today and bearing with us as we have lots of questions. Frankly, I wish we had more time, but thank you again for your time and attention and lots of really good information today.

Jim Craver: Thank you, everyone. I appreciate you having us today.

Nick Coussoule: We will move on, Rebecca, to the next item on our agenda, which is our PCS Subcommittee report out from the July 14 hearing. I do not know, Melissa or Jacki, who is going to take the lead on this.

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Jacki Monson: I am going to take the lead it and Melissa will chime in as she wants. Let us go ahead and get started since we are 16 or 17 minutes behind now. The plan for today is to review the hearing as well as the major themes, to review next steps from the project scope, the timeline, and then we hope to spend most of our time actually in discussion to get the committee's feedback based on what we share in our slides.

The first panel that we had, and I will just say high level. It was a very productive hearing, very robust speakers that we had. We, I think, learned a lot from it. If it feels like the slides have a lot of information in them, it is because they do, just given how robust the dialogue was among the various panels that we had.

The very first panel that we had was addressing healthcare security challenges. You will see the panelists listed below. This was really looking at the practitioner perspective. At least the first two or first three speakers are really practitioners who are with us every day. And then the last speaker, Denise Anderson, really is over what they call the Health-ISAC, which is the information sharing mechanism and organization for health care as it relates to cyber and information security threats and intelligence.

The major themes from this panel really were the need for more sharing and coordination of best practices for cybersecurity. As I am sure you know, there is quite a diverse population as individuals in the health care space whether it is a solo physician practitioner or a large health care system. Sharing among those groups would be helpful.

They also wanted increased awareness of HR 7898, which is a public law. You can click on the link and read it if you would like. The next one is really fewer penalties, more incentives for cyber. The incentives really would focus on those that have the need to update technology that might not have the latest and greatest security hygiene and fewer penalties for those who end up in a cyberattack.

The next one is sharing of threat information so threats, meaning particularly threats against health care and understanding how to address those threats to mitigate them as an organization or as an individual.

Another suggestion or theme was a playbook of the top 20 things to do for cybersecurity response. There was a robust discussion about the lack of expertise in cybersecurity in health care. What that really means is we have a lot of challenges as it relates to cybersecurity, but we do not necessarily have all the expertise to bridge the gap.

And then the thin margins in health care impact our ability to invest in the cyber hygiene that we need.

We asked every single panel what their top two priorities were if they asked us to focus our energy either to a letter to the secretary or other types of recommendations, what that would be. For each panel, we will share what those top priorities are. For this particular panel, they wanted a playbook that could be shared, more accountability for vendors on security updates. An example of that is patching requirements. For example, if there is a vulnerability in Microsoft technology, they want to know what the patching requirements would be for that particular security update and want the onus to be on the vendor versus on the health care organization.

They want more support within the operations division that represent the sector risk management. ASPR has a really small amount of FTEs. They really want more dedicated FTEs to be able to do more coordination among the government agencies who might be involved in any kind of cyber response.

And want the implementation of that public law. They wanted to bypass the RFI and go directly to the NPRM basically to not cause delay and hope that we can implement the law as soon as possible.

And then more coordination/collaborating when incidents happen. Most of the time when incidents happen today, it is mostly accountability of that organization or that individual. They would like more coordination and help and resources when those types of incidents happen because ultimately at the end of the day, it impacts patient care and – patient safety. Collaborating would help that.

That was really the practitioner perspective. Panel 2 was focused on state, tribal and other perspectives on health care security. The two panelists are listed below. Very diverse backgrounds, very interesting perspective.

The major theme in priority areas is cybersecurity governance, critical infrastructure, workforce development, going back to the last panel, really getting people to understand both from a technology perspective, but also the development of how you might respond or not, click a link – email. And then response planning so again how do we respond to a cyberattack that happens.

How to deal with legacy systems at the state level. There was a robust discussion about legacy technology, use of old operating systems and what that essentially equates to is oftentimes patching or any kind of security updates is not an option because the technology is so old. That is something that was a big part of the discussion in this panel. And then examining the risks for the organization and sharing threat information consistently with what we heard from panel number one.

The priorities that were recommended from panel number two was public health should have a seat at the table for a very newly designed Cyber Safety Review Board. Need help with legacy technology including financial support. That is consistent with what we heard from panel one. Public health and health care organizations are struggling on upgrading or securing legacy technology. And then more information sharing on threats including the risks and the remediation recommendations.

Security hearing panel number three. This was emerging security threats and preparedness across the industry. These two panelists, one is from NIST, the other one is from Verizon – had very interesting comments.

The major theme from them was the need to adopt practices to make data less vulnerable. Ransomware is 10 percent of all the breaches that are occurring. This is a major change from prior years, which we have also seen increases in cyberattack. It is very consistent. Cloud assets are attacked more often than on-premises resources because data is more accessible in the cloud.

Breaches are more often outsiders, motivated by financials. Criminals will follow money wherever it goes. The rise of social engineering attacks. Those are an example that would be a phishing attack where they are specifically targeting an individual or organization and trying to entice to click the link or to respond via telephone call.

Privilege misuse is common in health care. Malicious insiders, using access granted for a job to do something else. Snooping or stealing data to monetize it in some form. And then these incidents are of course more difficult to detect because they are employees with authorized access.

Additional major themes. The opportunities for outreach, not just putting out documents of videos or infographics to help people and organizations where they are. Ransomware is a service. There is a market for malicious capabilities, looking at the research opportunities to begin to have the guidelines and standards that we need.

Security is not one size. It really needs to be risk based so it should be tailored to each organization's own environment. Detection and response need to be prioritized. Incident response plans are key. Cyber is not a problem to be solved but managed. Ultimately, it is a risk management issue for every organization, large, small public, private, et cetera.

The major themes, as you can start to probably see, that the themes across the panels are very consistent. Security is not one size. It is risk based so people can tailor it to their environment. Detection and response need to be prioritized and incident response plans are again key.

With ransomware, the importance of being able to separate backups from regular systems, because they are actively looking to see if they can get to your backups as well as those regular systems.

Security panel number four. Panel four was focused on the federal perspective on security infrastructure and enterprise-wide risk management in health care. The panelists are listed below.

The major themes from panel four was a proactive view of not only enforcement but also the opportunity for education. The possibility of revisiting penalty caps needs to catch up with the multi-billion-dollar industry.

Cyber should be looked at from all angles not just IT, but also at the Board of Directors level. Education is needed for the C-suite. HR 7898, amending HITECH, addresses incentives for cyber. That is the same public law that was mentioned in the very first panel that they wanted active deployment of.

A focus on small and medium need for resources for cybersecurity. And amplifying existing public-private partnerships and tools.

The priorities that were recommended is CMPs and CAPs had not been updated for the growth in types of attacks and breadth. It could be an area to explore or develop a possible position for. Additional legislation may or may not help. We need education and enforcement to compel greater compliance. Risk management and risk analysis are seen as vague and cumbersome to do, and that lends itself to not knowing what they are supposed to be addressing or assessing.

I also thought it was relevant to mention developments. But since we have had the hearing, there has been a lot of activity going on. We have just put a list of those as well as links to that because I think it is relevant to what our work product could or should be.

The first one is actually a House Subcommittee on Oversight and Investigations, and the Committee on Energy and Commerce held a hearing on July 20. And the focus of that hearing was to stop the digital thieves, the growing threat of ransomware.

The second activity was President Biden signed a national security memorandum on improving cybersecurity for critical infrastructure control systems, which basically it addresses the critical infrastructure and implements efforts to meet the threats that we currently have today.

The White House held a meeting with private sector CEOs to discuss how we can work together to collectively improve the nation's cybersecurity. There is a cyber bill introduced by Senators Mark Warner, Marco Rubio, and Susan Collins that would require private sector companies to work with the government or provide critical infrastructure services to disclose cyberattacks on their systems.

Additional recent developments from CISA or the Cybersecurity and Infrastructure Security Agency. They launched a website that is about stopping ransomware. They released tips for actually preventing ransomware. The issuance of a blacklist or basically a catalog of bad practices. They have a Joint Cyber Defense Collaborative. And then just a few weeks ago, they introduced Cybersecurity Workforce Training Guide for really current and future federal, state, local, tribal, and territorial staff looking to expand their cybersecurity skills as well as career options. And then a Vulnerability Disclosure Policy Platform.

The last one is OCR and put out a cybersecurity newsletter in the summer about controlling access to electronic protected health information.

Review of steps from the scope of the project. Phase I was really to conduct an environmental scan to explore the key security challenges and opportunities for securing PHI. We have done that at least one time now. We just had a hearing in July.

The second phase of it would be to take what we learn from the environmental scan and develop a potential model and from their recommendations.

Phase III would to be prepare recommendations for the Secretary. This could be a framework of guiding principles, best practices in security policies, the levers that we believe HHS can apply and then legislative mechanisms such as enforcement. And then obviously, the last piece of that would be to actually prepare the letter for the Secretary.

Phase IV would be to prepare the report for the industry and the data stewards, report, primer or toolkit, et cetera.

Here is our timeline. It was first a hearing. Right now, we really want to discuss what is discuss, what would our work product look like. That would be the development of the draft framework. And then I think later on once we sort out what that framework or recommendation will be is when would start Phase III and Phase IV.

We drafted these questions. It is really meant to be a discussion with the committee. We are really looking for your feedback as industry experts on where do you think the biggest security opportunities are that health care industry and patient safety should address. And then what do you view as the most valuable next steps for PCS to focus on?

I will open up the floor for Melissa, wanting to make any kind of comments or anybody else who would love to entertain these two questions.

Melissa Goldstein: I think that was a great summary, Jacki. Thank you.

Nick Coussoule: Just one point. I think one of the aspects that came up in the hearings, not the hearings, but in our discussions were a focus on – I am going to sound like I am going to be kind of counterintuitive – but focus less on what I will call the penalizing aspect of something that happens and more on the education and capabilities aspects. I think of it almost from not just a protection model. I think historically when we looked at information security, we thought about how high can we build the walls, how deep can we build the moat. From a practical reality standpoint, I am a little bit of a fatalist in that and having had this responsibility for this for a lot of years. It is really not an "if" question. It is more of a "when" question and how bad.

The focus that came out of that – I think it was the third panel. It came up in others. As much of a focus on detection and quarantine and response versus a total focus on prevention. I think that is from a committee perspective, one of the things that we could take up a little bit is how we can also help with an education perspective on the thinking process of not just how do we stop things from happening, but how do we quickly identify – minimize the impact and deal with the response side of that because I think that is almost more important because the success rate of hackers if you look at nation states and other kinds of things is about 100 percent. We have to get past a little bit of the – not that we do not want to stop prevention at all, but we have to get past that I think to focus on the other side.

And then the other comment I would make and then really ask for a response from yourselves or other committee members is the penalty side of it. It seems a little strange on the surface to penalize people that get hacked. But what you are really trying to incent people is to do the right things. I think we have to change the mindset. It is not a penalty for being hacked. It is a penalty for not doing the things that you ought to be doing to protect as well as respond, et cetera. Just some thoughts and obviously any comments from Jacki or Melissa or others in regard to those.

Jacki Monson: Nick, I think that was very consistent with what we heard from the first three panels. I think we heard different perspectives from OCR and that potential increasing penalties that I think we,

as a committee, could potentially inform with whatever work product is going to be for recommendations and what we think the focus should be.

Nick Coussoule: It is an interesting question because if the penalties are small enough such that large entities decide it is actually worth paying the penalty as opposed to doing what is right, that is an interesting challenge. If you have a company that has $100 billion in revenue and you fine them a million dollars, it is a kind of a rounding error. At the same time, smaller companies that do not have the same wherewithal – it is an interesting mix of how you deal with appropriateness and incentives for people to do the right things as well as recognizing the risk of not doing the right things has to matter.

Jacki Monson: Absolutely. Denise.

Denise Love: Thank you for the overview. It is pretty comprehensive. It really freaked me out about the cloud. I think that is – personally and as public health goes more to the cloud and everyone else, that really got my attention.

My questions are on the scope. It is a great overview of the threats and the cybersecurity need. But I am going back to our listening session and there were some privacy-related issues that the industry brought up that may or may not be in scope. But I do not know where it would go. The laundry list just quickly – patient authentic – and minimum necessary guidance as we exchange data in more real time. Legal protocols for good faith sharing. Some of the clinics and others do not know what that safety net is. If they share something with the social service agency and good faith and it is misused, what are their protections? I think that is what it means.

Non-health exchanges. Some of the providers are concerned as they take PHI and share it with the food bank or other things as we are doing social exchange of data that is outside HIPAA and they are fearful that some of the information may go downstream or upstream beyond their control. And then API registrations. Those are just a few of the things that jumped out. I do not know exactly where to go with it for the committee if we just park it in your work plan or just acknowledge that these are issues to be worked on in the future.

Jacki Monson: I, personally, and will also let Melissa comment on this – I think there are some trends in what you just described around good security controls and good cyber hygiene that is probably relevant to what we are working on right now. And then I think it sounds like the rest of it at least what you described is more like use and disclosure challenges and opportunities, which would not necessarily be in scope of what we are doing right now with this. But we can certainly put it on our parking lot. I think it actually might already be on our parking lot of issues that we might want to focus on in the future.

Denise Love: Okay. Thanks. You will hear more about some of these privacy-related – that we were just going to punt to you anyway.

Jacki Monson: Other questions? Nick.

Nick Coussoule: One more topic and I know it came up in the last panel, which was in regard to education. Those of us who are in the practice area – I know you directly are finding people with the right kind of skills to help advance this is very difficult. But I think in some ways the unemployment rate

is probably negative for security professionals today with way more need than there are available people with the right kind of skills.

I think the big idea of thinking through ways that we can help create a broader audience of people with the skills with the kind of different training programs, reaching people who may not have normally approached this kind of skill or activity I think would really be important because I think this is a structural problem. I do not think it is a temporal problem. I think it is a structural problem. I think anything we can do to try to incent that or encourage that or look for those kinds of solutions would be really helpful.

Jacki Monson: I agree. I do not see any other hands up. Tammy.

Tammy Banks: I think we talked about this in the Privacy meeting, as well as the expansion of entities in regard to where the information is exchanged especially when we talk about social determinants of health of not only as the patient's information with the health care staff but as well as the community service organizations and other entities as we begin to roll out that public health piece.

Jacki Monson: Thank you. Rich.

Rich Landen: I am just impressed by the information coming out of this panel and how well it has been summarized here. Thanks a lot.

One of the things that strikes me is some of the similarities between the issues of security within health care organizations and what we in the Standard Subcommittee have been seeing about standards implementation. A lot of parallels there. To an extent, large organizations be they payer, provider, or vendor have the professional management, the ability to budget and dedicate resources. The smaller you get – I am using smaller here very relatively because it – maybe talking a mom-and-pop enterprise, one physician office or a small community hospital or a rural health center. They have neither the expertise nor the budget, nor the ability to attract the type of expertise that they really need to meet the objectives that the panelists have laid out.

No solution here but in terms of thinking there is a role for penalties if you do not do your homework. You should get a slap on the wrist. But also, incentives would help. It is easier to go with a carrot than the stick.

But above all, I think it is a matter of research and education, especially as we – health care in general for the last 10 or 20 years has been going gung-ho down into electronic health records and now data interoperability. We have APIs with the patient engagement aspects of that too. I think leadership and just sharing as much information and making it as simple for implementers as possible are things we should keep in mind as we go forward. Again, a great program. Thanks so much.

Jacki Monson: Thank you for your comments. I actually think the pandemic has made it worse for even large organizations to maintain talent because of the remote work environment. They can work anywhere. We are losing good talent in nonprofit health care to tech because we cannot compete with it. Even in my organization, we are having trouble keeping all of our talent because of that. I completely

agree that small organizations are even more challenge or now possibly impossible just given that. Thank you for your comments.

I do not see any other hands. Nick, I turn it back to you.

Nick Coussoule: I guess I would ask one other question, Jacki, of you or Melissa. What do you believe the next steps are for this work effort and how the rest of the committee can help participate in that beyond obviously the PCS Subcommittee?

Jacki Monson: I think it is probably forming a Letter of Recommendation. I think we have enough information, enough consistent themes now that I think we can start putting pen to paper and start writing what are our recommendations would be for the Secretary.

I think the one piece that we have not really had a lot of time to discuss as a subcommittee is whether there is anything else that we can do in regard to a toolkit or otherwise that might be useful for the industry in this area. That is one that I think is still outstanding just because we have not had the time to have a robust discussion around there that we would want to still explore.

Nick Coussoule: That sounds great. Any other comments from Melissa or any other committee members?

Melissa Goldstein: No, I think, as Jacki described, there was some interest among the panelists and some sort of toolkit guidance document. I do not recall whether they thought that we would write that or HHS would write that or OCR, but I think there definitely was interest.

Denise Chrysler: One of my observations from our speakers who pointed to so many resources, it was like drinking from a fire hose. There is just so many. It was not just at least as I heard things creating new resources and I believe it was, Jacki, you mentioned curating resources and especially resources that are geared towards smaller organizations and include those, as you had said, the essential steps of responding to a security incident. I know my take-home message for myself was how vulnerable you are on very simple things like the phishing email was the cause of one of the security breaches that was highlighted in the presentation and to what extent do we educate our staff about the very small things that can have major repercussions.

Nick Coussoule: Okay. Jacki and Melissa, thank you. You went through a very significant amount of material in a short period of time.

Maya, you have your hand up.

Maya Bernstein: I just wanted to add that in the past, if it is appropriate to suggest that if there are members of the committee who are particularly in this topic or want to follow this more closely, there is no reason why if they are available, they cannot join the Subcommittee in the development of whatever recommendations the Subcommittee comes up in. In that way, you have more buy-in, I guess, from the committee by the time that it appears – more people would be familiar with it. If that is of interest to the subcommittee chairs or the members of the committee, just a suggestion that that is available to you.

Jacki Monson: We would always love more help.

Nick Coussoule: I think sometimes we tend to operate in our lanes of particular expertise or background, but it is oftentimes very valuable to get perspectives that are not linear that do not necessarily follow the same path because it really helps inform it and broaden the discussion. I would encourage people also if you have an interest even if you do not think that you might have quite the right background. It would still be very useful to be participating if you are both willing and able to do that. Absolutely encourage that.

Again, thanks for providing some really good information.

Maya Bernstein: There is a question in the chat about the timing. Do the co-chairs – any sense of timing yet about how the process is going to proceed. We have another Full Committee meeting I think in – when is the next Full Committee meeting? Is it January?

Nick Coussoule: In January. Yes.

Jacki Monson: I do not think we have discussed timing in any degree because I think we have to sort out the toolkit piece and decide what we are going to focus our resources on. I would say soon. In the next few weeks, we should know more about timing.

Nick Coussoule: It is great. I missed the chat. Thank you.

Then I think we are actually at a break. We are scheduled to start at 1:45 to go over the 2021 Report to Congress. I think we will give people an hour for lunch. We will then reconvene back at 1:45 Eastern Time. Thank you, everybody, for a very productive morning. We will see you all in roughly an hour. We are adjourned until 1:45.

(Lunch Break)

NCVHS 2021 Report to Congress

Rebecca Hines: For members, if you want to pull up your electronic version of the Report to Congress. Certainly, that might help the process of going through section by section. I think I sent it out on the 31st if it is not at the top of your inbox.

Nick, would you like me to share my screen?

Nick Coussoule: Sure. That would be great.

Rebecca Hines: This is the version that includes the track changes and incorporates them. They are not showing. This is the close to final product here.

Nick Coussoule: Okay. Let us get started. The intent this afternoon is for us to spend the next period of time going and reviewing our 2021 Report to Congress. Some of you that have been through this before recognizing that we have changed it from the numeric sequencing of the report, i.e., 10th, 11th, 12th,

13th report to reflect the year where it is ideally issued, covering a two-year period. This report covers the two-year calendar year period 2019 and 2020 ideally to be issued in 2021.

A few things as background. Can you bring up just page 1 of the report, Rebecca? Because I think this will just help set some context for the background of the report. Keep going where it says introduction and report overviews. I am going to skip ahead and then go backwards just a little bit. But if you read the first three paragraphs in this section, it really tells the story about what the purpose of the report is.

I think we all know what NCVHS is. But we are required to file or require publishing a Report to Congress in regard to administrative simplification provisions and how well they are being implemented that started with HIPAA obviously I think as Sharon pointed out 25 years ago. This is our statutory obligation. There have been a number of other changes that have adjusted the content and things that we need to do. But basically, it is the purpose of our report is captured here.

There is some more specific language in the appendix, one of the appendices that actually covers the statutory language, but really just wanted to highlight a little bit that the part of report overview that says what we are obligated to do is kind of included here.

A couple of things, an introduction before we start running through the sections of report. One is I want to thank everybody that has been involved for the significant amount work that has been put together by the subcommittee members and staff. Something of this magnitude takes lots of people and lots of time and lots of expertise. We have been through iterations and iterations of this report. My guess is that everybody on the call is a little bit unhappy with a piece or two of the report, which probably means it is good from a standpoint of a committee provided product. But I do want to thank really lots of people. I am not going to name people because that would be unfair. Many people on this call, many of our staff have been very helpful in putting all this together and going through the iterations. And every iteration, I think, has made it a better work product. Thank you all for that.

I think we do have an informative document that does meet our obligations to Report to Congress. A couple of notes. This document is not intended as an ask. We are not asking or recommending necessarily that Congress do anything. It is really intended to be thoughtful provoking as well as to talk a little bit about what our future intentions are as the committee in regard to the topics that we are covering.

I am going to walk through the document kind of section by section. My objective is to get feedback from people that have questions or comments or concerns such that we can adjust as necessary or explain and/or adjust as necessary. Ideally at the end, hopefully, we can get to an agreement that this is a good document that we can then ask people for their approval to be able to pass it on to deliver to Congress and relative others that we copy on the document itself.

But please share your comments and suggestions and edit. We try to incorporate as many of them as we could in the document. Sometimes they are conflicted, and we had to adjust, and we had multiple discussions. It may even seem like we went back and forth a little bit on the iterations. But hopefully, we have captured as best we can everybody's comments and concerns and adjustments in here.

Let me walk through a little bit of the – I am going to walk through the table of contents, which is really just going to explain the different components of the Report to Congress. If you can bring up the TOC, please.

Denise Love: Rebecca, can you increase the font or the view just a little bit. Is that possible? Thank you.

Nick Coussoule: The executive summary is really just – it is exactly what it says. It is about a page and a half, that really just tries to highlight a little bit of the components that are in the Report to Congress. The introduction and report overview are what I brought up on the screen before. I had Rebecca bring up on the screen before. It really talks a little bit about why we are doing this.

But then it goes into what I will call three different components of the report itself. First is the evolving context for health information policy. This is really what has been happening across the industry and ecosystem that have affected the successful implementation and challenges with the administrative simplification provisions of initially of HIPAA. It is really getting into a little bit of the why or what has been happening to influence the current state.

Then the third section, section 3, talks about the progress and status of the implementation, which really is the obligation we have as a committee to report to Congress on both the transaction and code set standards as well as the privacy, security, and breach notification provisions.

And then the fourth section I should say in there is what is next. It is really talking about what we believe the challenges are across the industry related to this as well. And then some of the areas in NCVHS will be focused on. It is intended to set context for what has been happening to get to a report out of what the details are to talk about the current challenges and what is likely going to be next for NCVHS and related to the same topic.

Moving on, there are a number of appendices, which really just provides some context and other information relevant to the report, including statutory reporting requirements, which I hinted at earlier, a little bit of a primer about administrative simplification for those who are not as familiar as well as relevant recommendations reports and activities in this period that the committee has produced again as reference points.

And then finally, there are some acronyms and a membership roster and other things that just kind of close out the background information and relevant information for the report.

If we go on to the Executive Summary, again, my intention is not to read all of this, but to ask in each section for members that may have comments. Hopefully, you have had a chance to review it. Many of us have reviewed it multiple times. But I would ask if any particular comments or questions or concerns in regard to the Executive Summary from the members.

We will skip down past the Executive Summary into the – yes, Vickie.

Vickie Mays: I just had one question. Didn't we get asked to do the ACA review and should that be there as well? Aren't we charged by Congress with the ACA review?

Rebecca Hines: We are, but it is not – in other words, you would like to add that to our opening, Vickie.

Vickie Mays: I keep forgetting that I wanted to bring it up. But I think it is an actual charge that we have from Congress.

Rebecca Hines: It is. You are correct.

Vickie Mays: I think Congress should really – it is a good time for us to remind them.

Rebecca Hines: It is a different group of people that make up Congress today than the ones who put that charge in the ACA. You are correct. That is a really nice catch.

Nick Coussoule: That is, again, a good point, Vickie. Thank you.

Other questions in regard to the Executive Summary? Again, there is no new information other than what is in the report. It just tries to create an outline for people that are going to read the start and decide if they needed to get into more details.

We will get into the introduction and the report overview, which lays out the context for the report itself. It is just one page, those three paragraphs, which talk about why we are doing this. Questions, comments, or concerns? Please raise your hands so we can make sure we hear everybody.

Then we will go into the second section of the report, which talks about the evolving context for health information policy. The first section covers a bit of an overview and then we get into the five major trends. Any questions in general about the review section or intro section before we get to the trends? Make sure I give people a chance to go through it. I do not want to rush through it and skip people that have comments. We will take a little time going through this to make sure we cover everybody and get everybody's thoughts.

Vickie Mays: One little thing and it is this word physician, patient, health care visit. I think it should be health care provider because it was not just the physicians.

Rebecca Hines: Which paragraph are you in?

Vickie Mays: Go down. Right here. Transform the health care patient visit. Some people see nurse practitioners. Some people – that is the only thing. I was trying to look and I just did not follow up when I first read it to see whether or not the tele-visits were only for physicians, but I do not think they were.

Melissa Goldstein: I agree, Vickie. Could we put caregiver or provider?

Vickie Mays: Health care provider, I think, would work well. I meant to look up. I was trying to see when telehealth went through and I just --

Nick Coussoule: I think health care provider is probably a more accurate term. To Melissa's point, if we say caregiver, it can include family members or other kinds of things of that nature especially in long-term care situations. I think this is appropriate.

Any other comments or questions from the members in regard to that? Good catch, Vickie.

Denise Love: We do not really want to wordsmith, do we? Bad actors jumped out to me. Do we just want to say misuse? Some people who are not bad actors still misuse the data or is bad actor fine?

Nick Coussoule: Just my opinion. This particular one is geared towards people with malicious intent. It is different than what I would call the inadvertent kind of questions. Even insiders that have malicious intent would be bad actors.

Denise Love: Okay.

Nick Coussoule: Again, that is one person's opinion. Obviously, I would welcome other comments.

Denise Love: It is not a big deal. Every time I read it, I come up with new ideas and I am trying to muzzle it.

Nick Coussoule: We all do that, Denise. That is part of the challenge of going through a document, one, with so many people and so many tentacles, but there is just a lot of information, a lot of things that gets covered as well. My guess is we could probably revisit this and every time revisit it – ideas and thoughts. But we definitely want people's inputs. Do not take that as I do not want anybody's input.

If we then get into the five major trends, let me just read the trends off at a high level first before we start scroll through there. The first one is new technologies, platforms, and models for managing health information with varying degrees of maturity and implementation, have emerged to meet pressing business needs. Patients' roles in accessing and using their health data have expanded and evolved.

Convergence of clinical and administrative data standards has gained recognition, crossing the boundaries of traditional data and program silos. Fourth is that COVID-19 pandemic has exposed critical weaknesses in the public health infrastructure. Five, health information privacy and security challenges have proliferated. We did reorganize these a little bit to hopefully be in a sequence that reflected somewhat of the primacy of the activities. By no means because it is number five is unimportant where one is. But we did try to create a little bit of a sequencing to recognize the high-level importance of the platforms as well as the patient roles, et cetera.

If we go to the first one so the new technologies platforms, which you see on the screen here. Comments or questions in regard to that theme or that trend or the framing of the trend? As we all know, there are lots of references and footnotes in here with other documents that have provided references to other documents. We are not going to go through the different footnotes and questions, but we want to make sure ideally that we have covered the right kinds of supporting information in regard to the points that were made as well.

That wraps up the first trend. And then we go on to the next trend, which is the patient's roles in accessing and using their health data have expanded and evolved. Just one note, not necessarily directly related to this section, but one of the things that we did try to do in the report is it covers the period on the calendar years 2019 and 2020 although we tried to be cognizant of what is actually either changed or have been published or promulgated, et cetera, during the time to make sure it is currently accurate

as we can be with facts that have happened on the ground while we still include the same kinds of notes and challenges from the last two calendar years.

Jamie Ferguson: Just briefly, I noticed that this section refers to the ONC's interoperability and so forth, but not the CMS patient access to health plan records, which also is another thing that happened. I realized – I think the compliance enforcement date might have been after the reporting period, but it certainly happened during the reporting period.

Nick Coussoule: I think that topic came up. I think we did not include it partly because of that, Jamie, because the enforcement data challenge came up well after the fact. If any other member has a different thinking process there.

Would your suggestion be that we include it, Jamie. I am just trying to make sure I am clear.

Jamie Ferguson: Yes. I would suggest mentioning ONC's interoperability and information blocking rule. I would add "and CMS by rules require or enable patient access to health plan records".

Rebecca Hines: Jamie, does that work for you?

Jamie Ferguson: That works. Thank you.

Rebecca Hines: Can you send me the footnote for that?

Jamie Ferguson: I will do that.

Rebecca Hines: Perfect. I appreciate it. Thank you. Lorraine is not able to be with us; otherwise, I would have asked her.

Nick Coussoule: Okay. Go onto trend three, which is the convergence of clinical and administrative data standards as gaining recognition and crossing the boundaries of traditional data and program silos. Any comments, questions, concerns in regard to the third trend?

Just to Jamie's point, this section also highlights the work that we will do in conjunction with ONC's Federal Advisory Committee. The combination of both ONC's rules and the CMS rules is relevant as well.

Down to the fourth trend, health information identified, which is that the COVID-19 pandemic has exposed critical weaknesses in the public health information infrastructure -- good topical discussions in regard to some of that. Some of the footnotes even reference other review work that NCVHS has done in that regard too.

Vickie Mays: I am going to suggest next to the box where it says the wide disparities and equity among different US racial ethnic – I am trying to think which is the best term. Because they are paying attention to sexual orientation, I am trying to think of the best one to use. It probably is – since you have racial, ethnic, sexual orientation and gender identity. It is not a population. If we put LGBT. I just hate using that because somebody always feels left out.

Rebecca Hines: Is this a term we would use, Vickie?

Vickie Mays: Sexual minorities? Sexual and gender minorities. That is the way to do it. We are good. Thank you, Rebecca.

Nick Coussoule: Would it be sexual orientation and gender minorities?

Vickie Mays: I think it could just be sexual and gender minorities. I will check. The population thing is throwing me off. I will check. I will just send Rebecca an email.

Rebecca Hines: Here, racial is the adjective for population groups – everything has to refer to population groups.

Vickie Mays: Right. I think it is sexual and gender – I think it is fine the way it is. I want to make one check, but I think that is – we have done it the best --

Rebecca Hines: Do we want to use and footnote the department? Rachel is suggesting we use SOGI.

Vickie Mays: That is Sexual Orientation and Gender Identity. The problem is then we have to change everything else. I was trying not to. It is the word population. It is okay. We can fix this. I just wanted – because of the request, the attention to this that we try and make sure that we do raise it.

Nick Coussoule: I think this wording fits in with the other adjectives and components in there.

Other comments and questions in regard to the fourth trend?

We will move on to the fifth trend, which is the health information privacy and security challenges have proliferated. Questions and comments in regard to the language and content here?

That is effectively the lead in to – with some both histories as well as status of some of those challenges. Now, we get to the section on the progress and status of the HIPAA implementation in the first section of that and would be the transaction and medical code set standards so down to Section A. There are five different components of this: the transaction background, the transaction status, HIPAA transaction initiatives and actions, HIPAA medical code sets plus related terminology and vocabulary initiatives and actions and other HIPAA administrative simplification initiatives and actions over the last two years. Any questions or comments in regard to the first piece on the transaction background?

Then the second piece on the transaction status, which covers and then goes into a specific matrix or box, if you will, that demonstrates some of the transaction adoption rates and implementation.

Down to the table. Again, thank you to CAQH for helping us obviously with their efficiency index on a regular basis. Public call out.

And then the third component, which is the transactions and initiatives in action that have happened in the time period covered by the report, 2019 to 2020.

Moving onto the fourth component or item, which is the HIPAA medical code set plus related terminology and vocabulary initiatives and actions during the reporting period – topic we will take up later on in regard to ICD-11 as well.

And then the fifth item in regard to the transaction medical code set standards, which is the other administrative simplification initiatives and actions during the reporting period, again, 2019 and 2020.

Then we go down to Section B in the progress and status, which is the privacy, security, and breach notification components. There are seven sections in this report: the proposed changes to the privacy rule, the updated guidance on FERPA and HIPAA, the guidance on HIPAA, HIEs and disclosures of PHI for public health purposes, HIPAA and COVID-19, breach notification, HIPAA enforcement, and the HIPAA right of access enforcement initiative.

We will start with the first one, the proposed changes to the privacy rules. Back to page 19. I would like to be able to just quickly go back to the table of contents so you can follow along with my reading.

Rebecca Hines: I was following with you. I got all the way to the end of Section B.

Nick Coussoule: Comments on B1, the proposed changes to the privacy rule?

Second item, which is the updated guidance on the FERPA and HIPAA. See how many acronyms we can get in one place. In Section 3, which would be guidance on the HIPAA health information exchanges, HIEs, and disclosures, PHI for public health purposes.

And then four, which is HIPAA and COVID-19. Some very good information in regard to what happened and has happened and continues to happen during our pandemic.

And then five, which is the HIPAA breach notification component, which is the list nobody wants to be on. Some very good statistics provided by our wonderful staff in regard to this.

And then six, the HIPAA enforcement. It includes the good summary or details of the 2020 enforcement actions on the next page.

And then seven, the HIPAA right of access enforcement initiative from February 2019.

Any general comments before we close out that section?

Then we move on to the --

Melissa Goldstein: Nick, it is Melissa. I am trying to find – I am flipping back and forth so that I can see more of the document at once. Can you tell me – part of this is on proposed rules, the proposed changes to HIPAA. Do you know what page that was? Honestly, I just want to make sure that we are not calling something proposed that is now finalized.

Rebecca Hines: I thought we caught that. Because it is September now, I think things changed as you are pointing out. I remember making some edits.

Melissa Goldstein: Nick had used the word proposed when he read it and then I cannot find it in the document because I am slow.

Nick Coussoule: I hope I did not make a mistake. I know we did have a couple of those. As we were going through the different iterations of it, things changed. It became final or dates passed on those things. I believe we caught all those.

Rebecca Hines: I am going to stop sharing and I am going to do a quick search on the word proposed --

Melissa Goldstein: It just caught my ear.

Rebecca Hines: I do not want to give you all --

Nick Coussoule: It is a good question. We had a number of iterations of that during the time period where things – were initially March, but we were past the dates and now we had to make sure that it is accurately represented into both what was proposed and what happens.

Rebecca Hines: In the overview, it says Section 3 provides an update on proposed changes to the HIPAA Privacy Rule. Do you want me to share my screen so you can see every instance of the word proposed? It is basically – there is a whole section on proposed changes to privacy. Let me share my screen and you can see where that is.

Melissa Goldstein: It definitely was a notice of proposed rulemaking on December 10. The question is do we still call it proposed changes to privacy rule in the title or do we change that to changes to privacy rule. Rachel knows.

Rebecca Hines: Rachel, do we have a document that has incorporated the Final Rule?

Rachel Seeger: Folks, the Final Rule has not been finalized so this is – I do recommend proposed changes to the privacy rule.

Melissa Goldstein: Good.

Rebecca Hines: Now, we are in the – that is good. All right. Hopefully, Melissa, that is where it come from. There is that section called proposed. Because we do not have the Final rule yet --

Melissa Goldstein: Thank you for checking. I appreciate it.

Rebecca Hines: Absolutely. No. We do not want to look like we did not do our homework.

Nick Coussoule: Then, we will move onto Section 4, which is sort of the now what. We have covered the trends and things that led up to the results – impact of the results that we have had. We talked about current status and now we are talking about looking ahead. We talk about the near-term health information challenges and opportunities. There are five of them. Again, they are organized in one to five. It is not that any of them are unimportant, but we did try to at least highlight some of the critical nature of these things and from an ordering perspective, but it does not mean that five is unimportant.

The first one is the need for comprehensive integrated national health information standards, kind of a recurring theme. Questions or comments about that one? Clearly, a lot of work in Standards Subcommittee, especially in regard to some of this over time in the Predictability Roadmap, et cetera.

Down to the second near-term challenge and opportunity, which is the need to address increasing challenges to privacy, confidentiality, and security. I get the feeling that this will be on our reports for the forever future.

Rebecca Hines: It is probably not a bad bet.

Nick Coussoule: Any questions or comments in regard to the language in here that is covered?

The third challenge and opportunity. The need for enhanced data sources to support payment reform and price transparency.

Move on to the fourth. Near-term challenge and opportunity, which is the need for equitable information technology across the last mile in quotes to reach all end users.

And then the fifth near-term opportunity and challenge is the need for a nationwide digitized infrastructure for pandemic information collection and sharing. Some timely information this morning.

Vickie Mays: It is probably a technical question. When we talk about the pandemic and I want to make sure that this also applies to disasters, are we okay just using the word pandemic, which makes it just very COVID related, but what is happening – have these storms and tornadoes. I just want to make sure that we did not box ourselves in and that what we are talking about would apply in disasters as well.

Nick Coussoule: I do know we had some discussions earlier that we specifically did not call it the COVID-19 pandemic to be a little broader. I think your question is whether it needs to be broader than that.

Vickie Mays: It is whether or not just in one time we say pandemics and disasters and then keep talking. I just want to make sure disasters are in here because in the National Academy reports, they literally were talking about both and that the data infrastructure needs to accommodate – they were really more focusing on disasters I should say, and the pandemic was also included.

Rebecca Hines: Vickie, take a look at the screen and see if the sentence, which is in the first paragraph --

Vickie Mays: It is good. I just think once is enough so that it gets carried through. I am good with that.

Nick Coussoule: Other comments or questions from the members?

Melissa Goldstein: Do we want to say that or use our public health emergency language? Vickie, what do you think is more broad?

Vickie Mays: My thinking is about Congress, which is I like them to think about pandemics and disasters. I think somewhere else we should make sure that – because in public health emergencies, what it means is that we usually declared something. There is a difference between if there – usually, I guess, if it is a pandemic, it is declared a pandemic so that it then qualifies. But there are sometimes in which this is very technical because the states will complain that we have not declared it an emergency, but they literally have to deal with it as an emergency.

Nick Coussoule: -- this includes something like the opioid epidemic.

Denise Chrysler: Emergency and disaster are often defined in laws all over the country, especially emergency management laws have definitions for each. I would just play it safe by saying – and often a pandemic is within the definition – not an emergency, a disaster. I would just play it safe by saying during emergencies and disasters, including pandemics.

Vickie Mays: That is even slicker. It says there are things – I like that as a lawyer. I like that. That is good. There are emergencies in which we do need data for. I like that.

Nick Coussoule: Rich, you had your hand up. Did you have a related comment?

Rich lander; No. My concern and suggestion were taken care of with that last edit.

Rebecca Hines: Let us look at the beginning here. This is right up front.

Nick Coussoule: -- references COVID-19 and then gets into the broader topic.

Rebecca Hines: This is good to have in the first paragraph.

Nick Coussoule: Okay. Other questions in regard to the challenges and opportunities section?

Then we get into the last content section, which is the NCVHS focus areas in the period ahead. We have four of them. First is the promoting convergence of clinical administrative and social and public health data.

Rebecca Hines: We are going to hear about this project tomorrow morning.

Nick Coussoule: We will.

Rebecca Hines: I think that is all current.

Nick Coussoule: Second focus area. Improving the health care indices security posture. We heard about that this morning from Jacki and Melissa. There will be actually more even tomorrow in regard to that or later on this afternoon.

And then the third would be the monitoring and advising in ICD-11 readiness, which we will also hear about if I get my sequencing right tomorrow.

Rebecca Hines: That is this afternoon.

Nick Coussoule: This afternoon. Sorry.

Fourth is to identify to approaches for data collection sharing linkages and analytic methods to address health inequities. Again, we have some good information in regard to some of that this morning.

And then I think we will even hear a little bit that Sharon hinted at this morning of some topics for tomorrow afternoon for us to talk about and consider also as a committee.

And then finally, the conclusion basically just wraps up by saying we are happy to be able to do this and play a part in the advancement and then reiterate some of the importance of the work that the committee does and hopefully making it visible and having some impact through the Secretary.

And then finally, we have a number of different appendices. I am not going to go through those. If there are comments or questions in general, I would ask for that. I believe we have covered everything – anything in particular missing that needs to be address in there. I think we have links to a number of different reports. We purposefully did not include all of them. Otherwise, this would be 100-page document. But we include references and linkages to a number of different reports as well as we did in some of the footnotes.

Let me then take one step backwards. Any general comments and questions in regard to what we have gone over the report itself?

What I would like to do next is to ask or to recommend that we approve this report for delivery. I will make one caveat.

Rich, you had a question.

Rich Landen: I'm ready to move the motion.

Nick Coussoule: I would make one caveat to this. I would like to request approval to move this with the caveat that if we have any particular grammatical or other issues, that we find prior to delivery that we just have the ability to make those kinds of changes. Obviously, nothing content-wise or substantive without coming back to the committee. But if we find a period in the wrong place or a plural where it should not be as we do final reviews and prepare it for distribution that we would have the luxury or the ability to do that without coming back. I would ask for that. Motion to approve. I think Rich just made that. Second?

Debra Strickland: Second.

Nick Coussoule: All in favor please raise your hands so we can at least capture that on the screen.

Rebecca Hines: For the record, it looks like we have 11 so far hands up. There are 12, 13. Are we missing a member at this moment?

Nick Coussoule: I think it is just Margaret.

Margaret Skurka: I am a yes.

Rebecca Hines: Just raise your hand. There we go. All right. We have a vote of 14 approvals for the record.

Nick Coussoule: Wonderful. Thank you, again, for all the hard work that went into this and the stress and challenge of getting to something that hopefully is representative of the committee's work and the importance of what we do and the challenges that are facing the industry today. Thank you very much for that.

Rebecca Hines: We are 15 minutes ahead of the break, Nick.

Nick Coussoule: I had a copy of the old agenda in front of me. I am wondering why my timing was off.

What I would suggest then is that we go on break now and we come back 15 minutes early so that if we happen to run a little bit later on our further topics that we have a little extra time.

Rebecca Hines: Super. Do you want us to come back at three then?

Nick Coussoule: It is now 2:43. If we could come back at 3 o'clock and get rolling again that would be wonderful. Hopefully, that will work. We are adjourning for the moment. We will see everybody back here at 3 o'clock Eastern time.

(Break)

Nick Coussoule: Next up on our agenda is the Subcommittee on Standards, talking about our letter to the Secretary with recommendations for actions on ICD-11. I will turn it over to Margaret and Valerie. I am not sure who is going to lead this off.

Subcommittee on Standards

Margaret Skurka: I am. Thank you, Nick. Valerie and I are very pleased to have this time on the agenda to talk about ICD-11, something near and dear to our hearts for a very long time. I keep saying that I am so old that when I started my work world, we were in ICD-A8 if any of you remember that. And then in 1979, we went to ICD-9 and then we went to ICD-10 in '15. Some people will say we just went to it in '15. Why are we already going to '11? Because the World Health Organization has developed it. We will have to adopt it for mortality for death certificate recording. We have no options. And we should adopt and will adopt for morbidity also and hence our presentation today.

It was a wealth of information in the agenda book. I just want to – I am not going to go to any of it, but I just want to remind you that the old letter is there. That is the one we developed in 2019. But since then, a lot has changed. There has been an administration change and everything else, so hence we have the new letter. Both letters are in the agenda book.

There are three very good attachments. Attachment A is updated research questions that HHS has to evaluate for implementation of I-11 in the United States and attachment B is an outline of research questions to evaluate benefits and costs of the transition and that is certainly critical. And then Attachment C is a communication plan. There is also one more attachment – licensing agreements and terms of use and all of that.

And then just from the get-go, I want to remind you. We are just dealing with 11 this time, not PCS. That is where we had all the changes and all the issues last time. PCS is updated by the US once a year now. It is a build-a-cone concept, and we deal with that yearly. We are just talking ICD-11.

We have been charged – the National Committee on Vital and Health Statistics is the advisory body for health data, statistics, privacy, and national health information policy. In regard to that, our one key role

is to monitor the continued effectiveness of adopting health care standards pursuant to the requirements of HIPAA of 1996. This includes making recommendations for the adoption of I-11 in the United States.

Our purpose is to recommend timely action to enable the US to make informed decisions regarding adoption of I-11. But delays from the pandemic and the change in administration, NCVHS is updating our recommendations that we did. The letter was November 25. Actually, we had in-person meetings back in 2019. We were in Washington, a number of us for meeting all about I-11. That first letter came out regarding the need to do research and a strategic communication plan. Now, we have updated that letter. That is a part of our process today.

The committee process has been that we have worked with NIH and NLM researchers and they have attended our expert roundtable meeting leading up to the initial recommendation, that first letter, and that was Kin-Wah Fung, Olivier Bodenreider, and Julia Xu. And then Dr. Fung, you will remember, was with us just recently in March. We invited him to present his most recent research at our full meeting that was held remotely in March of 2021. Informed by the new information, the Standards Subcommittee developed updated recommendations for consideration by that full Committee.

We are going to propose three updated recommendations. There they are very clearly. HHS should conduct research to evaluate the impact of different approaches to the transition to and implementation of I-11. HHS should conduct outreach and communicate regularly to the US health care industry about the ICD transition. And HHS should examine how to best enable blanket access to I-11 and subsequent updates that could minimize costs to the industry.

If you want to have something to do tonight between meetings, you could Google ICD-11 coding tool. It will come right up and you too can be a coder in a matter of seconds. You can put in your favorite diagnosis and the options will come up immediately. There will not be books. It is built to be an electronic system. It is just really fun. That is something for you to do tonight if you are having a libation or something. We should connect that research. We should communication and we should give access to I-11.

A little bit of a background. It is a classification system developed by WHO as the foundation for identifying health trends and statistics worldwide and is an international standard for reporting morbidity and mortality and other conditions affecting health. It was first published for review in 2018. The World Health Assembly formally adopted it in May of ’19. Nobody has adopted it yet because you cannot. But there will be early adopters and they can start after January 1, 2022. I have heard rumors that Japan is all over it as well as several other countries. Nobody has announced a date yet, but it can start next year. In light of that, WHO plans to discontinue maintenance of ICD-10.

There is going to be three – we have identified three distinct dimensions for the adoption. Number one, for mortality. Now, that we have to do because it is a condition of our membership and the WHO contributing to worldwide surveillance. It is a UN treaty agreement with implementation obligations led by the National Center for Health Statistics in conjunction with state vital registration and statistics agencies. At some point tonight, you can also Google and review a good presentation there on some

changes from I-10 to I-11. There is lots of information there. Donna Pickett, who we all know, was certainly part of that and Dr. Robert Anderson.

We will adopt for morbidity and that is what we use for health care and public health systems. Diseases, disorders, injuries, and other health conditions are reported. The system is used for international public health surveillance, statistics reporting. It also supports administration, QA and research, public health surveillance to monitor incidence and prevalence of diseases, capture of data for safety and quality guidelines and state health data reporting.

And the third is for payment/money, because we submit codes and we get paid on those codes we submit. And wrong codes or we miss the complication or comorbidity or it went in the wrong payment bucket. We have coded something too far that we did not really do or worse, we have left something off and we are getting less money if we add that complication or comorbidity. It is about the money also. It is a HIPAA-designated medical code set, which is an essential component of all billing and payment processes. It is mandatory. It is just mandatory for morbidity and for mortality. And we use it also for morbidity.

Did we learn from the past? We hope so. We implemented the previous classification, I-10, in 1999 and then we finally adopted it for morbidity in 2015. Yes, that was just a few years ago. It took us 25 years after it was endorsed by WHO for us to adopt. A very protracted, that is a kind way of saying it and I think we use that word in the letter, process made the US the very last country to implement I-10 for morbidity reporting among industrialized nations. I do not think we want to be last this time also, but we will see.

The on-again, off-again regulatory implementation deadlines cause unnecessary costs and wasteful rework throughout the health care system. Those of us that were doing some work for HIMA as trainers spent a lot of years training on the road. It was an endless process.

Why are we going to do this? All those good reasons. It is a digitally curated system that takes advantage of modern information technology and automation. It holds promise for reducing the cost of implementation, that sounds good, and has other benefits.

It provides flexibility to eliminate the need for a clinical modification – we have been in communication, and I am fairly regularly with counterparts in both Canada and Australia. They have no plans at this point either. They feel very strongly that we look at I-11 because it is comprehensive enough that we do not need to dink or diddle around with it and add more stuff.

It is enabling for continuous updates, thus eliminating the need – we will never have a 12. That is what we are saying at this point. It will eliminate the need for future versions like an ICD-12.

It improves coordination with other classifications and terminologies. It improves comparability of mappings and language translations. And it is supported online.

Our rationale is that we – Recommendation 1. We should conduct research to evaluate --

Valerie Watzlaf: I think this is my part. This is where I start. This is the part of the letter where we are going to provide the rationale around the different recommendations that we had. For Recommendation 1 that was explained by Margaret earlier, it is going to focus on research on ICD-11 such as the extent to which it can be automated in real-world settings, the extent to which ICD-11 can reduce provider burden and increase interoperability and also how necessary and urgent it is to conduct this research now so that the different approaches to the transition and implementation can be fully evaluated.

In order to conduct the research, we have also been recommending the following actions. These are also outlined in the letter. The first and extremely important one – these are in order of importance. The first one there is to conduct research to determine if ICD-11 will need a US clinical modification or a CM version. And if it does, which areas might be targeted in the CM version.

If this occurs, it could extend the implementation timetable. It could possibly increase costs and require additional ongoing processes. It is very important to determine if the US clinical modification is needed or not.

The second action that we have there is to confirm the business case for why investing in this research should be a priority. This research area focuses on how ICD-11 could help with maintaining standard codes that could track and understand pandemics and future pandemics.

And the third area is looking to see if ICD-11 mappings are of high quality.

The fourth one there is to develop use cases on how ICD-11 will support EHRs across different provider settings and environments, for example, ambulatory care and so forth.

And the fifth area is to focus on research that will examine how efficient the ICD-11 digital capabilities are.

It is very important that this research start now and it be completed within the 12 months. The adoption and implementation could very much depend on the research results. We also understand that this will require the immediate allocation of federal resources to conduct this research.

Another very important reason to begin the needed research now is because there have only been three studies to date that directly compared ICD-11 with ICD-10-CM. Dr. Austin and his team compared ICD-11 to 10-CM. But the focus was on the capture of adverse events in relation to quality and patient safety.

As Margaret mentioned, Dr. Fung and his team – they completed two studies and the first focused on a comparison of six disease areas comparing 10-CM to ICD-11. And then his team expanded this in a second study and they included the comparison using a representative sample. There were 943 codes of the most frequently used codes in each chapter of ICD-10-CM that covered 60 percent of unique patients. For each ICD-10-CM code, they had two expert terminologists that recoded them in ICD-11 independently. And they achieved about a 76 percent agreement rate on the main code and almost a 79 percent agreement on post-coordination codes. In the past literature where we would do agreements on I-9 to I-10, they had a range of 68 to 80 percent of agreement. The agreement in Dr. Fung's studies here is quite high.

They also included an analysis of the reason why full representation could not be achieved. They reviewed coding guidance in relation to code differences and they did an overall assessment on the feasibility of replacing ICD-10-CM with ICD-11. Their overall conclusion was that ICD-11 without a clinical modification should be considered as a candidate to replace ICD-10-CM for morbidity coding.

These studies we feel are a very good start, but we still feel additional research is needed. We updated the research questions, and they are included in the letter as Attachment A. And they are also on the next slide. There are ten of them. I am not going to go into a lot of detail on each one, but these are the first six. I will just summarize them briefly. The first research question focuses on evaluating ICD-11 on cost and benefits and human factors such as provider burden, workflow, training, and so forth.

The other research questions include their number two of evaluating how ICD-11 adheres to accepted terminology practices. Number three, how alternative methods and infrastructure platforms support semantic comparability studies. For example, ICD-11 versus ICD-10. And then also examining each incremental revision to ICD-11 versus the previous version.

Number four is to examine technical and legal considerations. Number five is how well ICD-11 coordinates with clinical documentation and the nationally mandated interoperability content standards. Number six is looking how well ICD-11 coordinates with coding use for social services, social service coordination, public health surveillance recording, quality measures, or health equity assessments.

This just continues with number seven, looking at the – to research the impact of adding pre-coordinated codes to ICD-11 that correspond to a concept that was previously represented with post-coordinated codes.

Number eight is to evaluate the ability of ICD-11 to contribute to clinical, social, and administrative standards. For example, and this is just one example, to assess whether ICD-11 fully represents social determinants of health that have been added to ICD-10-CM.

And then the last two really address whether ICD can be implemented as a computable service, using the EHR and Promoting Interoperability Standards to record clinical care. And then the last one. Does the interoperability representation simply distribution and deployment of health terminologies and vocabulary standards and therefore what are the costs and benefits of supporting this by use case?

This is just giving the rationale for Recommendation 2. Again, it stresses how important it is for HHS to regulate and conduct outreach and communication to the US health care industry regarding the ICD transition, again, with a focus on lessons learned from the past, the need for accurate and consistent messaging from a single trusted source. We are also strongly recommending using the communication plan that was developed during the NCVHS August 2019 expert roundtable meeting – had significant stakeholder input. I think Margaret mentioned this. It is included in a letter as Attachment B.

This slide just includes what the focus of the message is. They include encouraging all stakeholders to begin planning now for how they will address the change, to provide education on how ICD-11 will work within EHRs and to share that the research is being conducted on ICD-11 use, to determine any costs and benefits of implementation and then to share the best path forward, and to communicate that the

decision to implement ICD-11 will be federal mandate and also communicate that if the US could implement this that they could also retain their leadership role in worldwide health initiatives. This is just some of where we believe the messages should focus. And, again, the communication plan that we have an Attachment B that contains much more detail.

This is the timetable behind it. In the letter, we also recommend that this be -- the strategic communications plan be executed as early as possible, running right alongside with the recommended research work over the next 12 months. And, again, we are recommending the detailed communication plan in Attachment B.

This is the third – the rationale behind the third recommendation, which again is looking for a blanket access to ICD-11 and any subsequent updates. Again, it could truly minimize the cost to the industry. We know that the WHO has developed and retained all rights to ICD-11 and ICD-11 software. We have attached the ICD-11 license letter in the draft letter as well. It is very important for the US to negotiate an agreement that ensures blanket access to ICD-11 and also any updates or any future modifications. This would be amazing if this could occur because then such an agreement would make that code set available at no cost for everyone in the US.

This is our conclusion that we have in the letter as well. Again, we believe that taking a proactive approach to ICD-11 is essential. That it should include the three areas: research, communication and outreach, licensing and copyright, as we just described previously.

And, again, that these recommendations should happen now. We would like to timely action that would provide a path forward for the US that is both beneficial and will also minimize cost. As Margaret stated earlier, the reason we are bringing this forward now is because of from the previous letter of November 25 of 2019, we had some delays there, resulting in the pandemic and also the change in administration.

We are bringing this forward to the Full Committee today to summarize of course the draft letter and to get your feedback and hopefully approval.

I just want to give a special thank you to our I-11 subgroup. They assisted in the development of the final draft of the letter, the entire Standards Subcommittee, the Executive Subcommittee. A lot of people looked at this. I know Nick and a very special thank you too to Lorraine and Rebecca for their input as well because we could not have done any of this without you and we appreciate that very much.

I think we can welcome your questions. After that, we could even pull up the letter, I believe. Any questions that we could address?

Vickie Mays: Thank you. Thank you for what I consider as a mental health professional, a very important piece of work, so thank you very much for bringing it back.

I have three questions. One is what is different now in the environment from when we sent this at the end of 2019 because we do not seem to have that. There are things that are very different that I think would help us to emphasize.

Two is what has the lack of response cost us because I think we need a greater sense of urgency of the time stamp for this to be done. I am afraid that where it is 12 months is going to turn into 24. I think if we do not say what the cost or the price or whatever it is that we have paid for this delay that it will not push it up because we are still going to do pandemic stuff for quite some time. It needs an urgency.

And three, one of the things I want to ask about is where we are relative to thinking about DSM-V and the crosswalk to ICD-11. While to get paid for a claim, one is going to have to use ICD-11. There is still for the mental health world this other diagnostic manual that is used and typically there is a crosswalk. Those are my big ones. And also, I think, specifying who you want to do this research or where you want the money or – again, I think helping them to do it faster is to me critical. Those are just some little things that I am curious about.

Valerie Watzlaf: Such easy questions. I know one of our goals, Margaret, was really when we were looking at the original letter was to condense it down so that I guess it would not be ignored and that people would actually read it. I think that was one of the things that we did differently from the 2019 letter.

Part of the cost – I think that is a really – I like that. That is a really good suggestion. I do not know that we looked at what this could cost if we do not implement. But we did bring up some cost issues in that letter I think as well.

I do not know, Margaret, if you know about the DSM-V part.

Margaret Skurka: I do not know. I could not answer that. I was going to say – the environment. It is not the environment – quicker and simpler because we are just dealing with diagnose and we are not dealing with procedures. For being very involved in teaching PCS – that was the hard part – getting to add that – changes that drug us on between 10 and 15 were changes people were making – in PCS. For starters, we are just dealing with the diagnosis system. It is free and it is online. People can – use it or play with it. That is different. Others will have better comments.

Valerie Watzlaf: We welcome anyone that was a part of this if they have answers as well. I know Denise has her hand up.

Denise Love: Yes. So many things. Vickie always brings up the hard questions. My feeling is the cost of the no response – it is not so great yet. We have lost a year or two. But the ICD-11 is fairly new. I do not see that as much of an issue as the cost going forward with the delays because then we start losing, I think, opportunity costs and time for research. I am wondering if the DSM-V question is more of an added research component. We do not know, but that is something that the researchers should maybe add to our list. We have some really good research topics. Whoever does the research does not have to start from scratch. They have some guidelines.

As far as who should pay? HHS should pay. I do not know how that politically plays out and when to get it in the budget cycle and how. I think last time it was RAND. They usually send out an RFP or something, I am guessing, or a sole source. I am less concerned about that.

I think just getting the attention now. I am not worried about the time lapse between the last administration and the no response. But now we need to get some – get it on the radar screen and get it in a budget. Does that answer some of your questions, Vickie?

Vickie Mays: Yes. But I do think the issue of the mortality issues that – morbidity and mortality issues because of the pandemic, because of the need to have this worldwide kind of accounting is really critical.

We also are getting ready to face what some of us are calling a syndemic in terms of mental health problems of suicide, substance abuse, and mental health problems. Making sure that we are going to capture those because that was where significant differences took place is in ICD-11. There are a lot of new categories that were introduced. They are great. We want to make sure that given what has happened in COVID that we are accurately capturing all of this. I think there is some significant pressures to get this working.

When I said who is paying, it is like is this research that you want at NIH. Is this, as you say, single sourced, get out the door, Westat, RAND, et cetera? I think we need to help them because I think the urgency issue is important. We do not tell them who to fund. But we tell them that we need an answer quickly because I think – hopefully --

Denise Love: Then when we go to the letter, we pay attention to that part. I think we tried to convey the urgency that maybe there is deeper – that could happen.

Rebecca Hines: I would like to jump in also if it is okay following up on Vickie because I want to remind us all that when we had the initial meeting of experts to develop the first letter, one of the findings was there was not research on the cost of the protracted implementation of 10 other than to say it was probably in the hundreds of millions to the system as a whole because of the start-stop, start-stop, the training, the not doing it, yes, we are going to do it, no, we are not, and all of the ripple effects of that.

I think we know – and that was actually a finding, is that there was not adequate research, which was actually one of the reasons the committee wanted to recommend to HHS to get on top of this because it was not done properly last time and there was a lot of lost information other than back of the envelop guessing. That was one of the things that we discussed at length, which I think really created the impetus for that first letter.

The other question – this is some degree protocol is how prescriptive you want to be to HHS in your language about how to get the research done. I guess as federal staff, I would encourage you to be very balanced and not necessarily saying it has to be done under contract or how it gets done, but just to say that the resources be made available as a priority. Denise, you really put it nicely. Like get it in the budget because that is how things get done. They are already working on certainly the ’22 and the ’23 budgets. That is really how this is going to get done. I just wanted to – when we pull up the letter and look at that section, I just want to encourage you to maybe not be – just be gentle in your prescriptiveness because I do not know that that will be well received, but rather just say that it be done and whether under contract or whether federal staff can be made available or whatever at the most. That would be my suggestion.

Nick Coussoule: If I could just add one thing to what Rebecca was saying. When we did the original letter, there was a distinction or there is a distinction between what I will call when we implement, number one, and two is having some degree of certainty about when we implement. You could argue that there is a cost of delaying an implementation generally. But you could also argue that there is a cost of re-sequencing or rescheduling it three or four times. As an implementer, I dealt with that. I was more concerned about that portion of it as opposed to the actual when is it going to get implemented, but it is going to be 2015 or then 2016 or then 2017. Those are two different topics, which I think if we – if we really want to talk about a cost perspective, there is an implementation cost and then a value proposition.

Valerie Watzlaf: Wu, I think was next.

Wu Xu: I wanted to follow up, Vickie talked about the mortality implementation. This may not be in the letter. But is it possible we recommend NCVHS to incorporate ICD-11 implementation in the vital records system in their data modernization project? This morning they released the vital records modernization project. I do not think they are included in ICD-11. I think that is the best opportunity when they train new workforce, upgrade technologies and the role that the ICD-11 in there.

Denise Love: Wu, just to follow up. On the Public Health Data Standards Task Force with ONC, I brought up their investment and infrastructure discussion. I said, ICD-11 is a major infrastructure piece. Are we talking about that? And it is just silence. I would just guess that the CDC Atlanta part – that is an afterthought. It is down the road afterthought. Because for ICD-10, even after implementation, the CDC systems were not ICD-10 ready. It was a few years to even educate about ICD-10. I think that is well put.

Valerie Watzlaf: Thank you. Debra.

Debra Strickland: I think, Vickie, to your point about the DSM coding crosswalks, I think that is a big area that we really need to cover. I think if this letter moves forward and they start to do the research, I think folks like yourself, and others need to band together to get that sort of behavioral health kind of aspect mapped to ICD-11 in the best way possible. Are there gaps or does it fit right in? But I do believe that that is a very important part. If we do not start now, people are not going to realize that. The dialogue has to start. The groups have to start coming together. People need to start talking and saying how important this is because that is a very big area that has been missed. I appreciate that comment, Vickie.

Valerie Watzlaf: I have a question back too because I thought we do have an area that we said needs to assess the quality of ICD-11 mappings. Would that fall under there? Do you want it to be specific to DSM-V?

Debra Strickland: I think we just have to look at the wording if it does cover behavioral health. We might be able to get more specific. I definitely think we want to look at that wording. But I think it is a good focus area. Even if we do not specifically mention it, I am sure that at some point, that will come – these groups will come together and be like a big miss here. We cannot have this going forward. We need you to start addressing this.

Rich Landen: On that same topic, thinking back to the first letter recommendation, we stayed very general without getting into specifics about relationships with other code sets and vocabularies. I have been trying to rack my brain and recall why we made that decision or have not been terribly successful.

However, the letter and the research questions just talked about quality of mappings, as was just mentioned, and specific use cases. In the current version of the letter, which I think we will get to shortly, we do have a little bit more of an explanation in Attachment A Number 1 where we talk about HIPAA and promoting interoperability code sets. I would suggest when we get there if it works for Vickie that we add DSM to that list, which already specifies SNOMED CT, LOINC, RxNorm, HCPCS, and CTPT.

Margaret Skurka: That is a really good idea, Rich.

Rich Landen: I think the lesson learned from the prior thing is there is a lot of intricacies and links and mappings and a whole slew of dominoes that I hesitate to start calling out one or the other. That is a personal feeling. No matter how many we list we are going to miss some.

Margaret Skurka: It should definitely go on there because we say specifically SNOMED CT, LOINC, et cetera, CPT so we should include this.

Debra Strickland: Do we say not limited to like that kind of wording there? You know the thought of an all-inclusive list. Things like go further than this list, but these are some of them.

Margaret Skurka: Specifically, but not limited to --

Debra Strickland: Just in case there is something else we are missing. But the research if they start it early hopefully will bag out some of the other things that were missing and they will be able to bring them forward and be able to see if they are covered.

ICD-11 is – there may actually be other avenues of benefit to that because – Rich, you will probably be aware of this. But all of the different – I do not know what they were called – appendices to it. That is like the type of bill, place of service, stuff like that, little things that are in the claim. We may be able to make the claim smaller as an industry because we can use ICD-11 and use all of those different things with it. There are other advantages that we may find by starting the dialogue sooner rather than later.

Margaret Skurka: One last little minor point. All those systems should be listed in alpha order so DSM first – CPT first so it does not look – they are in random order now, but it should be alpha order.

Rebecca Hines: Margaret, where are you in the letter?

Margaret Skurka: I am on Attachment A under number one in the bullet.

Rebecca Hines: And you want to put these in alpha order.

Margaret Skurka: Last sentence.

Rebecca Hines: Start with CPT.

Margaret Skurka: Yes. And then HCPCS. And then LOINC, RxNorm, SNOMED CT.

Participant: And add DSM.

Participant: And maybe add specifically, but not limited to.

Vickie Mays: One of the things that we discussed – it is in Standards actually. Standards discussed this – is the issue of social determinants. There are a lot of calls right now for social determinants to be a part of this. Would it be useful to think about calling that out now as part of also the research in terms of the things that are going to get mapped? I do not know how quickly we are going to get it. There was some capacity in ICD-10. It was criticized because it did not work well enough. It is a big push and we are probably going to hear more about that when Standards does its report about social determinants. Should we be talking about that?

Rebecca Hines: It is already in there. Margaret actually showed us that ICD-11 – if you go to the online tool, already includes those, Vickie. They are way ahead of us.

Vickie Mays: No, no, no. What I am talking about is the training for using it is going to be the big deal. For example, the ability to use it is there, but we do not have a great agreement on what to do. And then nobody actually is training how to do it. Maybe I am ahead because that is like implementation stuff. I just think that – because it did not work well in 10, can we make sure that part of the research is calling out its best practices? That is probably the best way to say it.

Valerie Watzlaf: I think that is in number one also, I believe, with the training. We do have training in there. I do not know. We just used the word. Not specific. It is overall.

Vickie Mays: I am saying call that out because it is such a big issue.

Valerie Watzlaf: We could probably do that.

Denise Love: My hand is not up but isn't one of the problems with using it in ICD-10 is it was never required by anybody.

Margaret Skurka: We have to have physician documentation. If the physician documents that the patient is homeless then we can – there is a code for that. That actually puts the patient – can put the patient in a higher payment bucket because you cannot discharge them to the parking lot. You have to work with --

Denise Love: From State reporting, it is just not – because the provider say it is not necessary to pay claims, so they do not have to report it. That collection is happening, but it is not getting reported out to secondary uses. That is a whole different issue though. That is enforcement and compliance.

Rebecca Hines: To Vickie's question, Number 6 in Attachment A, this is the slimmed down set of research questions. Did you include basically coding use for social services, coordination, public health case for surveillance reporting or quality measures or health equity assessment? Does this cover it?

Valerie Watzlaf: We also have it in eight, but it is really – the example there is looking to see, again, if ICD-11 covers social determinants of health. But I think what Vickie may be saying possibly and maybe we put it in the first one is maybe giving more specifics where we talk about training. Way up at the top there.

Vickie Mays: Also, I just want to say that I think that social determinants of health are different than social services. One is the social need, and the social determinants is a social risk. To me, those are different things. Denise's point is so on target, which is – I guess maybe the issue is not teaching people to use it. It is enforcing or forcing its use in some way.

Denise Love: Just from my ICD-10 and public health, first off is the awareness. They were not even aware what was in there. From people that are not in the billing arena were not aware of all the things that were in ICD-10 so it is outreach education. And then the second part is what you are getting at is training on implementation of how to properly capture it and use it. But awareness. There will be people who are not in the billing world who will not even know what is in ICD-11.

Participant: The billing world does not know, but the coding world does know. We can code it if it is documented. It is documented – then it is coded. Then it is sent to billing.

Rebecca Hines: The question – if you go back to your recommendations that you are proposing here, it sounds like this issue, Vickie, that you are raising really could be embedded into all of these recommendations because it is about implementation, getting this used, about communication. I do not know.

Debra Strickland: And outreach, I think, also covers outreach to find out what areas have not been well represented or well done within other versions.

Rebecca Hines: I guess my question is how do we – what are the outstanding topics that have been raised in the last half hour that will call for some edits either to the letter or to the list of research questions or both. How do we want to handle this?

Nick Coussoule: Sorry Rebecca. Just one other comment. The research questions – if you look at the letter from 2019, the research questions. There is a decent amount more detail built into that with some of the questions themselves. One of the questions I guess we have to answer is do we want to just use that as a reference point because it is included as a reference in our letter or do we want to call that amount more specifically. Because one of the topics – somebody was talking about training and ongoing support. That was called out as a very specific research recommendation in the previous letter.

Rebecca Hines: There was a strategic decision made when the subgroup went to work several months ago to try to keep things at a high enough level that somebody who does not have depth in the day to day of ICD would be able to get their arms around this. The concern was the first set of recommendations was so detailed that somebody might just say there is no way we can do this. The strategy that was agreed to by the subgroup and then the full subcommittee was let us keep this at a higher level. However, Vickie's point I think is a very – it is kind of essential. Is there a way we can – I do not know, Nick, if we want to point people. The first letter is an attachment to this. But I actually think it probably needs to be stated or named somewhere in here.

Nick Coussoule: Because one of the thinking processes or at least one thing going through my head is we could as simply as in the attachment that has the updated research questions, we could even create another footnote that references the questions in the other document. Because it does not then require us to redo a bunch of details that already exists. If somebody is going to be doing research, they are going to be looking at more than just a context and text in our letter anyways to do that. I think it is a good reference point without clouding up the message, which I think was the concern originally. We did not want to cloud the message up. That is just one suggestion.

Rich Landen: Building on Nick's comments, I am starting to get a little bit concerned about scope creep here. Getting into specifics of what is included in the good training program. Our purpose here is really to get the Secretary to commission research and we have -- between this letter and the original letter, we have a really good set of questions used to guide the researchers who will construct the actual research program. I much rather get this letter done today and out the door as we did a couple of years ago, rely on the researchers to actually identify specific use cases, identify specific code sets for mapping to test to identify best practices rather than going into detail about some of our specific things, which to me is getting more into the policy or the advocacy rather than – our main message is we need this research started and started now.

Margaret Skurka: I agree.

Tammy Banks: I was just going to echo Rich's comments. That was my recollection too is we really focused on just getting the research done. We were not focused on different entities because without the research, those decisions could not be made on the next steps. This was the basic block. Let us get the research so that then we can answer a lot of the questions, Vickie, that we are trying to add into the letter.

Vickie Mays: I agree with the need to get it out. But I think what my strategy is is to make it relevant. It is almost like we are repeating but making it smaller of what we said then. There is a different administration. There is a different set of priorities. To the extent that we are tapping into some of those and to the extent to which this gets raised faster. Right now, things that are – I do not know if staff can comment. But things that are like in executive where the column orders and memorandums, that kind of stuff. That is just stuff that is getting lifted up. Having a context of social determinants and how important that is. Having a context because of the pandemic being COVID related, all the mental health stuff that is about to occur. I think changing a little bit of the context may get you – in terms of priorities of this being done as opposed to just sitting.

The extent to which business as usual, I am not sure with all that is going on around the department that you are going to be – we are going to have as much priority.

Tammy Banks: Could I make a recommendation that we go through the letter because I know we addressed some of these points and then let us highlight where emphasis should be because cost is important. A lot of these things are already in it. But it does not mean it could not be worded or emphasized in a stronger fashion. I think we all agree on what the intent of the letter is. We need the research. In order to get that done, Vickie, I totally hear you. How do we make it so it is heard? Going

through the letter, I think, would help us move forward instead of kind of – because I think we agree with the themes. It is just – in this letter, is it in the next letter? That is my recommendation.

Margaret Skurka: Well said. Thank you.

Valerie Watzlaf: Do we have time to go through the letter now?

Rebecca Hines: We have until 4:15. And we also have time tomorrow afternoon to continue. If we want to identify areas and then make edits, we can do that and bring it back tomorrow if we are not quite ready by 4:15. Can you one of you walk us through this? Valerie or Margaret?

Margaret Skurka: Should we start with page 1?

Rebecca Hines: Yes. Let us just say – we have this opening section that basically this would be the first letter from this body to the current administration so the usual here is who we are. Short and sweet. And then second paragraph is here is why we are writing you. This might be one possible area where before we get into, we present the following three recommendations, maybe some context for Vickie's various astute positioning of this in the broader agenda. Maybe a sentence could be added here before we say we present the following three recommendations.

Tammy Banks: I did not read Vickie's cost statement. But I am wondering if before we say we present the following three recommendations if we want to say that this is presented to avert the – I do not think if we can say excess cost, but –

Participant: Significant costs.

Tammy Banks. Yes. Because it obviously took a long time. I am not coming up with the right words. From ICD-10 to ICD-11. Can we cite it? The number is what people – it resonates.

Rebecca Hines: We do not have a number. That is the problem.

Valerie Watzlaf: She has a footnote in there in the chat.

Tammy Banks: That has cost. If there is a number and it is something that we feel comfortable with, Vickie -- I am not trying to jump on your point. That number could resonate with why this is important. I think that is where we are struggling with, how do we say – it is really not something to debate. This has to be done. We have to avert the additional – the administrative burden cost that was incurred in ICD-10 especially if we do not have to go to an ICD-12. But we do not know that yet without the research, which is the frustrating part.

Margaret Skurka: That is why Recommendation 1 and 2 start with the words "we should conduct research". We should conduct outreach. But research is the first one.

Vickie Mays: Let me ask a question because I want to be respectful. This is our first letter going to the Secretary – because he is my guy from California, and I like him. Do we say anything about – I do not know – reaffirming an urgency based on our earlier letter. Is there any reason to say this is there, but it has gotten lost? It has only risen in importance as part of that why this is urgent to read this. We are

coming back a second time. It is overdue. Passed two bills the second time here. Something like that. I want to be respectful, but I also want it to be seen that we asked previously for this to be done in 12 to 18 months. We are back because its urgency because of the pandemic is becoming even more important. Something like that. Rebecca, you have to say --

Rebecca Hines: We say because of the resulting – the delays from the pandemic. My recollection is we have language to that effect, but it is not at the top of the panel.

Nick Coussoule: One suggestion if wanted to accomplish what Vickie was talking about is – frankly, all you really have to do I think is rearrange that sentence. Instead of saying because of delays starting with that, you start with NCVHS issued recommendations in 2019 because of delays, the pandemic, other things. Nothing has happened. It really is just a sequencing question that gets to that point a little more firmly. We made recommendations once. Because of these issues, nothing has happened. Just one way to --

Margaret Skurka: It makes it stronger.

Rich Landen: I would also include a phrase in there with Vickie's thought that we are back because it is important.

Vickie Mays: Would we start with NCVHS issued requests – NCVHS issued a request for timely recommendations. It was timely back then. Thank you. You got it out. I can see. It is hard for me to wordsmith --

Rebecca Hines: It is. But unfortunately, that is where we are at. We have to get this so that it is votable in the next two days.

Rich Landen: I put in where we are after the word pandemic, the point we made about but due to the pandemic, the research has not been accomplished in the 12 to 18 months that NCVHS had recommended. We are now updating our recommendations.

Vickie Mays: You are getting me. Be very respectful to my California guy, but getting the message across.

Rebecca Hines: Can you say that again? NCVHS issued recommendations - in 2019, but due to the pandemic --

Rich Landen: The research was not accomplished within our recommended 12- to 18-month timeframe.

Denise Love: It was not even started though.

Valerie Watzlaf: They did a little. They did do a little.

Rebecca Hines: Say that again, Rich. The research --

Rich Landen: The research was not accomplished within our 12- to 18-month timeframe.

Rebecca Hines: This is the first time we use the word research. I would say issued recommendations to HHS to conduct research.

Margaret Skurka: Yes.

Rebecca Hines: Okay. Now, the committee is updating our recommendations regarding --

Tammy Banks: Can we use Vickie's language? The committee is reconfirming the priority through these updated recommendations.

Valerie Watzlaf: Could I just make one point though? Not only the research was not conducted, but they did not do any of the recommendations. They were not able to do communication. There was nothing that was done.

Rich Landen: Big part of Recommendation 3, the licensing, but you are right. No strategic plan for communications whatsoever.

Valerie Watzlaf: Should we just say all recommendations or something? I do not know. If you want to make it specific to research.

Tammy Banks: Or we could say the recommendations, specifically the research, if you wanted something like that.

Rich Lander: The research and other recommendations were not aggressively conducted or something like that. Research and communications plan were not accomplished.

Tammy Banks: We may have to take out aggressively because I do not know if Vickie will think that is respectful.

Rebecca Hines: To me, reiterating is a little weak.

Tammy Banks: Reaffirming. I love reaffirming.

Rebecca Hines: I would say because of the immediate need. I would say why and then say what you are doing because that is what you all keep saying. Because this is so important, is there a better way to say because this is so important, and the committee is very concerned? That is what you are saying. Because this is so important –

Tammy Banks: Well, does industry priority warrants or something like that.

Margaret Skurka: This is a critical issue.

Rebecca Hines: I think we need to come up with something better than this, but this is a critical issue and thus the committee is reaffirming. Is that what you were saying?

Tammy Banks: Reaffirming.

Rebecca Hines: Reaffirming our recommendations regarding the immediate need for research and the strategic – okay.

Tammy Banks: Do we have to say revised because these are revised? Reaffirming – revised or recommended or updated recommendations.

Rich Lander: Reaffirming and updating.

Rebecca Hines: Do we want to do something stronger than this?

Vickie Mays: How about delays to the implementation of research, communication, and whatever the third thing is of ICD-11 are costly to industry and to – how do I say it – public health surveillance of mortality and morbidity.

Rebecca Hines: Can you say that again? The latest in this research and strategic – we said strategic communications.

Vickie Mays: I cannot remember the three things. Valerie has them. The third is copyright. I guess it is research and evaluation, communications and copyright and determination of copyright, detrimental to both health care industry and public health surveillance relative to costs and mortality and morbidity assessment. That is too long.

Margaret Skurka: Take out the first "and". Delays in this research, strategic communications, and copyright determination.

Rebecca Hines: Detrimental are or will be. Maybe we should be a little gentler. Will be detrimental both to the health care industry and – do you want to say public health or mortality, Vickie? You cannot have everything in one sentence.

Jamie Ferguson: I have to say. I was thinking of maybe a slightly different approach, which would be to say that actually the departments in action – I was thinking that the departments in action have increased the urgency of addressing these issues.

Margaret Skurka: That is pretty strong.

Valerie Watzlaf: Is that nice enough, Vickie?

Jamie Ferguson: That is what has happened.

Vickie Mays: Let us say the department was delayed.

Jamie Ferguson: I like inaction, because we called for action and we got inaction. Sorry.

Vickie Mays: I want to make friends with them since this is the first letter to them. We want their staff to like us and raise our letters up to higher priority. I think the person just got appointed who oversees preparedness and disasters. I do not want to hit them too hard.

Rebecca Hines: What if we do this? Jamie, this is your suggestion. Your suggestion is that the department's delayed action has increased the urgency to commend this research strategic communications and copyright determination.

Jamie Ferguson: Period.

Rebecca Hines: Period. I will move this down to keep it just in case and put this here.

Tammy Banks: Do you want to add immediately or at time type of stamp? We have immediate need. Forget it. Okay.

Rebecca Hines: Increase the urgency to commence research, strategic communications, and copyright determination as soon as possible. That is what you are saying, right?

Tammy Banks: Sooner than that because that is ten years.

Jamie Ferguson: I do not think you need to say as soon as possible. We are saying – the urgency has been increased.

Rich Landen: If I may, I suggest we not use the term copyright determination. That was the original letter. In this letter, we are using – didn't we call it blanket something or other.

Rebecca Hines: -- licensure.

Valerie Watzlaf: It says blanket access to ICD-11.

Rebecca Hines: Now, we are saying NCVHS issued recommendations to HHS in 2019. But due to the pandemic, the research and other recommendations were not accomplished within the 12 to 18-month timeframe. This is a critical issue and thus the committee is reaffirming and updating our recommendations regarding the immediate need for research and – specific. The department's delayed reaction has increased the urgency to commence research – and blanket access to – that all makes sense.

Nick Coussoule: A minor point. We said within the 12- to 18-month timeframe. Do we say within our recommended or suggested 12- to 18-month timeframe? Because otherwise the question is where the timeframe came from.

Vickie Mays: Within the requested. I think that the urgency is – the urgency is picked up if we say something about the cost next and something about that those costs are to the health care industry as well as public health surveillance.

Margaret Skurka: I am a still a little worried about blanket access because WHO says it is already there. It is free. You can Google it and see ICD-11 as long as it takes you to type ICD-11 coding tool. Isn't that what --

Rebecca Hines: Let us make sure we fix that but let us keep going here.

Jamie Ferguson: I am not sure about saying that – we do not know that we are going to avert significant costs. That is why we need the research.

Tammy Banks: The cost point is based on ICD-10. We avert significant costs and avert it to the US system that was incurred with ICD-10. I think that cost is important. I get – to avert the significant costs – it was $6.6 billion or something every year that we delayed last year. It may not be the same with ICD-11. But the point is there are significant costs.

Nick Coussoule: But, again, that gets to the distinction between the transition costs and then the change in the date of compliance, if you will. There is a big transition cost. But then there are incremental costs if we jump the dates out multiple times.

Rich Landen: We are not talking about the cost benefit of ICD-11 itself, just the cost of the delays and the transition.

Rebecca Hines: Do we want to put Tammy's footnote here. I have not had a chance to look --

Tammy Banks: It is Vickie's.

Rebecca Hines: Sorry. Vickie, do we want to put your footnote here, that document that is in the chat perhaps?

Vickie Mays: I was saying, let me just look at it and trace it back and make sure it is the most solid – put it in and then I will look tonight to make sure – sometimes the Internet can tell tales.

Rebecca Hines: We know we need a footnote for the cost. With this urgency, we present the following three recommendations. Do we want to keep going? It is 4:15. How do you all want to proceed?

Nick Coussoule: Rebecca, why don't we spend a few more minutes going through the rest of the letter, but only a few if we can get the key points and then we can try to bring back an updated version to be able to go through tomorrow? I just want to make sure if we get what I will call significant points here because we do need to leave enough time for PCS.

Rebecca Hines: Right. My suggestion would be to the subgroup or the subcommittee, is that I send this to you all, you work on it, and we send out another track changes version to the Full Committee overnight or first thing in the morning so that then everyone will have read it all and we can discuss it in the mid-afternoon tomorrow in terms of process.

Here we go. This is the background because we cannot assume whoever is reading this is going to know. A little bit of background. What is ICD? Why do we care? Here are its three components. We spend a lot of time wordsmithing this. Mortality, morbidity, and payments. We know it is required for mortality, for morbidity. This is where the research is really needing. And then we know that it is a HIPAA-designated medical code set. It has a whole lot of payment implications. And then here is the sad story about what happened. It took 25 years to be implemented from 9 to 10.

Then this does not show urgency to Vickie's question. But it gets to why do we care. Here is basically why ICD-11 is fundamentally different from the previous versions. That it would basically be the last ICD version because it would be updatable because of its logic design.

And then we can get into each recommendation's rationale. There are all kinds of details here. Val went over this on the slides. Here is the impact that needs to be evaluated. What is the business case, the quality of the mapping? This gets to your DSM. How does it map to the other code sets and so forth? This is why the committee recommends that this research be done. And then we added this since it went to the executive subcommittee. Val talked about this on the slide. There has been a paucity of research. Only three studies done.

Then Recommendation 2 gets into the whole issue around need for outreach and communication. Just all of this messages that were developed by the roundtable the committee held two years ago.

This is where we got the word blanket access from Recommendation 3. How best to enable basically access to minimize cost. And then the conclusions, taking a proactive approach is essential. It is at a pretty high level. And then there are the research questions. I think there are ten that you all have in your possession.

Process-wise, where are we?

Nick Coussoule: I think process-wise, let me make a suggestion. Can we get a clean version at least as best we know now out to folks ideally tonight to give them a chance to look at it? We have time in the agenda tomorrow afternoon. We can revisit and go back through other adjustments or changes. If we could do that, I think we are at least positioned to try to get to a conclusion tomorrow afternoon.

Vickie Mays: Can we leave the track changes in?

Rebecca Hines: Yes. We can send both versions. Vickie, I know you had something that I think is worth trying to find a way to weave in, which is how this relates to the current priorities. That does not seem to be reflected in this. If I send this out and you would have a suggestion for a sentence or two, please send that out so that we can send it out to the Full Committee.

Nick Coussoule: Does that sound good? I wanted to make sure that Val and Margaret are okay with that approach as well.

Valerie Watzlaf: That sounds fine. Thank you.

Rebecca Hines: Good discussion.

Valerie Watzlaf: Great feedback. Thank you.

Nick Coussoule: Then we will rapidly move on to our last agenda topic prior to public comment, which is our Subcommittee on Privacy, Confidentiality, and Security, talking about the update on data collection and use during a public health emergency. I will turn that over to Melissa and Jackie.

Rebecca Hines: If we could let Melissa share her screen to our Zoom techno gurus so that Melissa can run the slides. Thank you.

Nick Coussoule: Just one other request. If you are not talking, please mute your --

Subcommittee on Privacy, Confidentiality and Security

Melissa Goldstein: We are starting a little bit late, and we only have 45 minutes for the discussion to begin with. Hopefully, if we run over, we can take some of that extra time tomorrow afternoon as well if it still exists.

Essentially, our presentation today and Jackie is going to be on the phone, but she is still with us and will be able to obviously contribute. The major purpose of this presentation is to remind us all about the hearing that we did almost a year again on data collection and use during a public health emergency. First, I will go over the themes of the meeting, what we heard from our panelists, a few big points, and then essentially what I would like to focus on is a discussion among members, particularly the members that are not in the PCS Subcommittee about what our next steps should be, what you guys resonate with, ideas that you have, thoughts about the most important topics in this very large topic, very large overarching topic that would be best for us to focus on, moving forward, and such as a report, such as a transmittal letter to the Secretary with or without the summary of the hearing, which is posted on the website and we did recirculate for all of the members. I will go on now and quickly I think –

I will remind us all what the context was when we started this project over a year ago. Frank Pasquale was with us at the time and helped put together the hearing with of course our wonderful staff.

The idea was that we had a need for support of public health contact tracing activities at all levels of government so federal government, state activities, local practices, tribal, a need for contact tracing. And that there is variability, which we talked about several times today and data collection and use activities at all of these different levels. Variability, not even consistent variability at any particular level of government.

Our overarching question that we raised is what tools might we use for public health surveillance in a public health emergency? If you recall, different apps, different technology solutions were proliferating at the time. It was not clear what was working, what was not working, what the privacy implications. We really had a lot of questions.

For instance, exposure notification apps such as the Apple Google state-sponsored, others that would tell people who had these apps on their telephones, when they had passed by or talked to or been in the same place as somebody who was positive for COVID. And the apps all had different elements and different underlying structures and systems. We heard a lot from our panelists about differences in the various apps, particularly in the area of privacy.

Our objectives in putting together the hearing and the panelists, number one was understanding the current policies and practices for data collection and use with regard to privacy and security of identifiable COVID data. We were specifically focused on identifiable data.

We wanted to identify best practices in a public health emergency situation, not just a pandemic, but in general and what worked. We wanted to consider additional technical assistance that was needed, what did not work. We wanted to consider building upon prior committee work. For instance, the 2015 toolkit for communities using health data --

Maya Bernstein: Melissa, can I interrupt? This is Maya. Just for a sec. We are still on the title slide. Are you turning the slides and we are not seeing them or --

Melissa Goldstein: Yes. I will stop it and share it again. Vickie, you had your hand up. Is that what you were going to let me know also?

Vickie Mays: Yes.

Melissa Goldstein: Thank you. The idea of building on our prior work, the 2015 toolkit for communities, using health data, and the 2019 health information privacy beyond HIPAA work that the committee did then.

And then finally, the objectives were to consider developing recommendations on the values and opportunities and data collection used in public health emergencies.

Our panelists came forward with a wealth of information. These slides basically put together a few themes. They are not comprehensive. But we do have the summary of the hearing, which is very comprehensive and well done actually on the website.

The need for data collection and use framework. Many of the panelists actually focused on this idea. A framework that is overarching, integrating, well-funded at different levels of government, socially supported at different levels of government, and specific to public health emergencies, pandemics, or otherwise.

And another theme that came up quite frequently was the need to address health disparities and improve health equity particularly in the context of public health emergencies.

Other themes. Technology and ethics goals. A health data infrastructure for new forms of data collection and sharing in a public health emergency such as these apps. What is the infrastructure that we would want to happen? It is a new form, not necessarily in kind, but in application of data collection and sharing of this particular type of data.

The idea of removing data silos across public health and health care entities, which we also spoke about when we were reviewing the Report to Congress a couple of hours ago. The idea of the development of standardized data use agreements that various actors, government, nongovernment could use about data sharing. The idea of collecting and sharing complete race and ethnicity data. The acknowledgement that we do not collect and share complete data now in these areas, but they desire to do so. The goal of doing so in the future based on ethics principles and based on technology development. The idea of a potential data commons, combining data and the computing infrastructure so that we would have a data commons. Necessity of embedding privacy and security guidelines from the outset. And the

context of data sharing within communities in a privacy-appropriate environment, perhaps small towns, perhaps large towns, but the idea of being data sharing within those communities.

Other themes. A theme that we have heard before and that we talk about quite often is the difficulty of the multiple patchwork and variety of laws at the different levels of government. Do we need to develop national legal policy standards? I would say legal and policy standards, legal or policy standards that deal with public health emergency laws in general. That is not what we have now.

The questions about the definition of a HIPAA-covered entity. The apps themselves may or may not have been used by HIPAA-covered entities. Should we develop a broader definition? Should the idea of covered entity apply to more institutions/organizations than it currently does? Or would we approach the practices of non-covered entities in a different way? Again, this division between covered entities and non-covered entities – the application of HIPAA only being relevant and the idea of HIPAA-covered entities.

The standard of de-identification as the current backbone of using administrative data. The panelists weigh the idea of developing a new term instead of de-identification. The importance of assessing and communicating risks, the concept of risk assessment. And opportunities and redacting different identifiers so that the focus is not solely on de-identification. Should we develop new models for de-identification? Should we explore new ways to bridge that HIPAA/non-HIPAA gap in the area of de-identification?

The hearing was almost a year ago. Time has continued. Some of us can keep up with it. Some of us cannot. Some of the days all seem the same. We are still in a pandemic. But it is a very different pandemic. It has evolved. The technological tools have evolved. The priorities at different levels of government have evolved. We have had a change in the federal administration, the executive administration. Things have changed. We are not as focused on the idea of exposure notification apps now as we were a year ago.

Does that mean that what we have learned is not applicable anymore or that it applies in a different way? We did not adopt them in this country widely. Other countries adopted them much more widely. How could we use the knowledge that we gained in general for contact tracing? What did we learn? And most importantly for this discussion today, what are our potential next steps?

Some ideas that we have come up with as a subcommittee and with discussions with Sharon, Maya and Rachel, focus on how can we be better prepared for the next public health emergency whether it is a pandemic or not. The idea of exposure notification versus contact tracing. The relevance in general of registries. Apps that share vaccine status. Now, in other countries, you have seen the usage of the green card I think they are calling it or green app. I am not exactly sure what the technology is. And the idea of contact tracing, not just status, status of do you have the disease or do you not, but how do we measure attitudes about contact tracing. These are some potential topics.

Another possible list. Data collection and use and health care, public health, research in general. The CDC developed the V-safe app, which was essentially the after-vaccination health checker to see about side effects, to see how people did after the vaccination. It was not widely used, but this was another

app that was developed. The idea of vaccine status, of vaccine passports, which I have in quotation marks here, which we have all heard about quite a bit, the idea of them. What are the standards that we want to follow? What is their guidance that we think we should be following in terms of privacy and security for information sharing?

What is the relationship to foundations for Evidence-Based Policymaking Act of 2018, which we generally refer to as the Evidence Act? This law, which was passed in 2018, requires federal agency data, all agencies, to be accessible and requires agencies to plan to develop statistical evidence to support policymaking. What are the privacy issues that are raised when we are linking general data sets from housing, transportation, commerce with COVID data? I brought this up a little bit earlier when we were speaking with the speakers earlier about linking data. What are the issues with linking this type of data? How about the idea of long-term maintenance and use of data? We have collected all of this data now on COVID and we will continue to do so. What is going to happen with it? How do we maintain it long term? Who will have access? What are acceptable uses? What happens? Again, more potential topics.

Analysis of the federal program waivers, which we discussed briefly when we were discussing the Report to Congress earlier today. One of them was USDA, the Department of Agriculture flexibilities in the WIC program, for instance. Remote contact with eligible families to meet the demands while protecting health and participants and staff. The idea of waivers that were granted to mail drug-related supplies so in the mail when before that was not allowed. Waivers for tele-health access, which we discussed earlier. And notices of enforcement discretion of various HIPAA rules. This does not mean that the rules did not apply. This meant that OCR, the agency that enforces HIPAA, publish a series of notices of enforcement discretion on what they would be focusing on during the kind of pandemic.

Should we focus on strengthening the immunization information systems, in general? To reduce health inequities. To ensure that we conduct rigorous evaluations of vaccine campaigns. To make sure that we have comprehensive coverage of vaccine administration. To gather complete and again I emphasize the word complete demographic information and to focus again on increased linkage between the immunization information systems and electronic health records.

Finally, I believe this is my last slide. What do we do with these policy legal waivers, enforcement discretion, the ones that exist, many of which are still on the books? What is their timing? When should they be in effect? When should they sunset? Can there be a reapplication of people who benefited from the waivers? How do we evaluate what happened? How much data was exchanged? Do we know what happened? Accountability. What about breaches that happened during the time period when these waivers existed? Are we tracking the collection and use of data even while these waivers exist? Should we be? What are the standards for doing so?

And then finally, the idea of data collection and vital records to emphasize this again. States not sharing timely data on cases or deaths and there are many reasons why this might be the case. Should we move from weekly to monthly sharing of data? States do not want to look like they have a bad record of cases. We saw this in New York. It is a very controversial issue. Are there standards for detail on data or timing on what data, what the timing of the sharing is? What about clinical lab work, hospitalization data, et cetera?

Potential next steps. I was not honest. I told you that was my last slide. This is focused on what our next steps as a committee should be. Should we have a transmittal letter to the Secretary? If we do, should with the transmittal letter include the hearing summary? What other suggestions, recommendations, analysis should that transmittal letter include?

Should we focus on current HHS activities that have moved on perhaps from the focus on the exposure notification apps that we were focused on a year ago? What are the gaps in federal, state, and local data collection and use work and how can this committee contribute to that existing work in data collection and sharing?

Should we hold additional hearings on new topics? For instance, emerging COVID-related and/or public health emergency, security, and privacy issues. Should we return to the data stewardship theme that we focused on in the past? Should we build upon the 2019 Beyond HIPAA work and the 2015 NCVHS Toolkit, which we had first imagined that we might doing in this project? What about linking the various case studies that were presented by the panelists in that hearing a year ago?

Additional topics that we might want to address. Community outreach on data collection use and sharing. Even the idea of community consent. Communication with the various communication communities involved. Transparency. Should we focus on secondary use of all of this data that has been collected? Finally, an emphasis on public trust. We have seen during the past 18, 20 months how public trust vacillates widely and how we, as a country, and the sick and the healthy alike suffer from lack of public trust and our governmental institutions. That is a list of very few things that we have to decide.

But I would really love to have your input, especially those of you who have not been discussing this weekly. But we would really appreciate it. Ideas, instinct, both committee members, subcommittee members, non-subcommittee members. What do you feel like our next steps should be? What should we focus on? How should we use this wealth of information that we have gathered so far that we raised in the hearing almost a year ago?

Vickie.

Vickie Mays: I just wanted to start by saying you did a fantastic job. We had a lot of issues, and they needed to be made sense of, and so I just want to say to the group, there's a lot of richness there, and Melissa, thank you for the work you did to translate that as well as you've done. I'm going to let others talk.

Melissa Goldstein: Thank you, Vickie. I do have to point to Maya Bernstein, who put together the original list and did all of the hard thinking work. I'm just the speaker, but thank you, Maya, and thanks, Vickie.

Maya Bernstein: Actually, Valerie Watzlaf did an amazing summary early on, which I forgot about, recent discussions, so she deserves a lot of the credit, too. But really, we came together as a team and I think there's a lot here. I'm looking forward to the discussion.

Valerie Watzlaf: I shouldn't forget the contributions that Vickie made, either.

Melissa Goldstein: Teamwork. It takes a village. It definitely takes a village.

Nick Coussoule: Just a couple of thoughts. One is the first question, I think, is how do we sort of wrap up the work that was done, first? I think creating a letter, a transmittal letter, that creates at least a high-level summary of the work, and then points to the documents and things that have been created, would be useful to inform the Secretary of the work that happened.

The second question, for me, is really more of how do we pick and choose the right topic that we believe as a committee we can be effective on, that's either not being addressed by others or can complement what others are doing already? I'm probably not the best one to understand what else is going on in the ecosystem so that we're not duplicative, but we're additive.

I kind of have my own thoughts about some of the priorities, but I'll leave that to others as well. But I think that's the two things that we need to think about.

Melissa Goldstein: Thank you. Wu.

Wu Xu: First, thanks, Melissa, and the whole subcommittee's work. This is very good information for me for thinking what I see the state needs, the subcommittee, if in your future work, can provide more guidance, I think it's in the data sharing and the linkage domain between three parallel relationships.

One is the covered entity with uncovered entity, when they share data. What we need to pay attention, what the policy we should follow. And the second is social determinants data, environmental data, with healthcare data. Public health data. How should we handle that non-covered entity issue?

And the third point is the state and federal data sharing and the linkage. I think the states are willing to contribute, but we do have different policies, so how do we coordinate and communicate with all the states working on this issue, are very important, including in the pandemic. How do we report? They are ranking about the different states pandemic data transparency, among the associations, but how can we really bring that to every state a higher level, and share data, similar standards and the timeline? That's my field's needs.

Melissa Goldstein: Thank you, Wu.

Vickie Mays: I just want to respond to Nick. Because as you were presenting, I was really trying to think about the first question of what's the product here. So I think Nick has it absolutely right. We should share what happened and kind of why the context is different. Melissa you did great, because that was the issue then, but these are the issues now.

You know, I think the difference between what do we think we want to work on, and that's bandwidth, and whether or not to make the Secretary aware, because we have a special insight into data to make the Secretary also aware of all of these other issues so that those become a part of issues to be considered and let the Secretary also consider who our relationships might need to be. Because maybe there's work we can do, and it's not being duplicative, but it is being -- just like we are with ONC. So I think there's some groups that we might consider sharing some of these issues with rather than doing them alone.

Melissa Goldstein: Thank you. Good ideas.

Denise Chrysler.

Denise Chrysler: There was so much back then, and it feels like things have changed so much in one year, and what issues -- I know that Melissa pointed out the issues then and what are the issues now. It's important to say where we've been and what we were looking toward, except with the faucet being turned on for resources to public health, to modernize public health data systems, and all the focus on interoperability and linkages and so much has happened in the last year, even this morning's presentation on data linkage, which I was not aware all of that work was occurring now. I'm not sure with what we heard and what we were thinking of, a year ago, where are we today and what's already happening?

Melissa Goldstein: It is definitely hard to get my head around. I guess the challenge is that we will see apps, for lack of a better word, popping up again. They may not be exactly the same apps. A year ago we had these exposure notification apps, where they would have a little video of people outside on a bench and one person -- both of you had to have signed up for the app. I know Washington D.C. had one. And there was different uptake in different places.

And now we have this green app, or green card, in other countries, and there are some developed here. Do you have your vaccination card? And some of it's not an app, it's just you pull up a picture on your phone, right? And then there are the, quote-unquote, privileges to go into certain places if you have the vaccination app and if you -- picture, and if you don't have it, or if some reason you do have it and don't want to how it, then you do not have access to that privilege.

While many people would agree that that is appropriate, there are people that would question it, and how do we think about this from a not necessarily standardized, because every situation is going to be different, but what are our priorities, what are the principles that we would want to follow with privileges, especially with the idea of division of different groups in our country. And how do we think through these ideas? How do we raise them for the Secretary, and like Vickie said, what are other groups that are working on it, who could we work with, such as NCVHS has worked with ONC before on projects together, so that we're not doing it all by ourselves. What issues do we prioritize and raise for the Secretary in whatever letter or recommendations we develop, I guess? That's how I've been trying to think of it. But it does not encapsulate everything, you're absolutely right.

Vickie Mays: I get Denise's concern, because the landscape is different, but it's the lessons learned from the landscape then. So even though we moved ahead, we moved ahead in a crisis manner. So for example, I put up there the issue of the waivers. We issued waivers, and it's like the next time something happens, it's like what's the policy about waivers? We're not checking, what do we need in place, does somebody have a kind of tag that follows the data that's in the waiver? I had really moved on about how to handle it in COVID, but I don't think we've moved on in terms of we will do the same thing in a different kind of disaster, I think.

So we want to begin to look back to begin to talk about best practices. Because even some of the things that are moved on, I don't know if they're just moved on because they got money to do them right now,

or whether CDC, some of this stuff, they will continue to do. So that's what some of us worry about is services you see now, again, somebody may say I have to have a handout to make it work, and instead we need to say what must be, and who must do it, to some extent. So I think that, to me, is -- yes, we've moved, but we still should comment.

Melissa Goldstein: I generally fear repeating the same mistakes. I think it's human nature that we react in the same way, especially in an emergency situation. We react very quickly, we don't always think things through. We don't always anticipate unintended consequences. They're unintended, right? And some of them are impossible to anticipate, of course.

Jacki, do you have anything that you'd like to add for us to think about right now?

Jacki Monson: If you can hear me, I am good right now. Thank you, though.

Melissa Goldstein: Thank you. We have a few more minutes now. Rebecca and Nick, if we do have any additional time tomorrow afternoon, if there's any flexibility, if we can add another 15, 20, 30 minutes to discuss, but we have a few more minutes now, and then I think we need to move to public comment. I see Denise Love.

Denise Love: My head can't get around all the wonderful information that was presented, and of course, being me, I'd want to do it all, of course, and we can't. But one thing that stood out to me a little bit is I believe in building on some of the past work, and the data stewardship thing rung out to me as maybe for data custodians and others, to maybe update some of that for how to manage your data assets in an emergency and what are those principles and guidelines of things to be thinking about.

Melissa Goldstein: That is very helpful, because we have, considering the amount of data that we have on COVID, knowing that it's not complete, but all of the data that we've gathered over the past year, what have used, what have we not used? Who are the trusted stewards who can tell us the aggregation and what the data means, who translates it? I think those are very important issues.

Denise Love: Just one more thing, I think the data custodians out there in the field on the front lines would appreciate some overarching guidance, because in the storm sometimes you do what is right and what is legal, but it would be helpful to have some updated data stewardship considerations.

Melissa Goldstein: That is helpful, thank you, Denise.

Nick Coussoule: I would echo that as well. I think you do lots of things from an expediency perspective that is all well-considered and thought through with the time that you have and the information that you have. Hindsight is oftentimes much easier to go back and be critical. But I also think it's easy to go back and say, we did these things, they were reasonable things to do, but here's what we might do differently, or how we even cover for the things that happened. Because I think data stewardship is a big deal. So I think that's certainly worth considering.

Melissa Goldstein: Thanks, Nick, I agree. Rich.

Rich Landen: A couple of thoughts. First is just to agree with Nick's conclusion that I think one of the first products needs to be figuring out how we need to wrap up the report on this and get done with the product from last year.

Looking at the future, kind of along the concept what Denise was saying, a playbook for -- and I'm thinking not only for data custodians but also for jurisdictional authorities, whether that's state, county, local -- a playbook. And part of it is, we can talk about Evidence Act, part of it is what's the science? Part of the evidence, though, gets to the other theme that came up in your excellent description of some of the issues: how do you use that scientific evidence for decision-making in a population such as ours that rejects science?

A specific example is the mask mandates in schools. Some jurisdictions say thou shalt wear a mask. Others say thou shalt not wear a mask. How do we bring some -- how do we help people making those decisions understand the lessons learned from the current situation? I don't know the answer to that. But the conflicting leadership roles that we've seen throughout this pandemic has really exacerbated the crisis, and a playbook on how do you make decisions that balance the science with what you know that your population will accept or not accept.

Melissa Goldstein: That is a very helpful description, Rich. It makes me think about the ideas of communication, of transparency, of public trust, of the idea of working with communities. We might call it community consent, or we could just call it the working with communities and sharing the data. I know that there are groups that are doing it, but I think the idea of a playbook is very interesting and could be helpful to a lot of people.

Any final thoughts before we move to public comment?

Maya Bernstein: I had one thought, if you don't mind. Some parts of the discussion earlier in the subcommittee there was an acknowledgement that this might be one of the first products out of the Privacy Subcommittee to the current Secretary, and how to frame something that sort of seems like it's past. Like, its time has really passed and how to -- I just, that's why I think we talked some about the context of how this arose, really with Vickie's help and how to shape that, talking about why the committee was doing its work at the time in the way that it's supposed to, but it just didn't pan out because of the way the pandemic proceeded.

So if you were to do what Nick suggests, I think you would want to be careful to frame that like we're not back there anymore. We understand we're not back there anymore, but we're just putting a pin in this thing that we did and explaining where we were then, but maybe -- and describe what we did and perhaps here's what we're going to do going forward so you have a kind of forward looking way of framing that that might be helpful to the committee's communication/interaction with the Secretary.

Nick Coussoule: I agree with that completely, Maya. I think it's one -- it's a good way to kind of codify what happened but then also to highlight here's some of the things that we heard, which we believe are very relevant going forward, not everything, because some stuff has changed, but the things that are very relevant going forward that the committee could undertake and frame it up as a little more future looking as well. I think that's a great idea.

Melissa Goldstein: Thank you. Denise.

Denise Chrysler: One of the challenges I find is there is so much going on right now. This morning, I was surprised by some of the initiatives. I thought I was around things enough. For example, the one about public trust and the things Nick was talking about with regard to the struggle over mask and the issues of believing science and the public trust issues, and for us, thinking of are we in a position to make recommendations or are we maybe suited to support initiatives that are already happening that we see as priorities and want to hold up and support, just because I question whether there are things we're going to come up with that aren't already happening at some level and need to be supported.

Melissa Goldstein: Thanks, Denise. This does seem to dovetail a little bit with what Vickie said earlier.

Vickie, you had your hand up?

Vickie Mays: Sorry, I saw the time and so I was just going to say quickly that some of this isn't I think about us making a recommendation to the Secretary. It's about informing about the landscape and the implications of the landscape as opposed to a recommendation.

Melissa Goldstein: That is a helpful characterization.

Okay, so hopefully we'll be able to discuss for some time tomorrow afternoon as well. We will circulate the slides tonight so that you guys can think through and come forward with more brilliant thoughts tomorrow, brilliant and helpful, and I will turn it back over to you, Nick and Rebecca, for the public comment. Thank you.

Nick Coussoule: Great. I like the characterization of brilliant and helpful. That's important.

All right, Rebecca, can I leave it to you for public comments?

Public Comments

Rebecca Hines: Sure thing. We are at that magic moment of public comments. We have some folks here with us on the Zoom. If you would like to have an open line, the instructions are here. Raise your hand to have your audio unmuted, or you can type into the Q&A to request an open audio line if you're on the phone, and I don't believe we have any folks; we do have somebody. I see a hand up. Greg?

You can also send comments by email for me to read into the record, ncvhsmail@cdc.gov.

Greg Richard: Our first public comment is from Katherine. Katherine, could you please introduce yourself and state your organization?

Katherine Isbell: Thank you, sir. My name is Katherine Isbell. I am the education services manager at LexiCode, and we are a large coding consulting firm. I want to first of all thank you for the opportunity to speak today. I am commenting concerning ICD-11. I also want to thank Margaret for her many years of service to our profession and thank the committee for their hard work on this topic.

We are very excited about ICD-11. We have used it. I feel like it is far superior, as far as the classification is concerned. I really like the post coordination in the codes. I feel like that this will be an area that will improve the quality of the data. I feel like it will absolutely minimize our coding errors, having the post coordination as opposed to in ICD-9 and 10, where we have had so many combo codes, and of course when you have combo codes, the more components of the code, the higher probability of error with the coder. So I really like everything about it, just to be honest. The social determinants of health, there's a very robust -- in chapter 24, we have lots of codes in ICD-11 for that.

So also, I've listened a lot to Dr. Michael First, who is involved with the DSM-5, and of course he worked on the ICD-11. So I feel very confident and according to some of those experts who have spoken, that there is a greater confluence among our ICD-11 and these other classifications that are used. So I feel like that's going to help us a lot with documentation issues where we will be able to more accurately reflect the clinical components that are needed for accurate coding.

The training, of course, we learned many difficult lessons in the ICD-10 implementation, and so I just in studying ICD-11 and using it myself, I feel like the training will be much simpler. I have already started training our coders alongside of our fiscal year 2022 training this year. I have shown them the coding tool and demonstrated it. We've also coded side-by-side our ICD-10 and ICD-11 codes for this, the fiscal year updates this year.

So I personally agree that there's no need for a clinical modification. Likely it would not be needed, per Dr. Fung's presentation in March, which was excellent, and I just really want to encourage you in the work that you're doing. You're doing a great job and hopefully the Secretary will take your recommendations. Thank you again for the opportunity to speak.

Rebecca Hines: Thank you, Katherine. Much appreciated for your support of the committee's work.

Greg, we have another commenter.

Greg Richards: Yes, Bob.

Robert Gellman: Thank you. My name is Bob Gellman. I'm a privacy consultant in Washington. I'm not representing anyone here today.

I want to remind you or tell you about a report that's just about a year old today that I did along with Pam Dixon of the World Privacy Forum. The report addressed the waivers that HHS adopted because of the HIPAA pandemic. Some of those waivers were statutory waivers, which were perfectly legitimate. Some of the waivers were administrative waivers. The administrative waivers we found were -- some of them were questionable legally. All of them actually were legally. But some of them were essential. Some of them were overbroad, and some of them were wildly overbroad.

We examined the issue, and we made some general recommendations, which basically we thought the NCVHS at some appropriate time should take a look at this issue. It's a complicated matter. There are a lot of stakeholders, and it requires some careful consideration to figure out how to deal with this issue for the next pandemic, the next unexpected health emergency.

We didn't think a year ago that this was such an important issue that it warranted waving around at the beginning of the pandemic. I think I'd make the same judgment today, but the time will come in the future, possibly in the next year or two, when this issue will require attention, and I commend the report to the committee. Some of you might want to take a look at it. It's at the World Privacy Forum website, worldprivacyforum.org.

Thank you.

Rebecca Hines: Thank you, Bob. I do not see any other requests for public comment, Greg. Can you confirm whether anyone else is requesting the opportunity?

Greg Richards: None currently.

Maya Bernstein: I will find the link that Bob mentioned and send it around to the members of the committee.

Rebecca Hines: That would be great, thank you. We'll also be sending around Melissa's slides. So that brings this public comment period to a close. For those who are members of the public, we will be offering a second public comment tomorrow afternoon at 12:45 Eastern.

Over to you, Nick.

Wrap Up & Adjourn

Nick Coussoule: Excellent. So let me try to wrap up. We had a frankly very busy and productive day today. We had some good overview of a lot of the things happening within HHS that Sharon shared with us this morning. It's kind of daunting the sheer number of things that are going on, but it's great to hear the items and the priorities. We had a good discussion from NCHS in regard to DMI, Data Modernization Initiative, some of the linkage activities.

A couple of great topics from PCS committee. We finished the report to Congress and we're ready to get that published and did some great work on the ICD-11 letter. So thank you to the committee members and staff for a very good and very productive day.

A couple of takeaways from today that we will revisit tomorrow. One is the ICD-11 letter. Hopefully we'll get out an updated version of that to the committee and we'll schedule some time tomorrow afternoon to revisit that, as well, and then to revisit that, and we will also carve out some time in the afternoon to continue the discussion that we just finished, or at least I should say that we just conducted, not finished, in regards to PCS and some of the follow-ups to last year's committee meeting and some of the priorities that the committee may undertake. So I think that was a very good discussion that I think we'll continue that.

One thing I would ask the committee members is if you look, if you get a chance to look through Melissa's deck that she presented, I think that would be a good trigger point for you to consider other things that we may be able to talk about as priorities tomorrow.

Tomorrow, we have another busy day. We spend the morning with standards as well as our friend Steve Posnack from ONC, and then we'll have a good discussion in the afternoon in regard to the health equity update from Sharon, and then we'll schedule some time, as I said, to the two topics that we've just covered, and then some amount of time for the workplan that we will cover, but I think the workplan is pretty straightforward right now. Some of it will be informed by the other discussions that we have.

So with that, any other comments or questions from the committee members or staff from today to wrap up today?

Rebecca Hines: Just to confirm, to sum up, Melissa's slides and the link that Maya just provided in the chat will come out to all of you to inform your thinking between now and this time tomorrow, and a revised ICD letter with both tracked changes and a clean version will come out. Hopefully no later than first thing tomorrow morning. So again, if you all would please take a look at both of those, the slides and the revised letter, so that we can come to some kind of closure on what the follow-up is on both of those tomorrow afternoon. So a little homework. Not our normal thing, but a little homework.

Denise Love: Start time tomorrow is?

Rebecca Hines: Thank you, Ms. Love. So 10 a.m. Eastern. We're starting half an hour earlier. My apologies to those of you in the western time zones, but Steve Posnack is a tough man to schedule with. He will have to disappear by 11:30, because ONC actually has a big event tomorrow and he has to get to that. So we are starting at 10 so that there's enough time to make sure we can have a rich dialogue with him to align our ongoing activities. Thank you, Denise.

Nick Coussoule: Great. I think with that, we will see you all a few minutes before 10 to make sure everything is set up and working. Beyond that, again, thank you all and we are adjourned for the day. Talk to you all in the morning.

(Whereupon, the meeting adjourned at 5:15 p.m.)