National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**HHS**	**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
Jamie Ferguson	Kaiser Permanente	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
Tammy Banks	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
Natalie Gonzalez	CDC	Staff
Marietta Squire	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Shawna Webster	NAPHSIS	Executive Director
Jeff Greenland	NAPHSIS	Senior Development Advocate
Katherine J. Sapra	CMS/CMMI	Director, Division of All-Payer Models
Chris Muir	ONC	Director, Standards Division

Call to Order/Roll Call

Rebecca Hines: Good morning to members of the committee, federal staff, HHS colleagues, and members of the public. Welcome to the winter meeting of the National Committee on Vital and Health Statistics, NCVHS. Good to see everyone here today. It has been a while. I hope you are well and ready for two days of productive committee time.

My name is Rebecca Hines. I serve as executive secretary and designated federal officer for the Committee. As we start off for the new year and we are meeting virtually again obviously, we hope that conditions will permit an in-person meeting of the committee at some point. It has been two years now. There are several members who have not actually met in person. We are still hopeful that that will be possible later in 2022.

We have a rich agenda planned for today and tomorrow. Let us move to roll call, beginning with our new chair, Jacki Monson.

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

Rebecca Hines: Thank you. Deb Strickland.

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

Rebecca Hines: Denise Chrysler.

Denise Chrysler: Good morning. I am Denise Chrysler. I work for the University of Michigan School of Public Health. I am director of the Network for Public Health Law's Mid-States Region at the university. I am a member of the Privacy, Confidentiality, and Security Subcommittee, and also co-chair of NCVHS' Workgroup on Sexual Orientation, Gender Identity, and Social Determinants of Health and I have no conflict.

Rebecca Hines: Thank you. Denise Love.

Denise Love: Hi. I am Denise Love. I am the co-chair of the Standards Subcommittee, member of the Full Committee, independent consultant, and no conflicts.

Rebecca Hines: Jamie Ferguson.

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

Rebecca Hines: Margaret Skurka.

Margaret Skurka: Hi. I am Margaret Skurka. I am a member of the Full Committee. I am a member of the Subcommittee on Standards and I also have no conflicts.

Rebecca Hines: Melissa Goldstein.

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

Rebecca Hines: Tammy Banks.

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

Rebecca Hines: Thanks. Valeria Watzlaf.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I am a member of the Full Committee and also member of the Subcommittee on PCS. I have no conflicts.

Rebecca Hines: Vickie Mays.

Vickie Mays: Good morning. I am a professor at the University of California Los Angeles. I am a member of the PCS Subcommittee. I am the co-chair of the new work group on SOGI and Social Determinants of Health. I am a member of the Executive Subcommittee. I have no conflicts.

Rebecca Hines: Wu Xu.

Wu Xu: Good morning. I am Wu Xu. I am with University of Utah. I am a member of the Full Committee. I have no conflicts.

Rebecca Hines: We have our executive staff, Sharon Arnold and Maya Bernstein. Sharon will be speaking shortly. Let us move to lead staff. Lorraine Doo.

Lorraine Doo: Good morning. Lorraine Doo with the Health Informatics and Interoperability Group at CMS and Lead Staff to the Subcommittee on Standards.

Rebecca Hines: And our latest addition, Natalie Gonzalez. Good morning, Natalie.

Natalie Gonzalez: Hi. I am Natalie Gonzalez. I work at the CDC as the lead of their Privacy and Confidentiality Unit and Office of Scientific Integrity and I am the new lead staff for the Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Fantastic. Welcome, Natalie. We are so delighted you are here. We have Marietta Squire behind the scenes. Is there anyone else who wants to say good morning that I missed.

Maya Bernstein: Good morning. I joined a minute or two late. I am Maya Bernstein. I am the senior advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation. I am the

Lead Staff to Sharon Arnold in a role as executive director of this committee. I am staff to the Privacy, Confidentiality, and Security Subcommittee.

Rebecca Hines: Good morning, Maya. Thank you. For members of the public, just a heads up that the agenda includes time for public comment both today and tomorrow. Today's public comment period is scheduled for 5:20 p.m. Eastern. Tomorrow public comment is scheduled for 4:50 Eastern. If you have attended committee meetings, you know these times could shift, hopefully not by too many minutes, depending on how the discussions unfold. We do suggest that if you are planning to comment to be aware of the agenda in case we are running ahead of schedule or behind. And also for awareness, public comments can be sent by email. You can see the address here on the slide, ncvhsmail@cdc.gov. We can read them out into the record if you are not available to be present for the public comment period either today or tomorrow.

With that, Sharon, over to you.

ASPE Update

Sharon Arnold: Thank you very much, Rebecca, and Happy New Year to everybody. Thank you for joining us at this meeting of the National Committee on Vital and Health Statistics. I have a lot of material I want to talk with you about today. I am just going to plow through and try and leave some time at the end for questions and discussion.

In what has become a regular refrain at my briefings for two years, the vast majority of the Department's workforce continues to telework due to the Pandemic. The Office of Personnel Management, the Office of Management and Budget, the General Services Administration, and all of the US government agencies continue to work together to plan for returning to the workplace. The major agencies are represented on the White House Safer Federal Workforce Task Force, which continues to rely on the science and best available information, including guidance from CDC.

For HHS' part, HHS has announced a return to office policy in the fall, which was planned in phases, starting with political leadership and career executives such as myself, and then the rest of the career staff. Both the political leadership and career executives have been going into the office on a part-time basis since the fall, although the Omicron variant has delayed full implementation of these plans. We are very fortunate to be able to operate relatively seamlessly on a remote basis.

Across the nation, as of Thursday, over 80 percent of eligible people in the US have been vaccinated with at least one dose of the COVID-19 vaccine. In September, the president signed an Executive Order requiring all federal employees and onsite contractors to show by November 22, proof of vaccination status. Those who have requested religious or medical exemptions are still being processed. And until their cases are decided will be subject to masking, social distancing, and regular proof of negative COVID-19 tests before entering a federal facility.

The latest development in this area happened just Friday where a federal judge sitting in the Seventh District of Texas issued an injunction against the president's federal work force mandate, pausing implementation of the requirement for more than two million civilian servants, including members of this committee who serve as special government employees during their tenure. The administration has

already filed an appeal. While the suit is pending, we thank you for protecting your community by getting vaccinated and for cooperating with the paperwork to confirm your compliance with the president's order.

Two other lawsuits affected the Department's vaccination goals. On January 13, just a little over a week ago, the US Supreme Court blocked President Biden's vaccination mandate for large private companies while allowing the mandate to stand for medical facilities that accept Medicare or Medicaid payments.

Thursday marked the anniversary of President Biden's inauguration. Secretary Becerra made the following remarks on medication. He said, as we mark the one-year anniversary of the Biden-Harris administration, it is highly encouraging to see data showing the number of uninsured Americans drop significantly from July 2020 to September 2021, especially among working age adults and people with low incomes. This is welcome news particularly on the heels of a record-breaking year of affordable health care enrollment with nearly 5 million Americans having newly gained coverage under the Biden-Harris administration.

Turning to more specific information about COVID-19, HHS continues to devote a great deal of resources to support the pandemic response. On January 14, Secretary Becerra signed the eighth renewal of the public health emergency declaration for COVID-19. As with others, it will expire in 90 days unless it is renewed.

On December 22, FDA issued an emergency use authorization for Pfizer's Paxlovid pill marking approval of the first oral antiviral for COVID-19 treatment.

Also on December 22, the HHS Office for Civil Rights issued guidance tied to legal standards and best practices for improving access to COVID-19 vaccine programs and ensuring nondiscrimination on the basis of race, color, and national origin.

Last week, the Federal Government launched www.covidtests.gov, allowing Americans to order free at-home rapid COVID tests. Each household may order up to four tests.

Starting this week, the White House plans to source high-quality N95 masks for adults from the Strategic National Stockpile and will distribute them free of charge at thousands of pharmacies and other locations around the country.

And CDC continues to regularly provide an update of its' COVID-19 guidance based upon current science and the best available information. Notable recent guidance has addressed the spread of the Omicron variant, guidance for K through 12 schools, and information on boosters.

COVID is not the only contagious disease to which the Department is paying attention. Shortly after the last NCVHS meeting, the president signed an Executive Order adding measles to the list of communicable diseases that could require quarantine. This action was taken at the request of public health officials after several Afghan refugees were diagnosed upon arrival in the United States and after previous outbreaks of measles in recent years.

On January 3, the secretary signed a renewal of the Public Health Emergency Declaration that results from the continued consequence of the opioid crisis. This public health emergency has existed since the first such declaration in October 2017.

On October 27, the fourth anniversary of the opioid public health emergency, Secretary Becerra announced the HHS Overdose Prevention Strategy, which is designed to increase access to the full range of care and services for individuals who use substances that cause overdose in their families. The new strategy prioritizes four key target areas: primary prevention, harm reduction, evidence-based treatment, and recovery support.

The HHS Office of Refugee Resettlement in the Administration for Children and Families continues to support placement of large numbers of refugees, resulting from the crisis on the Southern Border as well as thousands of Afghan refugees evacuated from Kabul.

The No Surprises Act went into effect this month, protecting people from surprise billing. ASPE's Office of Health Policy published a report in November with useful information, providing background on surprise billing practices and the implementation of this law.

The Office of the National Coordinator for Health Information Technology and its recognized coordinating entity, the Sequoia Project, announced on Tuesday the publication of the Trusted Exchange Framework and Common Agreement.

I know some of you here may have worked on this project either directly or tangentially, and it is an important step. For those who are not familiar with, the Trusted Exchange Framework is a set of nonbinding but foundational principles for health information exchange and the Common Agreement is a contract that advances those principles.

Entities will soon be able to apply and be designated as qualified health information networks that will connect to one another and enable their participants to engage in health information exchange across the country.

Since the last NCVHS meeting, there have been a number of personnel changes and new appointments along the political ranks. In October, Dr. Rachel Levine, the Assistant Secretary for Health, was sworn in as an Admiral of the US Public Health Service Commissioned Corps, making her the first openly transgender four-star officer across all of the United States uniformed services.

Carole Johnson is now the administrator of the Health Resources and Services Administration. She was previously the testing coordinator for the White House COVID-19 Response Team.

Lawrence Tabak will serve as acting director of the National Institutes of Health while a national search continues for a permanent successor to Dr. Francis Collins, who retired at the end of last year.

Angela Ramirez, assistant to Anne Reid is deputy chief of staff.

I am also pleased to announce within ASPE, that Dr. Susan Jenkins joined my team last month as the director of the Division of Evidence, Evaluation, and Data Policy. Susan is a methodologist who comes to

us from the Administration for Community Living where she was the director of the Office of Performance and Evaluation, coordinating ACL's activities in this area. Several ASPE staff who support NCVHS worked for her, and I am particularly thrilled to have her on board.

A big lift for ASPE is our lead role in the development to complete the HHS Strategic Plan for fiscal years 2022 to 2026. We are just finalizing that, and a draft will be posted for public comment later this month.

On January 11, the White House Office of Science and Technology Policy released their report of a Comprehensive Assessment of Scientific Integrity Policies and Practices in the US Government. The report is a requirement from one of the first Biden memos upon taking office in January of 2021, entitled Restoring Trust in Government through Scientific Integrity and Evidence-Based Policymaking. My office is leading the response for the Department, including the review of existing scientific integrity policies to identify areas needing updates or new policies.

The memo provides a broad scope for the application of scientific integrity beyond the traditional science agencies. Therefore, we anticipate a need to expand such policies across HHS.

ASPE continues to work on the implementation of the Foundations for Evidence-Based Policymaking Act. We have developed the HHS Evidence Building Plan, the Evaluation Plan, and the Capacity Assessment, which will be posted shortly. We have not yet received final guidance from OMB on the open data or statistical confidentiality titles of the law.

ASPE is also responsible for making recommendations for the Paperwork Reduction Act labor process. We continue to process requests for the waivers under the public health emergency. We have approved 16 total waivers in 2021.

ASPE has released several new reports and briefs over the last few months with an emphasis on COVID-19 and agency efforts to combat the pandemic. This research includes work on vaccine hesitancy, regulatory impact analyses for regulations and policies that combat the COVID-19 epidemic, and the effects of the pandemic on HHS data collections.

Some example reports include parents' intentions to vaccinate children aged 12 to 17, demographic factors, geographic patterns, and reasons for hesitancy, child and adolescent mental health during COVID-19, considerations for schools and early childhood providers, associations between county-level vaccination rates and COVID-19 outcomes among Medicare beneficiaries, COVID-19 vaccination associated with reductions in COVID-19 mortality and morbidity in the United States, and variation in use of monoclonal antibody therapies by social vulnerability and urbanicity.

We have several personnel announcements to make regarding the committee both among members and the staff. First, Geneva Cashaw, who served in an administrative role with Rebecca and Marietta, retired at the end of last year. We really appreciated her support to the Privacy, Confidentiality, and Security Subcommittee over the last few years and wish her well in her next chapter.

Rachel Seeger, who served as the lead staff to the Privacy, Confidentiality, and Security Subcommittee since 2016 has taken a more responsible role as senior advisor for communications in the Office of Civil Rights and her new duties required her to step back. Rachel will be responsible for all communications

and outreach for OCR on both HIPAA and traditional civil rights sides of the office, a huge job given the administration's priority for equity.

I am pleased to announce that Natalie Gonzalez has agreed to take on the lead staff role for the PCS Subcommittee starting for this week's meeting. Natalie is an attorney with a Master of Law and Health who started her career in Human Subjects' Protection Office of CDC in 2008. She is now lead of the Privacy and Confidentiality Unit at CDC's Office of Scientific Integrity where she provides technical assistance on the impact of privacy laws, regulations, and policy on public health practice and research.

Natalie has served as staff to the subcommittee for many years. Her expertise and experience and relationships that she has with the subcommittee will serve her well. We thank her leadership for lending her time and expertise and we look forward to her taking on the key role.

Dr. Vickie Mays and Ms. Denise Chrysler have graciously agreed to co-chair a new working group to Assess Sexual Orientation and Gender Identity and Social Determinants of Health, Data and Measures Definitions, Collection and Use. I am not going to say too much more about this at the moment because you will hear about it later during the meeting. We had a very engaging and productive kickoff on Wednesday afternoon, and I am looking forward to seeing what the workgroup produces on this important and timely administration priority.

Finally, you all know that Nick Coussoule has decided to step down from the position of chair of this committee at the end of last year. Nick took a big promotion as the senior vice president for Enterprise Business and Technology Solutions at Horizons Blue Cross Blue Shield in New Jersey. He told us in his resignation letter that the accelerating demands of his new job along with the additional responsibilities he anticipated seeing this year and his family relocation, that he would not be able to contribute the time necessary to be an effective member and chair of the committee. We have appreciated Nick's knowledge, time, and expertise, which have contributed to the outstanding and impactful work of the committee during his six and a half-year tenure.

Nick served as co-chair for the last year, but prior to that as co-chair of the Subcommittee on Standards. His leadership in completing the 2021 Report to Congress was invaluable. I appreciate his collegial approach to guiding the committee through the transition process of bringing new members on board and supporting several of them in their work.

We thank Nick for his distinguished service on the committee and we wish him and his family the best of luck in the big transitions they are making this year.

As you all know, I could not be more pleased to acknowledge Nick's successor. The Secretary has nominated Jacki Monson to be the next chair of the NCVHS. She has agreed to take up that gavel and lead the committee for the next two years.

As you know, Jacki is a widely recognized expert in the health industry with extensive knowledge and experience in health care privacy and security law and compliance. She is the vice president, chief technology risk officer, chief information security officer, and chief privacy officer at Sutter Health in Sacramento, California, a $14 billion company with 12,000 physicians, 60,000 employees, and 3 million patients.

Prior to her position at Sutter Health, Ms. Monson served as chief privacy officer at the Mayo Clinic in Rochester, Minnesota.

In her current professional role, Jacki advises senior leaders and is accountable to the Sutter Health Board on issues relating to technology, risk, information security, and privacy. She provides advice and education to programs and constituents about HIPAA, HITECH and other information security and privacy laws and regulations that are critical to this committee's work.

Jacki has been a tremendous asset to the committee since her initial appointment in 2017, bringing vital, real-world experience to our work together. She has served as co-chair of the Subcommittee on Privacy, Confidentiality, and Security and served on the NCVHS Executive Subcommittee in the past year. The department believes her to be a well-respected leader with board and taskforce experience, including an appointment to the HHS Cybersecurity Task Force in March 2016 and she has the confidence of the secretary to lead the committee for the next two years.

Jacki, I know the committee is in great hands and I look forward to working with you closely in this new role. Please join me in congratulating our new chair. I know you all will give her your support as she makes this transition.

As Jacki takes up the mantle as chair, she leaves a vacancy as co-chair of the Privacy Subcommittee. It is the chair's job to appoint subcommittee chairs after consultation with me and the other subcommittee co-chair. We will be having this conversation very soon.

We are also keenly aware that we have lost several members in the last year due to resignations and term expirations. We now have six vacancies on the committee, five of which can be appointed by the secretary. We are working on identifying nominees particularly those that will expand the diversity of the committee along a number of axes. It is our hope that the nominations will move quickly through the process so you will have new colleagues among whom to share the work of the committee very soon.

I said that was a lot. I raced through it. At this point, I am happy to take any questions or we can move on in the agenda. Any questions or comments?

Vickie Mays: Good morning. Thank you, Sharon, for that update. One of the questions I had was on the scientific integrity work that is moving forward. One of the things that has come up on several occasions is kind of what the – what do I want to say – the bounds that have been put around IRBs that would help in terms of their ability, I think, to see very early on if there were problems in terms of some of the scientific integrity. Areas that that has come up in is, for example, the use of AI in research and the ways in which sometimes that is a problem. I know that SACHRP, for example, has been trying to update the notion of what justice is and talk a little bit more about social justice. But those things do not seem to be having a place to have a broad discussion about. Is that at all a part of what will be undertaken in thinking about scientific integrity?

Sharon Arnold: I think those are really important concepts and we continue to work towards thinking about justice more generally in the context of HHS business. But I think that the scientific integrity policies are more narrowly focused although they are broad to anybody doing science, communicating

science, including data analysis, social science, to make sure that there is not inappropriate interference in science. It is really focused on guidance and having a process to record inappropriate interference but broadening it significantly from bench science to all kinds of social science, including data and communication. So more narrowly focused than what you were talking, but still pretty broad.

Vickie Mays: I can tell.

Sharon Arnold: Any other questions or comments? Thank you so much for your attention. I look forward to interacting with you throughout the rest of the meeting. Back to you, Rebecca or to Jacki now.

Welcome Remarks/Agenda Review

Jacki Monson: Good morning. Thanks, Sharon, for your kind regards. I just want to also reiterate my thank you to the previous co-chair or the previous chair of NCVHS, Nick Coussoule. I think we are all going to very much miss him and all of the contributions that he gave both from a knowledge standpoint, a mentoring standpoint, and just a big picture thinking. I know I have big shoes to fill and hopefully will be able to fill them with some mentoring from him offline. I just wanted to thank him again.

I think we are ready to go through the agenda. We have a very robust, exciting day. First, we are going to start with Melissa Goldstein, covering the draft recommendations on data collection use during public health emergencies. We are going to take a little break and then we are going to move into the Subcommittee on Standards. They are going to provide an update on the Convergence 2.0 project. We also have a very robust reactor panel and want to get into future directions and hopefully have a robust discussion around that. We are going to take another break. And then we are going to move into another topic on the Subcommittee on Privacy, Confidentiality, and Security. And that is a letter with recommendations to strengthen cybersecurity in health care. And then we will have public comment and wrap up and adjourn.

I just wanted to share a stretch goal of mine for all of you to help us with the two letters coming from PSC. We are really hoping that we can get those as close as we can to across the finish line for approval so really hoping for robust discussions and review of those letters to get them as close if not to actual approval from the committee tomorrow.

Melissa, I will turn it over to you to start talking about the draft recommendations on data collection.

Subcommittee on Privacy, Confidentiality, and Security

Melissa Goldstein: Thanks so much, Jacki. I have enjoyed working with you as my co-chair on the Subcommittee on Privacy, Confidentiality, and Security. I am glad you will still be around. Congratulations. We have absolutely confidence in you. Thank you for introducing our first topic today.

As you all can tell from our agenda, the subcommittee has been working quite a bit since our last Full Committee meeting. We have made significant progress on two draft letters to the secretary. The one that we will be discussing now for the next hour or so is the letter on data collection and use during a public health emergency.

Our initial focus what I am going to describe first, a little bit of background on the letter, background on the hearing that we held in September 2020 during the pandemic, which of course we are still during the pandemic, which I do not know that any of us had anticipated at that point and how we have developed the recommendations, stemming mostly from that hearing, but also with some of the information that we had developed afterwards.

We are going to discuss in detail each recommendation, there are five in the letter, and the language of the recommendations themselves. If we are able to go beyond that, we are also prepared to discuss the actual supporting language for each recommendation. We would like to get as far as we can on consensus during this meeting, definitely on the recommendations themselves, but possibly even on the language that supports the recommendations. We appreciate everyone's comments and ideas as we move forward. Like I said, we will focus first on the recommendations and then get to the contents of the letter.

We will be focusing on the security draft letter I believe tomorrow. Is that correct, Jacki? We will get more into the details of that tomorrow.

Rebecca Hines: Actually, later this afternoon, Melissa.

Melissa Goldstein: Great. You are going to hear a lot from us today. Our subcommittee members, feel free to give us also your comments and reasoning for the recommendations that we have made. We have put a lot of work into this, multiple meetings, multiple revisions, multiple ideas. We have gone back and forth on lots of ideas. There has been a great deal of work put into both of these letters. We will specifically talk about this one first.

The context. If we can – I can take you back to the time, way back in September of 2020. We were dealing with the idea of public health contact tracing at the time and the need for support for public health contact activities at every level of government, federal, state, local, and figuring out how to do it, what was the best way to do it, what was most useful for data collection, all of those ideas.

We were also handling really a lot of variability and data collection and use activities. Between the federal government versus state activities versus local practices, a lot of variability within each state, between states, and between the states and the federal government. It was a time of – not uncertainty. There were different practices. We were trying lots of different things to try to get a handle on what was going on in the country.

Part of the goal of this particular hearing was to focus on what tools might be useful for public health surveillance particularly in a public health emergency. Now, this emergency could be a pandemic like we are going through now still or it could be other types of public health emergencies, natural disasters, for instance, things like that. We are not limiting our recommendations to infectious disease pandemics. We are thinking beyond that as well.

And then finally, we wanted to get the ideas of experts and panelists and each other and our own experts on the committee about how privacy is implicated by all of these issues. At the time, we were thinking about exposure notification apps such as the one developed by Apple and Google and the ones

that were state sponsored, others. There were a lot of apps being developed in other countries. This was a time of technology, looking towards trying to help us collect data.

In a nutshell, the objectives of the hearing that we held in September 2020. The first one was to understand the policies and practices that we were looking at for data collection and use with regard particularly to privacy and security of identifiable data during the crisis.

Number two, identify best practices in these sorts of situations, what works, what doesn't necessarily work as well as we would want it to and that would be number three. Consider additional technical assistance that we might need during situations such as this.

Four, consider building on prior committee work. In 2015, the committee developed a toolkit for communities, using health data. We have a link here, but it is also on the website of the committee. And in 2019, the committee published a report on health information on privacy beyond HIPAA, the idea of organizations, institutions, companies that are not covered by HIPAA and that documentation is also available on the website of the Full Committee.

And then finally, we wanted to consider developing recommendations on values and opportunities and data collection and use in public health emergencies. That was our goal a long time ago, a year and a half ago at this hearing.

What we heard from our panelists is what we will discuss, what I am going to show to you next. We heard a bunch of different themes actually. It was a very full hearing. There is a summary published on the website. There is also, I believe, the full transcript. I am not exactly certain about that, but Rebecca can clarify on that of the hearing itself or it might just be the summary on the website.

Rebecca Hines: It is all there.

Melissa Goldstein: Great. It is all there on the website for those of you who would like to refer to the full document. This is a summary that we put together just for purposes at the beginning of this discussion.

One of the first themes that many of the panelists discussed was the need for a data collection and framework in this context of a public health emergency. Overarching were words used. Integrated, well-funded at various levels of government, socially supported at various levels of government, federal, state, local levels, not only financially supported, but also socially supported among the policymakers, among people at the various levels of government also, and specific to public health emergencies. We have generally data collection and use frameworks. Although they are continually being improved as well in normal times. The idea of this particular framework we would like to talk about is in public health emergencies specifically. This was one of the big themes that the panelists, many of the panelists, if not all, during the hearing actually focused on.

The second idea that we want to point out that we heard from a lot of the experts on the panels was the idea of addressing health disparities and improving health equity in these situations as well. We know that we have a lot of work, and we also have a new work group focused on these ideas of addressing health disparities and improving health equity. But for our purposes, we are focused on the idea in

public health emergencies and from the perspective of privacy and security in public health emergencies.

Another large theme discussed by the panelists. Many of the panelists and some of the discussions between the members of the subcommittee and the Full Committee and panelists themselves. Technology and ethics goals. Health data infrastructure for new forms of data collection and sharing in a public health emergency. Patient-reported data, apps, like I mentioned before, new forms of data collection and sharing that are developed during these times and how do we build a health data infrastructure around and including those forms of data collection.

Removal of data silos, something that you hear us talking about quite a bit actually across the public health and health care entities, the idea of integrating the data and enabling exchange among the different areas, not just holding them in different silos.

Development of standardized data use agreements that various entities could all base their particular data use agreements upon to try to also ease the idea of data collection and use and sharing.

Collection and sharing of complete race and ethnicity data. This also goes towards the discussion we had a minute ago about health equity and supporting health equity, but making sure we have complete data, not partial data from some places, but not other places.

Potential data commons, how they might be used in this example of a type of pandemic that we are going through now, but also other kinds of public health emergencies. The commons, for example, would combine data and a computing infrastructure that could be used in times of emergency.

How do we embed privacy and security guidelines within an infrastructure and among our technology and ethics goals? And then finally, data sharing within communities in a privacy-appropriate environment. Keeping privacy at the forefront of our ideas and then basing data sharing and making sure that we keep privacy in mind while we are developing recommendations for data sharing and activities and operations that support data sharing.

Other themes. The difficulty of the multiplicity and patchwork and variety of laws. We know that every state has different laws. We know that many local jurisdictions have different laws. We have seen some conflicts between those levels of laws over the past two years of the pandemic. The panelists expressed a question of should we develop national, legal and policy standards. Remember, this is not a position of the committee, of the subcommittee, but these are ideas that the panelists during this hearing brought up. This is a particular question.

Also, another question brought up by the panelists that we spoke with. The definition of HIPAA covered entity. What is a covered entity underneath the law and the regulations? The panelists questioned whether we could develop a broader definition of what a HIPAA-covered entity is. Could we expand that definition to include other types of entities that are not currently included? How would we approach practices of non-covered entities even if we had a broader definition? Not everybody is going to be covered. Certainly, not everybody in the field is covered now. How would we approach practices of non-covered entities during public health emergencies?

The idea of deidentification was also brought up. The committee has addressed ideas of deidentification quite a few times, mostly particularly in 2017 and issued recommendations at the time, many of which have not yet been implemented. The panelists during our hearing in September 2020 brought up the idea of reconsidering deidentification and deidentification as the backbone of use of administrative data. Should we develop, for instance, a new term instead of using deidentification? That was one of the ideas brought up by the panelists.

Another point brought up by the panelists. The importance of assessing and communicating risks and opportunities in redacting different identifiers. Even in the context of deidentification or however deidentification evolves in the future, we need to assess in communicating risks and opportunities and redacting different identifiers from data from identifiable data. This was one of the points that the panelists brought up.

Are there new models for deidentification that could be developed? And then finally, the panelists brought up the idea of exploring new ways to bridge HIPAA or non-HIPAA. That gap in between what HIPAA covers and what HIPAA does not cover for deidentification. Currently, there is a gap. Some entities say that they are HIPAA compliant. Some do not even if they are not required to be part of the HIPAA ecosystem. How do we explore ways to bridge that gap?

We all know that the hearing was a while ago and we all know that things have continued to evolve after the hearing. We have seen the pandemic evolve continually. We are now looking at Omicron. In many places in the country, Omicron – a number of cases has begun to recede. We know that the pandemic may continue to evolve. We really are in a situation of uncertainty.

We have also seen an evolution of the technological tools. We have seen a change in priorities among different levels of government, among people, among the social structure in various areas of the country.

The US never widely adopted the apps that were being discussed at the time of the hearing for exposure notification or contact tracing. Different areas of the country, different states, different cities, different groups, different populations developed different types of apps, but we never really widely adopted what was being considered at the time.

What lessons have we learned since this hearing? What has been useful towards us? What would we like to base our recommendations upon? And then of course, what are the next steps in terms of recommendations for the secretary, but also in preparing the country for whatever comes next? We know that there will be more additional public health emergencies. Some of us do not like to think about it all the time, but we know that they will occur. What are our steps, our next steps that we should take for that purpose?

Now, I am going to get into the draft recommendations. If any of the other committee members have questions or comments at this point on what we have heard at the hearing, please go ahead and let me know before we dive into the actual recommendations that the subcommittee has developed. I do not see any virtual hands. Are there any real hands that are poking up, Rebecca? Do you see anyone?

Rebecca Hines: Maya has her hand up.

Melissa Goldstein: Maya, please go ahead.

Maya Bernstein: It was a mistake. Always defer to the committee to speak first and to see what our colleagues, who are members, it is your opportunity to discuss amongst yourselves now.

We do have, I think – are you just asking now for general comments, Melissa, on the comments that you just made?

Melissa Goldstein: Yes. General comments on what the hearing itself, the time period since the hearing, the work that we have done since then, before we start an in-depth discussion of each recommendation. I just wanted to capture before I just kept talking. It does not sound like there are any. I do not hear anybody piping up. Okay.

We will move into the individual recommendations now. We have five, like I have mentioned before. We are going to go step by step and then we can come back and look at them as a whole.

Member of the committee, members of the subcommittee, feel free to raise your hands and let me know. Rebecca, I will ask you to let me know if somebody wants to comment that I do not see at the moment, as we move forward. Thank you.

Rebecca Hines: it is a plan.

Melissa Goldstein: Our first draft recommendation. Develop a governance strategy specific to public health emergencies with associated methods to ensure the privacy and security of data that increases public perceptions of trustworthiness in the public health ecosystem and measures to monitor and address public trust.

We are emphasizing public trust, advancing the idea of public trust based on a governance strategy that has methods to ensure the privacy and security of data. This is the first recommendation, the one that is focused on initially in the letter itself. I would love to hear anyone's comments on the recommendation itself. I see Denise Love. Please go ahead.

Denise Love: I appreciate this work and I support it. I support this recommendation. Is this the place to ask of how that might be implemented or is that just – my brain is going into how this would be implemented in practice. But maybe that is not the purpose of the recommendation at this point.

Melissa Goldstein: We would like to focus on the recommendation language itself. You all do have the language of the letter with the supporting language in the packets as well. Once we discuss the language of the recommendations then we can move forward I think into the specifics. Does that sound like a good plan?

Denise Love: Yes. That sounds like a plan. I like the recommendation. Thank you.

Melissa Goldstein: Thank you, Denise. Rich Landen, please let us know your thoughts.

Rich Landen: Like Denise, I fully support the recommendation. My question is that the governance here is – it seems to be explicitly focused on privacy and security from the Standards Subcommittee

perspective. We also have similar concerns in the health data flows during public health emergencies. We do not have a resolution to that, but I am wondering if there is something that we can put into the eventual language that would at least go on record to saying whatever governance structure even though this recommendation focuses on privacy and security. That same governance strategy should also address some data standardization as it evolves from the Standards Subcommittee later on.

Melissa Goldstein: I think that sounds like a great --

Rich Landen: What I am trying to avoid is two separate governance structures, one for privacy and a different one for the data.

Melissa Goldstein: I think that sound great, Rich. It is a great addition. I think the two goals are absolutely complementary and will go along with each other.

Rich Landen: One should not hold back the other.

Melissa Goldstein: Absolutely. I agree entirely. Thank you. Thank you for that.

Other ideas?

Maya Bernstein: Melissa, earlier in the briefing, she talked about that of kind of coming up with data standards in a privacy and appropriate environment. I think that is meant to encompass both of those things the way that Rich has been talking about.

Melissa Goldstein: I agree. I think they make total sense. There may already be language. I cannot recall right now in the supporting language, but we can look at them and make sure that there is and discuss that later on also.

Maya Bernstein: If I could respond just a little to Denise, asking about implementation. Often the committee does not direct specifically recommendations to how things should be implemented unless there is some particular idea that it usually leads to the discretion of the secretary of how they best want to implement it unless there is something – directive that the committee wants to do. The committee will often, like I said, allow a discretion or creativity in the ways to implement. Depending on what – might or might not go into that type of detail.

Denise Love: I was just questioning whether it is piggybacking on the existing IRB structure or a separate governance. But again, I am getting into the weeds maybe a little bit too much at this stage.

Melissa Goldstein: We certainly do intend to involve other partners to work with other partners on implementation. We just wanted to point out that in a public health emergency, the idea of keeping privacy and security and public trust and trustworthiness might talk on different implications perhaps than during whatever we consider normal to be. We thought that there may be differences in the governance strategy that we want to point out, but implementation like Maya said will be left up to the secretary on the best way to do it and the idea is to work that these recommendations would encompass working with other levels of government, other parts of the federal government, the state

governments so that they would – recommendations for state governments but working at other levels of the federal government for the secretary.

Any other comments on draft Recommendation 1? Any member of the subcommittee want to emphasize various thoughts that we were having when we developed Recommendation 1? We certainly have more time to discuss it now, but also later on today and tomorrow in the committee.

Maya Bernstein: We can move on. And we will have more time for discussing the actual language of the letter if you would like if people seemed satisfied.

Melissa Goldstein: That sounds great. Thanks, Maya.

Draft Recommendation 2. Piggybacking on what Denise and Rich have actually pointed out. Supporting the development of real-time interoperable, information sharing for public health emergencies that prioritizes privacy and security. Emphasizing interoperable information sharing, real time for public health emergencies, but also remembering the privacy and security elements of that. Very similar to number one, but also specifically calling out the idea of supporting the development of real-time interoperable information sharing.

Tammy.

Tammy Banks: I would like to offer a friendly amendment. Could we add support the development and use of real-time interoperable information sharing? Obviously, the focus on development doesn't reap the benefits unless it is actually widely used.

Melissa Goldstein: Good point. Thank you. That is very helpful.

Denise Love.

Denise Love: I am wordsmithing here. I am having a little problem and it is not – I need to be set right. Prioritizing privacy and security in a real-time emergency brings some conflicts up and some tensions, which are natural. Is there another word that says like embeds or incorporates privacy and security? It is a nuance here.

Melissa Goldstein: Maybe incorporates. Maya, help us with – what do you think about incorporates? We do want to emphasize that privacy and security is still important and that it should be the idea of privacy by design. It is built in.

Jacki Monson: Melissa, perhaps we use the word privacy and security by design.

Maya Bernstein: I have some issues with that partly because it is a Canadian concept originally, not American one.

But also, Denise, could you say a little more about the concerns that you have about this language? Could you talk a little out louder.

Denise Love: My perspective might be a little different. But sometimes in data policy for public reporting in the past, prioritizing privacy and security is an excuse to hold information because that is the priority. But sometimes when the house is burning or the population has a real emergency, privacy and security needs to maybe have a different risk algorithm or assessment that maybe absolute privacy and security from a research standpoint is not the same as during real-time emergency. I am struggling a little bit with it because I do not want to diminish privacy and security by no means. That is critical. But I also do not want it to be used as an excuse not to share information in good faith. Good faith protections, safe harbor protections that sometimes they are a little different in an emergency, I think. I am articulating that poorly, I am sure.

Melissa Goldstein: It is a good point that you bring up for us to think about. Rich, do you want to jump in here?

Rich Landen: Similar thoughts with Denise Love that the current language about prioritizing privacy and security has the connotation at least in my mind of increasing privacy and security. I think what the experience is is we need to have a little bit of flexibility around privacy and security during emergencies. I would support a language change but cannot offer specific language for that.

Also, the privacy by design. Yes, that was Canadian originally, but I have some recollection that it has been since adopted internationally. I do not see that as an impediment other than a discussion of US honor.

Denise Love: Maybe in the description underneath. I am struggling with prioritizes. But what I am really looking at is also transparency and accountability in the information exchange. But anyway, I will let it go at that.

Melissa Goldstein: Tammy had up her hand.

Tammy Banks: How about wording that prioritizes privacy and security governance. It is focused on the process, not on some of the issues that Denise Love mentioned. I know where you are trying to go. It is like where is the balance of focusing on the implementation of privacy and security protocols versus the misapplication of privacy and security.

Melissa Goldstein: We do not want abandonment of privacy and security. We definitely do not want that. Like Rich said, with the idea of flexibility, I guess the concern there would be that the flexibility is too broad or too longstanding.

Tammy Banks: Or put incorporates. They have to use privacy and security governance, which leads into Jacki's letter later on.

Melissa Goldstein: Right. Exactly. Maya, I definitely want to get your opinion.

Maya Bernstein: I think the main thrust of the recommendation, the first part of it is that the main goal is to support the development of real-time interoperable information.

I bristle sometimes – many of you have heard me talk about how I do not like the word balance. Forgive me, Tammy. And that is because it gives the idea that more data sharing, you have less privacy. And sometimes that is true. But I prefer a metaphor kind of a rising tide lifts all boats. New technologies. We have new techniques. We have new ways of thinking about governance that should allow us to both share information and use technology and techniques that will allow that to happen in a privacy-appropriate environment.

It is obviously very important what we have learned in the last couple of years about making data available and sharing it so that we can improve our understanding of what is happening and outcomes and so forth. But I fear that a tone that suggests we are going to push privacy and security away during an emergency because it is an emergency. In fact, that is a lot of what we have done. We talk in some of the later recommendations, we are talking about the waivers, something that was meant to be a short time and limited geographically has now gone on for almost two years. That removes people's rights to privacy during that time. We did not anticipate I think that this would go on so long.

But now that we see that it is possible to have an emergency that continues for quite a long period of time, maybe we need to think a little bit differently about how we are managing privacy. Maybe it is the development of different tools. But I think I would like – I am not the committee, but I would like to find some language that says both of those things that we need to share information to make it available and also that we need to be respectful of privacy and security and not just damp that down until we get over the emergency because apparently, the emergency can last a couple of years. It is a long time to be without rights and protections.

Melissa Goldstein: Thanks, Maya. I can see where emergencies themselves can fluctuate and can evolve like we have seen. I am thinking back to the discussions about break the glass abilities that we used to have maybe five to ten years ago. You do not want to be breaking the glass all the time. When is it appropriate to break the glass? How much glass is broken? Denise, to use your words, when is the house on fire and when do we have the fire under control to a certain extent that we are still in the emergency?

Denise, back to you. I see your hand up again.

Denise Love: I just think maybe adding because I like the recommendation but perhaps adding while providing for good faith protections or some legal term that you all can come up with. I think that would maybe embed some balance. I will let it go now.

Melissa Goldstein: Thank you. I will also note two things noted in the chat. Denise Chrysler has raised the idea of recognizing tradeoffs, which is good for us to think about in the language here.

And also from the cybersecurity executive order last year, a quote, in the end, the trust we place in our digital infrastructure should be proportional to how trustworthy and transparent that infrastructure is and to the consequences we will incur if that trust is misplaced, the idea of equity adjudication. These are good ideas for us to keep in mind moving forward. We have them down, right, Maya? We have everybody's ideas down.

Anyone else want to comment on this particular recommendation? Jacki, do you want to tell us your thoughts?

Jacki Monson: I would just echo what Maya had articulated. I think a goal for this particular recommendation is to make sure that when we do have public health emergencies that we actually are not just forgetting about privacy and security, but we are contemplating it upfront from a design perspective however we want to articulate that. I think a lot of us on the privacy group would like to see the public health emergency exceptions for HIPAA go away and just it becomes our ability to have a design in such a way that we contemplate privacy and security upfront and do not have to worry about making exceptions during a pandemic.

Melissa Goldstein: Thank you. Thanks to Tammy, Rich, and Denise for giving us your thoughts. We really appreciate it.

Let us go on to number 3. Draft Recommendation 3, which of course follows on our discussion we have been having. Review the current process for issuance of public health emergency waivers. First, the issuance of the waivers themselves. Issuance of notices of enforcement discretion and sub-regulatory guidance so all of the things we have seen over the past two years of the pandemic. When are the public health emergency waivers issued? How long do they last? How frequently are they reconsidered? Same goes for notices of enforcement discretion particularly in terms of compliance with various HIPAA requirements, HIPAA regulatory requirements. How long do they last? How often are they reconsidered? And the same for sub-regulatory guidance. Interpretations of HIPAA compliance. Interpretations of the waivers themselves, the public health emergency waivers. Sub-regulatory guidance is not issued with notice and comment. It is more interpretations of the agencies themselves.

But the idea is do they continue until they are stopped. When do they sunset? How often do any of these legal elements actually get reconsidered? Should it be more frequently than it has been during this particular pandemic? Should they be reconsidered every month, every 2 months, 90 days, quarterly? Should they continue forever? Is there a point of time where they cannot be renewed, and they have to be reissued entirely? Those are the ideas that we are getting at and that is what the supporting language includes also.

We need to review the process. It may be that the federal government is entirely content with the process. That it supports trust. That it supports transparency. There may need to be changes made. But our goal is the idea that the issuance and the lasting language of them should be reviewed.

Any comments? Questions?

Wu Xu: I have a comment or question. Here, you describe what is the review outcomes. Those questions sound like evaluation. Should we see the review and evaluation or just evaluate the current --

Melissa Goldstein: Thank you. That is also part of the idea. What happens during the notices and enforcement discretion? Do we know what has happened among the industry? Do we know what people have been doing? Have we been evaluating all along? Should this be part of the process also? Great point. Thank you.

Any other ideas? Subcommittee members, committee members. Maya, Jacki, other ideas?

Maya Bernstein: The only thing I might add is among the things you described about the cadence on which you review these things and whether we are evaluating along the way is at what level they have to be signed off. These notices and enforcement discretion were fine, for example, by the director of the Office for Civil Rights. But maybe at some point you want the secretary to sign off or you want – if it gets to be – I do not know, I am just throwing it out there. Is there a level at which it is appropriate to make this kind of waiver and is it at the right level now?

Melissa Goldstein: The idea of levels of approval to make sure that it reaches certain eyes perhaps at a certain time that they, for lack of a better word, break the glass happens quickly but then it needs to be reviewed by different levels of people. That kind of idea. Is that what you mean, Maya?

Maya Bernstein: I mean the idea of after a certain point, maybe initially it can be done by some level, but after a time, it gets higher or perhaps you want a high-level review at the beginning because you feel that these rights that are being waived or pushed off are so important.

Just is the level of review that we have the right level or should there be escalating levels over time or for different types maybe of this type of waiver. It is okay at a lower-level official to make and different kind of waiver or different kind of pushing off of regulatory enforcement needs, a different kind of level. I am not sure. Just an idea.

In terms of how you manage or govern the way or pushing off of certain rights, you might want to think about who is the responsible party. Who is accountable for that decision?

Melissa Goldstein: Thank you. I just want to check to make sure whether there is any additional comment before we move on to Recommendation 4. I do not see any or hear any.

Address health disparities in and health equity of data collection and use at the federal, state, and local levels. The idea of addressing the disparities and the health equity in both data collection and use at the levels of government, particularly federal and also recommendations at state and local levels.

Again, as I mentioned before, this was an idea that the panelists in our hearing in September 2020 brought up repeatedly so both data collection, data use, disparities existing in, addressing them. We now have a workgroup focused more specifically on the collection side. We do want to also focus it on this particular letter particularly in the area of privacy and security.

Ideas? Vickie or Denise Chrysler, anything in particular since you guys are leading the charge and the workgroup that you wanted to ask before we move on.

Vickie Mays: Thank you. I was going to suggest something here. I am a member of the group but I did not really think about it until I have been working on the other stuff and that is maybe changing this to talk about addressing inequities and that the inequities –- and to be specific about which inequities that we are talking about, which might be to address inequities in the data collection and timely reporting of data points on disaggregated race, ethnicity, geography, and age. That really comes from other hearings. I am not sure whether to mix or match here.

But in the group that is going to talk later today, they are going to talk about, for example, the difficulties that we had getting children's data and there are times at which age is really not being reported. One of the most secure things that as soon as you add a geographic point then the data really gets a set of shutdowns because of the ways in which it can potentially identify. But yet in the public health emergency where things were happening were important because we were trying to transport and get things like where should the vaccines go to, where do we need cold storage facilities in order to be able to even set up pop-up vaccination sites in the very beginning. Again, it kind of came up as I was preparing for what we are going to be doing tomorrow and thinking about other things. If it does not fit here, it is fine because I think we will capture it in other places.

Melissa Goldstein: Thank you. Somewhat like we have discussed with Recommendation 1 with incorporating the idea of standards like making sure that we are complementary at least with the work of the workgroup. Making sure that there is a connection there, a reference at least.

Vickie Mays: However you want to do this is fine, as I said. Those things are going to come up in the panel tomorrow. I just do not know where we want to place it. You can just leave it in ours, which is also a public health emergency, or we can kind of do it twice. I am just putting that out there.

Melissa Goldstein: Thank you, Vickie.

Denise Chrysler.

Denise Chrysler: Since you called on me, I will just mention the tradeoffs that always come up --

Melissa Goldstein: Sorry. I cannot get beyond the professor calling on people thing.

Denise Chrysler: Because since disaggregation of data inclusion of unique characteristics make data more useful and helps us in measuring and addressing health equity, as you mentioned and point out. It also means that it is accompanied by increased concerns regarding privacy and security.

Melissa Goldstein: Thanks so much, Denise.

Other ideas in general about Recommendation 4? Wu, go ahead. Thank you.

Wu Xu: I like this general theme addressed disparities and equity. But I just feel since the language is too general, do we want to insert emergency data collection or what makes it more specific to the emergency data collection, the privacy and security?

Melissa Goldstein: That is a good point to make it relevant to this particular context that we are thinking about. Thank you.

Other ideas? Anyone else?

Last but not least, Draft Recommendation 5. Develop data stewardship responsibilities based on principles of fair information practices for entities collecting, using, and sharing data during a public health emergency, including responsibilities relating to privacy, security, life cycle management, protection from reidentification, and responsible communication. Addressing the responsibilities on

entities that collect, that use, and that share data during a public health emergency. The idea of data stewardship. Focusing on an idea that the committee has focused on many times before. The responsibility of entities in the eco structure. Including privacy and security, including life cycle management of the data, protection from reidentification, responsible communication, transparency, all of those ideas.

Denise Love, thank you.

Denise Love: Yes. I agree with it. I am concerned again with protection from reidentification. What brings to mind is the difficulties we are having with substance use data because of the 42 CFR restrictions from reidentification and the tendency to then silo that information. I am not sure in an emergency protecting from reidentification – it depends – for public reporting, yes, but not for contact tracing or – that is a problematic term for me. How about – I think it can be wordsmith.

Melissa Goldstein: Thank you. I do want to recognize, however, the important equities that Part CFR Part 2 is actually supposed to protect, which are the interests of the people that are involved in the substance use and the encouragement to participate in treatment and not be afraid of being outed for lack of a better word. I am sure there are much better words.

Denise Love: Prosecuted is the word.

Melissa Goldstein: That is a good word too. But the idea is we are balancing ideas here. We are thinking about the interests and equities on both sides. Reidentification is a very important thing to avoid for people that have particular sensitivities about the information. We do need to acknowledge those as well. The question of whether to particularly call it out in the recommendation itself or in the supporting language, I can see some flexibility there. But I do not want to lose the importance of the original idea.

Denise Love: I understand. I just have from a political standpoint, not a legal standpoint, I do not want that to be a barrier to data exchange and sharing because at some point, any data could be reidentified with the right practices. That concerns me a little.

Melissa Goldstein: Especially with the mosaic effect with all of the different various databases.

Rich Landen and then Vickie.

Rich Landen: A couple of comments. Unlike the previous recommendations, I am a little fuzzy on who this is really directed toward. The recommendation itself does not say, but the language that supports it clearly says HHS. To me, what we are elaborating here is not really within HHS control when we get down to state and local level.

Thought number one is should this really be a subpart of the first recommendation that talks about setting up the framework.

Melissa Goldstein: That is a great question, Rich. Actually, at first, we have the two ideas together and then decided that it was too much for one recommendation, so we separated them and tried to explain in the supporting language what the differences were. The developing. We are intending for HHS to do

the development part of the data stewardship responsibilities. Is that what you mean by who it is directed to or do you mean the entities themselves?

Rich Landen: Yes and No. I am trying to follow this to the chain. Assuming HHS acts on this, how would they act and how would it then – what is HHS' authority if any to drive this down to the state and local level? I would see all that tying back to Recommendation Number 1. Obviously, I am commenting just on a 24-hour review but I have not been involved in the thick of things. I understand there may be reasons for not doing it the way that it strikes me.

Let me move on. My second thought is there is a lot in here especially when you get down into life cycle management. That is a lot broader than a public health emergency. I am wondering if this maybe can be focused a little bit more narrowly into what is the difference. What are the differences in what we are trying to say? What is the playbook for normal times versus what is the playbook for public health emergency? I do not see easily how life cycle management constraints would fit into a public health emergency scenario. To me, that just adds burden to the process.

Melissa Goldstein: Thanks. Vickie, do you want to jump in here?

Vickie Mays: I do. Thank you. I was involved in the writing of this. First of all, the thinking about this is in the public health emergency. What happens is that data that comes forward then gets used as the public health emergency goes on and it gets churned into different kind of use. This life cycle management is not the life of the data. It is the life of the public health emergency that I think we are talking about.

What it means is that we have waiver sometimes. People get data. They use it in ways in which normally they might not have the opportunity to. And this allows us to say even though we have waivers in place, you should still be tracking and keeping eyes or guardrails around that data. It may even mean that you need to come back and make sure or assurance that because these waivers are in place that it is going to be okay in terms of you are still protecting it. I think that is one issue.

The other is – again, this is a public health emergency and this data stewardship that we are talking about really is at the federal level. When we need something done, it really is a relationship with the states. The federal government can put out the – what do I want to say – the principle that this is how this data should be collected in the states. The federal government is saying to the American people in order to increase the trustworthiness that we expect that this data that we are using to make these decisions in this public health emergency has been collected in this responsible way. They do not have the ability to make it happen. They have the ability to establish a context in which it is an expectation. I do not think they are trying to make the states do something.

But it is a context in which if there is a problem, the request has been that the data should be collected in a way in which it is for the public good because the states are asking for a lot of information. The federal government is saying when you ask for that information, we want to use it. We want to make sure that you are still protected – that is to Rich. Those were my responses to Rich. But I have my own question. I do not know if Rich wants to say something or if I should just go on with my other comments.

Melissa Goldstein: Before it gets lost, Rich, do you want to respond to Vickie's idea/explanation?

Rich Landen: As always, I learn something every time. My concern is then not at all based on what Vickie is saying. It makes a lot of sense. But will the reader of the recommendation, the reader of the letter understands it the way that Vickie described it? I can just say I did not.

The other thing I will point out here is unlike previous recommendations, language in the recommendation itself does not – I am not quite making sense here because I am --

Vickie Mays: Rich, I think we got it in the sense of maybe we need to do something about the language to be clear. There is also supporting language after these things and that may help. But I hear what you are saying is that if somebody just had the executive summary and they go through this quickly that it might actually raise the ire of say state people or something like that. I got it.

Rich Landen: Okay. I will rely on the committee to do the usual excellent work. I will just say that, Vickie, my somewhat deviant understanding was from included reading the supporting text, not just the recommendations. Despite having read that, I did not wind up in the same place you were.

Vickie Mays: Okay. That is on us then. That is a writing problem. If you agree with the ideas, we are good. Thank you, Rich.

Melissa Goldstein: Thank you, Rich.

Vickie Mays: My other thing is I want to think about this notion about risk communication. A question is the surgeon general has bene very active about miscommunication. I am wondering if maybe that should be evidence-based communication or evidence practice communications or something. Responsible may be interpreted in many ways and maybe it should have something to do with evidence.

Melissa Goldstein: Beyond the idea of transparency itself.

Vickie Mays: Yes. But in a public health epidemic, one of the things we had is the difficulties around miscommunication. Given that we are trying to help HHS and that has been a big agenda that has been charged to the surgeon general, I think maybe either spelling out or changing the word responsible because I think that is left up to a personal perception of what is being responsible to maybe doing this based on data or science in some way.

Melissa Goldstein: Like scientifically based communication. So maybe an additional phrase there. Okay. Would you take out the word responsible or would you add to it?

Vickie Mays: No, I would take it out.

Melissa Goldstein: Thank you. That is helpful.

I know that Tammy and Denise Love both had your hands up. Maya, do you want to comment now or do we want to get the additional questions first?

Maya Bernstein: I was going to suggest exactly what Vickie – maybe that is – of the first line. That is the problem. We can try to find a different word.

Melissa Goldstein: Okay. Taking away the idea of responsibility, which of course is up to interpretation.

Maya Bernstein: Do not take away the idea, but just – because the true HHS can not dictate the states or localities what they do. But there are other ways that HHS can influence either by resources or guidance or even if you really – legislation or promoting legislation. There are other kinds of things we can do. It is a little bit either amorphous or maybe has the wrong connotation – the word responsibility – because we cannot develop them for states or localities.

Melissa Goldstein: We can work on that. Good.

Tammy.

Tammy Banks: I think I have the same issue as Rich and Vickie, not issue, but – because I am looking at it from a health plan provider perspective so the entities. When you look at the entities and the exchange of data, that is when the protection from reidentification becomes an issue. But when you expand it and you think about the data from a population health perspective, then you are looking at it from a different perspective.

I do not know if just for the recommendation if you can put a period after PHE and then expand what the entities are and what you mean by the population health emergency data because the impact of the life cycle management protection from reidentification from actual clinical practice is different again than the broader public health emergency data that a state or other local government agency would use. That is just what I am confused with.

Melissa Goldstein: Of course, that is going to depend on how the states develop their ideas of public health emergencies and what different activities they are doing at the same time. I believe 32 states during the course of the pandemic, have actually changed the powers during public health emergencies. So I am not exactly sure. I have to think about that a little more.

Vickie.

Vickie Mays: I think Tammy makes a good point. The difference between when you think about this as a more clinical entity and you think about it as more population health entity, what is in here has some different connotations. Thanks, Tammy.

I think we just need to kind of go back to the drawing board a little bit and fix this. But Tammy, I think that was a very important point because the issue of what happens in a public health emergency in terms of the data flow and even its cycle – its cycle will last in ways in which in the public health emergency is different. Those things were put up to do a public health and it is over with, but the data that end up in the clinical context will continue to have that life cycle. We kind of chill one and regulate the other. Regulate is a bad word. Guide the other. I see your point and I think it is a great one for us to reconsider.

Melissa Goldstein: Agree. Thank you, Vickie. Other ideas, responses? Maya, anything to add at this point?

Maya Bernstein: Would it help to look at the language or more expository language or you are not ready to go there yet? It is fine, but I have it here.

Melissa Goldstein: Supporting language.

Maya Bernstein: The members have it in front of them. It is in the packet that came around Wednesday – chance to review. The expository language is in there.

Melissa Goldstein: I am open to the idea. I am thinking perhaps we need to do a little bit of thinking and changing of language of a couple of the recommendations before we get to that stage.

Jacki, what would you like to do?

Maya Bernstein: We have a good amount of time still for this discussion if you want until 12:45.

Jacki Monson: What I am wondering is if we can actually pull up the letter and potentially finesse the language while we have at least 30 minutes of time to potentially finesse the language to get more alignment in the particular – I think we have some recommendations that we do not have comments on. We have a couple on one, a couple on three, and then obviously this one. I am wondering if we should spend some time live going into the language or the body of it beyond the recommendations to see if we can gain consensus.

Melissa Goldstein: I think that is a good idea. Should we start with the ones without comment or the ones with comment?

Jacki Monson: I think we start with the ones with comments.

Maya Bernstein: Do you want to just give people the one slide with all of them so they can see together what we are talking about here and then we can move just to remind people what all the – give people a review of what all the recommendations are as a whole. And then there is one that you particularly want to start with, and I will draw up the letter.

Jacki Monson: Why don't we focus on five since we had so many comments?

Melissa Goldstein: Vickie, were you going to say something?

Vickie Mays: I am kind of in – authority on this. I think this is really hard to do because I think we really need to think this through. I think five is hard to do. The others I think we might be able to do. Maybe with the whole other committee we can. The will of the group does this one.

Melissa Goldstein: Let us go ahead and pull up – we will try. We will give it a try. Recommendation 5. We might get bogged down. We will see what we can do. Maya, can you bring it up without any margin comments? Can you do it without the margin comments so that we can see it better?

Maya Bernstein: I have to get the right document here. I thought that was going to be easier. It claims to be sharing this and yet this is my email for how to get into the meeting. Sorry.

Greg Richards: We see your Word document right now.

Maya Bernstein: What I see is different. You can see it?

Melissa Goldstein: We can see it but I would like to get rid of the margin comments so that we can just see the text. That would be great. Perfect. If you can enlarge it a little bit for those of us who cannot see anything. That helps a lot. Go down to Recommendation 5.

Maya Bernstein: I could put it on two pages, but I do not think you will be able to see it. It is not that long, this section. I will just remind everybody on the committee that you have this language in your packet. If you have another screen to pull it on, you can look at the full thing as well. If I edit here, then you will be able to see as we – I can make changes here while you are discussing.

Melissa Goldstein: Before we get into changing the language of the recommendation itself, the bold language, let's look at our supporting language here. Encouraging HHS. It does make it clear that it is HHS. To define and employ data stewardship responsibilities based on principles of fair information practices for entities, collecting, using, or linking to data systems during a public health emergency. According to Tammy's idea, we need to put in an acknowledgement that there are different types of entities. Public health entities versus clinical entities.

But then we spell out the principles a little bit. These principles draw on from health information ethics. It would include but not limited to principles of accountability, security, openness, information privacy, and disposition and least intrusive alternative. We have a citation there. We could add to this list if desired.

This guidance should include responsibilities relating to privacy, security, life cycle management, identification of use or reuse outside of the declared public health emergency, notification of data use and purposes of collection when feasible. It has a limitation there. And protection from reidentification guided by the principles. Maybe that limits the reidentification that Denise Love was pointing out there, the ideas there.

And then the next page, Maya, if you could scroll down a little bit. The importance of the responsibilities should be widely disseminated to raise awareness about the risks and potential consequences of misuse and reuse of data, including reidentification to individuals, vulnerable groups, and establishments, and focus on uses of data that go beyond their original purpose. The purpose being collecting during a public health emergency for clinical and public health purposes.

Every effort to communicate to the public, expectations of good data stewardship. This could also be science based. Data protection practices, methods from reporting, and perceived abuse, to promote greater understanding, trustworthiness, transparency, what good data stewardship is, methods, even in the face of waivers that seek to protect it from misuse or unapproved reuse. Stewardship practices should include procedure to assess at regular intervals. This is the idea of how often it is done. Whether methods employed by data stewards continue to be appropriate. And then we give a few examples. Use of algorithms, methods of estimation of resource allocation, evaluation. Supporting language that helps flesh out the recommendation more. And the steward's action should be guided by the growing public

expectation that individuals will be informed about how their data are being used and disclosed, with what parties that it shared, and how it is being protected.

Maya Bernstein: The rest is the sort of closing paragraphs of the letters. This is the part that supports that recommendation that Melissa just went through.

Melissa Goldstein: There is a great deal of explanation here and support in a few short paragraphs. We could highlight the words responsibilities and responsible. Maya, maybe we put science-based in that last line of the recommendation. I think that is what Vickie meant.

Maya Bernstein: Tell me exactly what you want and where.

Melissa Goldstein: The recommendation itself?

Maya Bernstein: Wherever you want the language I will put it in there if you tell me exactly where to edit.

Melissa Goldstein: I would put a comma and say responsible, science based. Vickie thought we should take out the word responsible, which I would be fine with also.

Maya Bernstein: Vickie, I see you lighting up. Do you have a thought?

Vickie Mays: I almost would say maybe evidence-based scientific communication. I was trying to get to it, but I was not doing it fast enough, the surgeon general site because he has some language about these things. There have been some releases. For now, if we can park this, I am okay.

Melissa Goldstein: Tammy has suggested that we simplify the recommendation language itself and simply put a period after PHE and then expound on the rest of the recommendation, which we do in the supporting language.

Vickie Mays: I think it is better to fix it than drop it because I think – that is why I was saying – it just takes some thought because I think what we want to get at is that this first part is the principle, and this next part is more about in the where. Again, if someone were to just have the executive summary, it does not land it where I think we want it to be landed. We have to make sure we do not say something that ties the hands of the clinical people. Maybe I am just brain dead here. I cannot quite fix it.

Melissa Goldstein: It is a long sentence like Rich said. I wonder if we break it up into numbers or small letters or something just to make sure that it is a big list.

Rich, go ahead.

Rich Landen: A comment here. I am wondering if we need to define entities. We just say for entities collecting using. That is pretty broad. I am wondering if we should move up from what is several paragraphs further down. We are talking specifically about federal, state, and local entities. I guess what my concern is is we are thinking federal, state, and local I am presuming. But there is a lot more entities that collect and use and share data during a PHE so maybe just describe that we are really talking about the public health authorities at those three levels.

Melissa Goldstein: Interesting because earlier we were talking about public health versus clinical kinds of entities. There are a couple of dimensions on which you are talking about the types of entities you mean.

Rich Landen: The other thought that does not necessarily apply right now but it might be is I still think we need to somehow tie this back to Recommendation Number 1. I understand the arguments that you gave for separating it out. I do not disagree with them. But I think we need to include some reference here that this is part and parcel of the data governance strategy.

Melissa Goldstein: I am wondering if we move it so that it actually appears as Recommendation Number 2 and that way it is easier to reflect back to the language in Recommendation Number 1 and make sure that it is a clear connection. Would that help do you think, Rich?

Rich Landen: Until I see it, I will not be able to answer definitely. But I would say 90 percent plus probability that it would resolve it. It is hard when you do this on the fly. There are always some things that you see later on when you are a little bit more calm and can reread the whole thing.

Melissa Goldstein: It is hard. I agree. We appreciate you helping though.

Vickie Mays: Can I comment, Maya, while you are doing the moving? This is relative to what Rich was saying. Again, kind of in the panel, the April 1 panel on race ethnicity and public health emergency. We had someone who was with a private entity that was collecting data and doing things that were somewhat worrisome to the IRB but they had no authority to deal with it.

I think we can more than just state – federal, state, and local, but we have to think of pharmaceuticals, for example. We have to think of private because there are people who in this were using data to develop, sell products, et cetera. It maybe a little bit broader than just that. Again, it is the federal government making the suggestion that that is the bar in which people should operate. It cannot legislate or regulate all of it. But it is a – we do need to think about particularly like pharmaceuticals because that is part of the public trust issue that people are struggling with.

Melissa Goldstein: I am also wondering about research data, which of course would be covered by the common role if it is involving federal money. But if it is not, it is just people gathering information that is posted on the internet. We might be concerned about that as well.

I just wanted to remind everyone that we could bring an edited version back to the Full Committee tomorrow afternoon if we wanted to edit it in the meantime and work on it later in the afternoon and discuss language in particular.

Vickie, I am sorry I cut you off. Go ahead.

Vickie Mays: No. It is fine because you were going exactly -- I think that you are going exactly where if you keep thinking, you realize there were these other things that happened that we should be maybe trying to at least have an aspirational principle for. We cannot regulate, but we can be aspirational for how we want them to perform in a public health emergency.

Melissa Goldstein: Exactly. To that add, I would ask you guys specifically to focus on this list of principles. Of course, we wrote include but not be limited to. Accountability, security, openness, information, privacy, and disposition and least intrusive alternative. Thank you, Maya. That is helpful. Are there any we should also include in this list? This is from a progress report. It is 24. I cannot see what exactly the citation is, Maya. It is from an article. Obviously, this is not all the fair information principles.

Maya Bernstein: Purpose – use limitation. Those kinds of things. They are controversial in this group. The idea that if you collect something during an emergency, maybe you should – because you got extra special access because it is an emergency, you should then be more careful on the other end in sharing it after the emergency for something that is not related to the emergency.

Melissa Goldstein: We can include, or we can include but not limit it to means that there might be others that people come up with and that we leave that up to the secretary and the agency to make decisions on. But that we want – like Vickie said, aspiration. This is what we would like for people to be doing with data collected and use during the public health emergency.

I think we have about 15 minutes left. Is that correct, Rebecca? A little more. Maybe let us move back up to Recommendation Number 1, Maya, since these two are closely linked.

Maya Bernstein: Thinking about that, as Melissa mentioned that we can have staff help here. We can edit and overnight make edits and turn around another draft if you have time. I know it is a very busy day for everyone and you have other jobs to do. However, if you want to send me markups and suggestions, I can put them together into one document and show them to you tomorrow all together.

Melissa Goldstein: This is Recommendation 1, which focuses on governance strategy. And then just as a reminder, Recommendation 5 that we were just looking at is data stewardship principles, guidelines so related to Recommendation 1. We could put what we have been calling Recommendation 5 as directly following this one.

Here, we explain what data governance is first. Framework or structure for ensuring that an agency's data assets are transparent, accessible, quality to support its mission, approve the efficiency and effectiveness of the operations. Then we talk about how the pandemic has underscored the urgency to develop a governance strategy specific to public health emergencies. That ensure the privacy and security of data, promote trust, demonstrate the trustworthiness of data collection, again, emphasizing public trust. That we have learned from other outbreaks: Ebola, Zika. That public health needs easy and rapid access to support surveillance, research, policymaking, communication. We can only make data driven public health policy decisions if we have the data and it is shared.

Then the next paragraph we say NCVHS recognizes the need for improved information system capabilities and public health agencies across the board. We recommend that HHS develop a governance strategy. We point out that one of the panelists noted that at the hearing itself in September 2020 noted that, unlike countries with national healthcare systems, our system is decentralized, which means that there are silos, public health department work, individually oftentimes, and emphasized privacy and security must be embedded. Here is a word we could use – into local public health policies and practices and that a strategy should be overarching, integrated, well-resourced, and

supported. We could add the word socially supported here like we did to indicate the difference between financial support and social support.

Benefits and possible risks of data collection and use should account for use of new technologies that are coming down the pike all the time, and that we consider privacy and security issues, the importance of management of public health data. So all of these important things. Life cycle is mentioned here. Building public trust. All of this focus on a governance strategy.

Denise Love.

Denise Love: All of this is fine but as you go through this, I am wondering if footnoting some of – and we will hear more about it later from Public Health Data Standards Task Force from ONC. They also reference some of these needs for public health emergency, minimum necessary, clarity guidance. I do not have the exact recommendations drawn out. But I am just wondering if a footnote this referencing their report.

Maya Bernstein: Where would you put the footnote, Denise? I will make a note of it so we can get that.

Denise Love: I can give you that. Like the second sentence, just to acknowledge that – independent tracks here because I think you are saying the same thing. I think it would support what you are saying here in their HITAC report. I will give it a little more thought, but I think it is just reinforces what you are saying about public health emergency data practices.

Melissa Goldstein: I think that is great, Denise. Thank you. That is really helpful.

Rich, go ahead.

Rich Landen: Two comments. Despite the education I got from Vickie, I am still struggling with life cycle and wondering if the subcommittee would entertain something. If you look at the language that is in the last paragraph of the recommendation – public health data collected in emergency throughout its life cycle. It would be helpful to me if I am understanding is does it pertain to the duration of the public health emergency or does it pertain to the life cycle of the data that has been collected.

Maya Bernstein: It refers to the data, I think. The point of the – issue -- life cycle of the pandemic but a life cycle of the data before the collection, the protection, disposition, eventual sharing and disposition of the data. That is what we refer to as life cycle.

Rich Landen: Is that sufficiently clear among the professionals that they will know that for sure, because I certainly do not?

Moving on then, my other comment is the two examples we cite of the public health emergencies are both viruses. Should we include something in there like Hurricane Irma to make this clear that this data governance strategy and then the rest of these recommendations, do apply to other types of public health emergencies?

Melissa Goldstein: Right. I think that is a great idea.

Rich Landen: Hurricane Irma.

Melissa Goldstein: Of course, I think back to Katrina, but we do not even need that.

Rich Landen: Katrina is probably actually what I was thinking of and the crisis there was the flooding of all those paper records and the nonexistence of the electronic records ages ago.

Melissa Goldstein: And people not knowing what pills they took.

Maya Bernstein: I think of Irma and Maria going together because I was deployed to Puerto Rico in the aftermath of those hurricanes. So they are fresh for me.

Is Sandy, is that a better example? I do not remember. In New York. All the flooding in Sandy.

Vickie Mays: I just want to remind us that there is a little bit – in what happens with infectious diseases as opposed to wildfires and tornadoes and floods, et cetera. I do think this was crafted to think about the infectious disease because there are rules about confidentiality and infectious diseases depending on what they are, so that will differ from this.

Again, if we are going to now put these other things in, we need to go back in and make sure because they are very different. It is like this is more like HIV/AIDS than it is like the wildfires and all that. I specifically thought about that when we were doing this stuff and left it out because this really does apply to a great extent about infectious disease. And the infectious disease really is like primarily integrated into the health care system in the way in which a lot of these other things are not. We would just have to go back through it and make sure that we are clear.

Melissa Goldstein: Vickie, do you think that we could address some of those differences in a footnote perhaps or at least note that there are differences in the context?

Vickie Mays: I think we should because it is written for -- that is why Ebola and Zika are in there. This whole thing I think is written to really deal much more with infectious diseases than it is all the kind of privacy issues that come up in general, all the way from hurricanes, wildfires, tornadoes. It is kind of different.

Rich Landen: I think Vickie brings up an excellent point, but it is critical that if we are just talking about infectious disease public health emergencies, we cannot simply use the term PHE. We need to be very specific on the first reference, and then follow through that we are only talking about viral PHEs or infectious disease PHEs. Because the way it is written now it applies to all public health emergencies.

Melissa Goldstein: Right. So maybe we should put it in a footnote to clarify towards the beginning that some of these recommendations – many of the recommendation may be relevant in another context too, but we do note that there are different contexts and it needs to be considered very closely.

Rich Landen: I am sorry. I am not sure that I am comfortable with that and obviously it is just my opinion. But if we are setting up a strategic approach, why would we differentiate between different types of PHEs? If you are looking toward the implementation step of this, there is a PHE. The rules are

different. What are the different rules? It gets really complex, and it then would presume yet another governance strategy for a non-infectious disease, public health emergency. I am not sure that that is a good approach.

Vickie Mays: I think one can say what Melissa was saying is that this applies in particular to infectious disease. But there are lessons for other public health emergencies as well.

There is to me a distinction because in states, there are different rules when it is an infectious disease. It also is a difference in the life cycle because of how the clinical setting is so specifically involved.

In Hurricane Katrina, you do not necessarily have to worry about lab test results. But in infectious disease, that is exactly what we are worried about, needing data from there, needing that data to move quickly. It is a little different.

Again, I think this has to be – we have to decide. If we are going to do this then we just need to go back through and make sure what we are saying can fit either one, the other, or both.

Melissa Goldstein: Maya, go ahead.

Maya Bernstein: So I think much of what we are talking about has to do with infectious disease, but there are several things that we have already talked about, for example, the waivers that are not just specific to infectious disease like the ability to do telehealth, which you would want to do in a hurricane, for example, or (indiscernible) because you cannot do it in a natural disaster kind of thing for a fire or whatever. There are multiple things that are referenced in this letter that would still be relevant outside of the infectious disease context. Let me just stop there and put that thought in your head.

Melissa Goldstein: Thank you. Tammy.

Tammy Banks: I was just going to concur with just revisiting this like Vickie had said and look at it for the complete public health emergencies because it is obviously exchange of personal information regardless of what the source of it is. 911 who is involved. What about the medical care? What about the exchange of records? There is so much crossover. I would really support Rich's comment.

Melissa Goldstein: I think there is a lot of crossover. I agree. I like the idea of adjusting public health emergencies in general. I think we do need to acknowledge the nuance between different types of public health emergencies. I do not know that we need to make recommendations about what the different governance strategies or data stewardship strategies would be in various different information. But I think it is important for us to recognize that nuance.

I think when we look over this again tonight, I think we can read through the letter again and the recommendations again to make sure that we clarify that according to Rich's ideas.

Rich, go ahead.

Rich Landen: I like that approach, Melissa. I think we acknowledge our limits in terms of what we are doing here as infectious diseases, but then recognizing that if there is an overarching strategic approach

that others then need to fill in the blanks for the non-infectious disease type of public health emergencies because certainly physical damage, tornadoes, hurricanes is outside of our scope.

Melissa Goldstein: At least right now.

Rich Landen: Not outside of our experience, but outside of our charge.

Melissa Goldstein: Thank you, Rich.

Maya Bernstein: Melissa, just a time check. We are almost out of time. We have a couple more minutes. Do you want to return to the other slides or check in with the rest of the committee if anyone who has not spoken yet wants to speak up with some final thoughts here?

Melissa Goldstein: I think final thoughts and then we have some homework later tonight. Please send us comments if you are able to, if you have time to read through. Give us your comments later today or tonight. We will do what we can to bring it back to you tomorrow afternoon. We will work with Rebecca on the agenda with Rebecca and Jacki. Any last comments right now before we move on to our break?

Maya Bernstein: Is there anyone among the membership or the staff that did not get a chance to weigh in?

Melissa Goldstein: Thanks, everyone, for a great discussion. I really appreciate it.

Jacki, I will hand it back to you and then we will move on.

Jacki Monson: Thank you, Melissa and Maya. We are committed it sounds like, to get a draft back to the committee perhaps tomorrow morning for their review. Is that what I am hearing?

Melissa Goldstein: I think that sounds okay.

Jacki Monson: Okay. In the meantime, if everyone can channel anything else they think about with respect to this, including actual red lines, it would be really helpful to Melissa and Maya. We are hoping we can bring this back for approval tomorrow. If we do not quite get there, then we are looking at perhaps a special meeting in the next couple of months specific to this letter to gain approval.

With that said, I think we are at a break now. We will break from 12:45 or 9:45 my time, until 1:30, 10:30 Pacific. I will see all of you then. Thank you.

(Break)

Jacki Monson: Good afternoon, everyone. Welcome back. I am going to hand it over to Denise and Rich to kick off our Standards discussion.

Subcommittee on Standards:

Update – Convergence 2.0 Project

Rich Landen: Are we live and ready to go?

Rebecca Hines: We are indeed.

Rich Landen: Very good. This is a report to the Full Committee of activities of the Subcommittee on Standards. Specifically, today, we are going to be focusing on what we are calling Convergence 2.0 project, which you have all been briefed on previously. We held a hearing session last August and we are going to present some of the preliminary findings today. There is nothing for a vote or action today. We intend to bring back recommendations at the next Full Subcommittee Meeting, not tomorrow, but the next Full Meeting.

What we are going to do today is go back into a little history just set the stage, talk about what we have heard, what we concluded, and then look for input form the Full Committee similar to what we did for PCS this morning. Then we have a couple of other sources of information from ONC HITAC-related task forces that Denise Love and Tammy Banks will talk about. And then we have a reactor panel that we will introduce later.

Our reactor panel is from a number of organizations that may have or will have a lot to tell us about some of the aspects of what we are concluding from our listening session as part of the Convergence project. We hope to learn and have a good conversation and dialogue with those organizations.

This is a description of the project that you are all familiar with. We are a year into this project. The first year was a landscape assessment. What we are doing now is the analysis, deliberation, report and potential recommendations based on that landscape assessment and other inputs into the work.

And then from a historical standpoint, this project builds on earlier work done by the Subcommittee on Standards and work through the Full Committee. The key highlights, which we went into the listening session, is concepts like envisioning a more industry-driven standards development adoption framework that currently exists. We are looking for more timely updates. That means more frequent, but smaller, more digestible bites. We are looking at enhanced pre-adoption testing. There have been issues reported with the adoption process and actually considering standards that have not been fully tested or at least fully enough tested. Building in value assessment, including return on investment, which is required for federal rulemaking. Burden determination.

And then a key concept you will be hearing more about is societal benefits. One of our concerns is that the traditional way of looking at the fiscal impact, return on investment is a little bit too cost focused or economic focused. We want to make sure that taken into consideration while considering these mandates under HIPAA and other legislation that we really take a broader look rather than just the financial.

And then finally, some of the themes then from earlier about enforcement and conformance.

The intent is to build on the previous history with appropriate innovations and priorities. First phase is what I described as we elicited written comments back in August. We had a listening session. The subcommittee has been busy analyzing the comments and listening session, the panel information, and identifying opportunities for intervention or specifically for recommendations.

We are working on conceptualizing potential solutions to improve efficiency and reduce burden for the full industry. And then part of that is developing a work plan for the remainder of this year.

Phase II, which is coming up this year, is standards. We are looking at development and maturity, regulation, implementation, and enforcement aspects of the HIPAA and related standards. For convergence, we are definitely coordinating efforts with ONC and HITAC. There will be others as we look into the expanded scope of actors who were not the historically designated actors, again, relating back to some of our conversation this morning. This gets to who is a covered entity. Who should be a covered entity? It was one thing in 1996 when HIPAA was enacted. It is another thing in 2022. Convergence and collaboration with other entities to redefine the universe, redefine the dataflow infrastructure. And network is part of what we will be doing this year.

And then finally, identifying other opportunities related to the various HHS priorities.

Some of the additional opportunities that we are thinking about is FHIR and APIs. We will have much more on that a little bit later on.

All-Payer Claims Databases, APCDs, and the Common Data Layout. We have got more experience now with that than we had a few years ago.

Consistency of reporting and/or exchange of social risk data. Conformance or enforcement. Those two are similar, but not synonymous. There is enforcement in the HIPAA world, but we are looking at kind of updating the way the industry looks at it and taking some lessons learned from other industries and some developments within some of the standard development organizations that focus a little bit more on conformance than enforcement.

We are looking at probably, not possibly, but probably sanctioning some exceptions and alternatives to the HIPAA standard transactions. Again, we will get more detail as we get later into the presentation.

We are looking at health data flows beyond their traditional HIPAA and HITECH trading partners. New since HIPAA, new since HITECH, are structural and social determinants of health and involvement in the routine data flows that involve patient social service programs and other types of data users, data consumers beside the patients themselves that were not contemplated when Congress formulated the HIPAA structure.

Looking at public health and infectious diseases and vital statistics. Again, a scope well beyond HIPAA, and looking at pandemic-related lessons learned. Again, a lot of overlap with some of the topics we discussed as part of the PCS session in this morning's agenda.

And then finally, looking at patient and consumer-driven data. Again, historical frame of reference. HIPAA was the transactions under HIPAA and the concept covered entities were pretty much a business-to-business or B-to-B concept. In this day and age, the consumer, the patient, is much more either definitely an included entity in the data flows or potentially included in data flows. Again, something other than what was in the minds of the framers at the time HIPAA was indeed framed.

The listening session, and again this is back in August of last year. Some of the highlights there. We had received 31 public comment letters and those 31 letters included I think over 100 different signatories. Many signatories on some of the letters.

We had four panels of industry experts. The first panel was on lessons learned from national standards coordination, beyond health care. Other industries that have standards in effect be they regulatory or voluntary and what health care can learn from those successes and stories.

Panel 2 was just a general update from the standards organizations and industry. The standards organizations include National Council for Prescription Drug Programs, ASC X12, Health Level Seven, HL7, and then we had also a comment, not directly from, but including references to the – why am I blocking on the name --
CAQH CORE and the Operating Rules.

Panel 3 was about semantic harmonization. Always a challenge when data is collected for one purpose or using one code set and then repurposed and either used without translation or used in a different context. There were interpretation issues. There are interpretation issues in some of those reuses.

Then the final panel was about public health and social risk data.

These next two slides are just kind of a raw and unranked listing of the key inputs we got from the public, again, from those letters. I will go through these just very briefly. The first concept was test standards, evaluate return on investment before federal adoption, adopt health care attachment standard. For those of you not in the transaction standards world, there has been no standard adopted for health care attachments. That was one of the things that HIPAA stipulated should be adopted, but to date has not.

The third topic was adopting acknowledgments as a HIPAA standard. Acknowledgments assure that when let us say a transaction is sent from a provider to a payer that the sender receives an acknowledgment that the receiver actually did receive the communication. Without an acknowledgment being a required part of the process, the testimony was that sometimes the senders do not know if their message ever got through to the receiver.

Number 4, publish prior authorization, API, regulation. We talked about that a little bit more as well.

Five. Improve regulatory processes for adopting standards under HIPAA. One of the things to consider maybe the ONC Standards Version Advance process or SVAP.

Number 6, and again no particular order, implement a patient education campaign specifically how information necessary to patients to stay safe and stay effective with us of patient-focused apps and privacy and not mentioned here, but also brought up was security.

Seven. Implement training programs for provides on data exchange to support bi-directional data exchange. We heard that even though the standards may have been placed, there is a large component of people who can benefit from these standards that really do not know how to use them.

Eight. Identify, implement, adopt standards for payers and other organizations to exchange data bi-directionally rather than just one way.

Nine. Develop a universal solution for patient matching.

Ten. Consider expansion of HIPAA to non-covered entities, for example, holders of data from covered entities. You heard that theme this morning with PCS.

Some of the themes emerging. Again, these are kind of raw. This is not necessarily the focused deliberation of the subcommittee. But again, we are setting the stage. This was the input, which the subcommittee received, and subsequent slides will tell you where we think we are going after we digest it, analyze, and discuss all the data, all the input.

Data sharing across all actors and types. The world is no longer limited to administrative data. We have both clinical data and other data too that we are calling social, but it is not limited to social.

Data sharing is not limited to HIPAA-covered entities. For those of you that need a refresher, the covered entities are exactly three: providers, health plans, commonly referred to as payers, but in HIPAA technical parlance, that is not exactly accurate. It is health plans. And then the third category is the clearinghouses so providers, clearinghouses, health plans. That is it.

Data sharing is not limited to EDI transactions. HITECH has some clinical exchange. There is health, wellness, and pandemic-related data that also flows.

As I mentioned before, it is no longer just business to business. Patients are included in the communication flows. The new concept of advanced explanation of benefits has been added.

Data is collected at any point in the system does not necessarily flow to all the points of usage, for example, the All-Payers Claims Databases, SOGI, and SDOH.

Issues with privacy and security beyond HIPAA. We now have third-party apps that accesses the data that are not highly regulated. Data moves regularly beyond covered entities, and I should say both regularly and legitimately. It moves beyond covered entities. And once it gets beyond the covered entity is technically no longer controlled by HIPAA with the exception of the business associates.

New developments and professional hacking and ransomware are now commonplace. It is a challenge to educate consumers. Right now, there is no – we are thinking or what we heard is there is no practical informed choice or consent in some of the decisions that consumers are faced with in order to manipulate their data.

Continuation of the themes that we heard. Regulatory challenges in rule promulgation. There is need for greater transparency in the process. It is not always clear whether a regulation under consideration is progressing or has been halted or what the status is. As a result, industry cannot rely on any particular timetable and therefore cannot plan for the rule adoption until it is actually published.

Conflicts between standard development process, HIPAA legislation parameters and the Federal Administrative Procedures Act creates a lot of barriers and hurdles. Not easy to navigate. Many parties have obligations in here that must be fulfilled and yet that series of individual obligations under those authorities serves to be detrimental to the efficient achievement of actually publishing regulations.

As I mentioned before, the need for more pilot testing and return on investment determination.

One of the things we heard that we will talk about in more detail later because this is one of the things we agreed with strongly is the support the ability of the industry to use multiple versions or different standards simultaneously.

Trading partner agreements there and could govern some of the data exchanges that are currently exclusively governed by regulation and actually bring the system more to an implementer-driven approach, in other words, an approach that the implementers determine how much they need at what pace.

We talked a little bit earlier about conformity assessment. Conformity assessment is essentially a framework for measuring and reporting conformance to the standards. That is done objectively typically by a third party or a third-party test bed. And then incorporating a feedback loop to the entities that they know whether they are conforming to the standard and also providing feedback to the developers of the standards that would show what pieces of the standard entities are having challenges conforming with.

And then lessons from other industries, as I mentioned before.

Other challenges and opportunities, as mentioned earlier. Patient matching. ONC did a Report to Congress on this. There is a lot of activity going on in this area. But it is something that is essential to the flow of health and wellness data so therefore it is important for us to recognize this in whatever we deliver as far as recommendations.

Universal Device Identifier was brought up. Universal Device Identifier coding exists. But it is the implementation and the data sharing that are lacking at this point.

Semantic harmonization I talked a little bit about earlier. When you move data from one context to another, you do not necessarily get the semantic precision and you may lose something in the translation.

Data exchange between public health systems, states, counties, local jurisdictions. We heard this not only from the administrative and clinical data that must be reported beyond the payer-provider relationship. But we also heard this coming out of the pandemic experience. Just to be clear here, we are looking for federal leadership and leadership does not mean federal regulation that would preempt state's ability to control what they do.

The previous slides all talked about either historical stuff done under the roadmap project of NCVHS Standards Subcommittee and then the more recent slides then from the August of last year comment letters and the listening session with the panels.

This slide talks about other important inputs that the subcommittee has been taking into account, and that is the Clinical Administrative Data Task Force, ICAD, in which NCVHS participated with HITAC under the auspices of ONC. The ICAD task force made certain recommendations that align with our charge and then the site there if you want to read the whole thing.

The second major source of input was the HITAC Public Health Data Systems Task Force, which identified a number of recommendations that are of interest or overlap with activities. Denise Love will be talking more about this a little bit later in this session.

And then finally, there is a brand new Electronic Prior Authorization Request for Information Task Force, again, working on building on earlier developments. HITAC and ONC have just formed this. Our own Tammy Banks is going to be a co-chair and Tammy will talk a little bit more about this later.

The subcommittee has been deliberating. We have been meeting biweekly since the August hearing session. We have reviewed input from each panel, and we have reviewed multiple times I might add all the submitted comment letters. We have discussed themes through a wide lens and from multiple perspectives, for example, the IPAA regulations, just thinking about how data flows through the system, thinking about privacy, thinking about things like source of truth. We have had lots of discussion about cost/benefit/burden. We have come at it from equity perspectives. We have come at it from who are the traditional HIPAA actors and who are the new entities that are involved in all these data flows that HIPAA did not contemplate.

We talked about state and territorial perspectives rather than just HIPAA as a federal mandate. We have talked about standards development processes and organizations. We have talked about predictability and reliability of the process and on and on. There has been a lot that we have tried to take into consideration and look at all this information that we got from the listening session and what we got out of the roadmap.

We have done a lot of the deliberations. We have achieved many areas of consensus and we will list those in the next slides. We have identified obviously a few more areas for additional inquiry.

Here are some of the areas in which we have consensus and which it is our expectation that we will be able after listening to the discussion that will be coming up after my presentation here. We will be able to take this back and start framing recommendations to bring back to the Full Committee at the next meeting.

First, the HIPAA concept of standards adoption and the current regulatory adoption processes so both legislation and the regulation are obsolete and require major updating. They are just not working to meet the needs of all the actors, all the participants for what we will call industry.

We need to allow multiple standards to co-exist and be used by stakeholders, which means a payer or provider can pick and choose among NCPDP, X12, and HL7 standards. That includes the apps such as being developed under the HL7 FHIR program and related programs. Those stakeholders then need to make the choices so they can most effectively and efficiently meet their business needs.

I will point out that the terms effectively and efficiently here come right out of the HIPAA legislation. Effectiveness and efficiency were two of the key priorities for which HIPAA was passed.

We also think that we will want to allow multiple versions of a standard to be in production and in use simultaneously, assuming that multiple versions are both available and have been tested.

For instance, using X12 example, X12 has three main versions, Version 5010, Version 7030, and Version 8020. Those versions are roughly five to ten years apart from each other and yet right now, one and only one of those is the HIPAA standards. The other one is prohibited. What we are saying here is based on the SDO's determination of continuing need for the older standards and for industry is determination of how many versions they want. All three should be allowed under regulation.

And then the example is National Council for Prescription Drug Programs, Version D.0 versus Version F6. Currently right now, adoption of F6 would mean retiring D.0. But we are saying allow D.0 to persist if there is industry need for as well as allowing Version F6. That is quite a change. But that is also -- as we have heard in our deliberations, that is also is consistent with – the ability to use multiple versions simultaneously is a standard practice in health information technology and in IT, in general.

Also, modify the standard adoption process under HIPAA, including consideration of the ONC SVAP as appropriate. In other words, we are looking to how can we change the adoption process such that it will be effectively able to include the principles that I covered under those first two bullets.

Also, eliminate the opaqueness of the current standards development, readiness and adoption processes and establish a predictable and dependable cycle for adoption of any appropriate updates of the standards. There is a lot baked into that. That would translate into something like we will set a data and say June 1 either every year or every other year or every third year, whatever it turns out to be, and industry then can plan its resources, do its budgeting to expect standards version update on that specific date.

Now, important to understand in that is this would not be a total replacement. That on that set data every year, every two years, every three years, whatever it is, only those standards would be updated for which an SDO certifies there is a need to upgrade, for example, an update to the X12 institutional claim 837I, but not the dental claim, the 837D. It is hypothetical. But it means that consistent with what we talked about is the updates would be more focused on what does the industry need and that would reduce the size. The package would reduce the burden on industry, and we think would provide a better framework than the one that was first established in 1996.

Also, we agreed with some of the commenter themes that we should amend the exception approval process for testing emerging standards to be less burdensome for the testers and more proactively supportive of innovation. For those of you not in the standards world, the HIPAA mandate is that you – if you are a covered entity, you must use one of the adopted standards. There is a process through which entities can apply to the secretary for approval to test standards other than the adopted standards. And what we are saying here is even though that exception approval process exists, it has not been widely used and we think if we make it a little bit more proactively supportive of innovation that would better allow the industry to test the evolving standards. Again, thinking back to the environment that I

described where there may be multiple standards available and multiple versions of those standards. This sort of approach would be more conducive to the interests of the industry.

Amend the Direct Data Entry exemption. Here, what we are talking about is payer web portals to be more user friendly and less burdensome to providers. Again, for those that do not live in this world, if you are using a HIPAA transaction and sending it to your trading partner with electronic data interchange, you must use the standards. There is an exception to that that we are calling the DDE exemption that allows a payer to set up a website that are required to use the standard data terms and formats and codes, but not the transmission standards. That is good in some sense that it is simpler for providers. It can be simpler for providers to use. But it is also a complicator because we found through input that it is impossible for providers to manage different web portals for multiple payers. Each payer's portal is different. It requires different log on, credentials, security. It is a very labor-intensive system to learn for a provider's office staff when that staff has to interact with multiple, unique portals. If there is something we can do there to make the portals more friendly to the providers who have to use them, we are not trying to do away with the portals. But we are trying to reduce the burden.

Develop, implement, and fund a national system of testing, including test tools and test beds for standards in development. One of the comments we heard is that it is hard to test the standards. Standards are not being well tested. Our concern is how do we get them well tested that works both for the SDOs and that works for giving the regulatory authorities what they need to determine the readiness of the standard.

Develop and publish criteria to determine the fiscal impact, the value, the return on investment, and incorporate those criteria, where appropriate, in the development path of candidate standards or operating rules and other agencies where federally mandated. Ensure a quantitative fiscal analysis is a balanced assessment of value to society rather than a cost accounting of implementation. That is what I was talking about earlier where the value of standards is not all about how much does it cost to implement the new version, it is about is society better off with the new version than with the older version and is the cost of doing so reasonable relative to the cost of not doing so. A bit of a different approach from the accounting approach.

The subcommittee is thinking that HHS should act on previous recommendations and industry priorities. We need a standard for health care attachments. We need to adopt a standard for acknowledgements, both of which I have talked to before and need to publish the regulation that has been pending on prior authorization.

Non-regulatory actions that we are considering recommending is to implement a patient education campaign regarding patient apps and privacy policy. To implement training programs for providers on data exchange to support bi-directional data exchange, to reduce manual transactions. To identify, implement, and adopt standards for payers and other organizations to exchange data bi-directionally. To support capture of ICD-10-CM social determinants of health data elements across the health care ecosystem and footnote that ONC is developing additional data elements besides what is in 10-CM.

More non-regulatory actions. Develop a solution for patient matching. Working with state and territorial of course tribal officials and their authorized workgroups to provide and fund federal thought leadership

to provide guidance to implement locally run health and wellness data systems that collectively funnel up to provide national data for policymaking and research such as public health emergency data collection, APCDs, public health surveillance, infectious disease reporting, contact tracing, and non-claims encounter data. There is a mechanism for capturing claims data. But when you are into a non-fee-for-service world, how does that data – how does on collect that data?

Work with the American National Standards Institute and standards organizations to identify an equitable method for compensating standards development work for federally adopted standards. Use that funding mechanism to ensure good SDO productivity and to provide minimum-hassle availability of adopted standards to all end users and their systems/software vendors.

What this gets to is that right now each SDO owns the standards, it's proprietary. It takes a lot to develop standards so there is a lot of actual real-dollar cost and investment of time and resources. Some of the SDOs have – all the SDOs have their own policies on how they make that data available and what the cost is. HIPAA recognizes that data does not necessarily have to be free. But what we found is that the inability to easily obtain the standards work is a barrier to effective implementation. What we are saying here is we need to rethink how the economics work there and ensure that the standards organizations have a way to be compensated for their work and funded for their work because they are producing something for the public good and yet at the same time, reduce the barrier to the end users and to the system providers of those end users that would allow the whole system to work better and get those standards incorporated pursuant to the federal mandate.

The previous things where what the subcommittee has already come to a general consensus around, and we are going to be welcoming your thoughts on those. These next couple of slides talk about concepts that we still have interest in, but we have not completed our deliberation and do not have a clear consensus that would lead to a potential recommendation.

First bullet, Work force training and development on implementation on emerging standards. Then collaboration among advisory committees. There is a lot of coordination work that is possible. A lot of collaboration that needs to be done, but who and how and how to prioritize are things we need to look at.

Collaboration among standards development organizations. Yes, there is some. It can be improved. And if the structure around the standards adoption by regulation changes, then the collaboration among the standards development organizations will need to be amended to reflect that new process as well.

Understanding after-the-fact enforcement relative to before-the-fact conformance testing. As I mentioned before, the HIPAA legislation has an enforcement. But what we are trying to do is shift the focus away from enforcement mindset to a conformance mindset. Conformance testing can be done earlier in the process. If it is done early in the process, it will be fewer implementation and shall we call them disagreements among the sender and receiver of the transactions.

And then specifically per the American Dental Association comment letter, will the industry request a FHIR or app-based standard to replace the current X12 standards for certain provider types? Right now, not possible under HIPAA. But it is an interesting area to pursue.

Code set adoption and coding guidelines for the medical code sets. HIPAA gives the secretary authority to adopt code sets and coding guidelines. There are some aspects particularly around the CPT versus ICD where coding guidelines are included for one, but not for the other so something else we need to dive further into.

Apps. Third-party apps. New since HIPAA. Privacy and security concerns. Consumer education. Provider education. Additional public health emergency or pandemic lessons learned. Again, a lot of the same things we were talking about this morning, but more focused on the data flow issues in the privacy.

Greater collaboration among standards organizations and among coding bodies. That gets both to the process and to the semantic interoperability. Considering approaches to expanding the concept of covered entities. Actors in the HIPAA world who are not covered entities include workers' comp, property and casualty so automobile accidents, ERISA plans, and then privacy and security, again, referencing this morning's discussion. Data does not stay exclusively within HIPAA-covered entities under normal business operations.

And the last point is virtual credit cards and electronic funds transfer brought up by the industry, something we need to think about as a subcommittee.

Beyond the input from the listening session and the public comments, the subcommittee has taken a lot of other factors into account here. Some of the things coming from our own experience and from other sources. The nature of e-commerce has changed dramatically since 1996 when HIPAA was adopted. It is our opinion that the HIPAA framework has become fairly obsolete and dysfunctional.

Evaluation would be appropriate to determine whether legislative remediation and/or regulatory modifications provide the best glide path. Do we need to change the legislation? Do we not need to change it? Is it sufficient to change? Only the regulatory process or do we need both?

Some standards development is not meeting the needs of the regulated industry. Processes need to be amended and best practices adopted to ensure it meets industry expectations. It is a little vague. But we can do better than we were doing under the current structure.

Standards development organizations could collaborate more to conduct effective stakeholder education for implementation. Subcommittee still needs to understand HHS priorities to support development of these recommendations. In other words, whatever recommendations we come back to the Full Committee, we want to vet beforehand to the extent we need to know whether aspirationally they are in the right direction or not.

I know that was heavy. That concludes kind of what I am throwing at you, what the subcommittee is throwing at the Full Committee. What we would like to hear from the Full Committee members are things like -- are there points in the presentation that need clarification. I went over a whole lot. I stayed as high level as I could even though for some you think I probably went pretty down in the weeds. I assure you that I did not.

Given that the subcommittee expects to bring recommendations to our next meeting, what concerns do you have about our areas of consensus? Is our direction sound? Are there gaps that you can see? What

do you think the subcommittee to be aware of as we continue our work into the areas of further exploration? And then anything else we should be mindful of? And then the other "other" is whatever else are you thinking that you think we should be aware of in order to achieve a successful product and something that truly reflects the consensus of the Full Committee.

Let me pause here. And while the committee members are thinking about what they're going to raise their hands about, why don't I invite other members of the Standards Subcommittee if they want to add any comments to either clarify or add on to what I have explained?

Denise Love, let us start with you if there is anything you want to point out.

Denise Love: You did an excellent job of covering where we have been and the great work that the subcommittee has done. I think the next part of the discussion will broaden that lens a little more and bring in a few other issues. But I think that your presentation reflects where we are in the Convergence work plan right now and then where we go is hopefully the next section of the discussion might open that aa little bit.

Rich Landen: Thanks, Denise. Any other subcommittee members want to add anything? Okay. Let us open it up then. Committee members, what are your questions? Let us start with anything that needs to be clarified.

Participant: Val's hand is up.

Valerie Watzlaf: Thank you. I think based on our discussion earlier this morning, you brought up about the focus on data flow issues during a public health emergency and that is focused more on data flow rather than privacy and security. I am just thinking do we need to do more with our letter or is this something – how can we address some of those concerns a little better, I guess?

Rich Landen: I am trying to get my arms around your question.

Valerie Watzlaf: I am wondering. Do we need two separate recommendation letters when you talked about data flow and what you focused on here or could that possibly be merged more into the recommendations that we had earlier form the privacy – subcommittee. Sorry.

Rich Landen: I love these questions. It makes one think. It is a good question. As I am looking at it, our timeline for these recommendations is not for another four or five months. We certainly – it is beyond the Standards Subcommittee ability to say that we need to tie these to move these along rapidly enough to tie together with the letter that we are considering from the Privacy and Confidentiality Subcommittee.

What I would say is I have every confidence that when we come together on the PCS letters the subcommittee – as a Full Committee then that kind of establishes a direction that the Standards Subcommittee will be able to roll into how it formulates its letter of recommendation June or July or whenever our next meeting is going to be.

Valerie Watzlaf: That makes perfect sense.

Denise Love: I am trying to understand, Val, if I may. What our perspective, I think, is the – across platforms and data systems. I think the two letters, or the two recommendations, should reference each other. But the privacy-security issues might be a little unique. They overlap. But I am struggling with what the hard line is.

Valerie Watzlaf: That makes sense too. I think I was not thinking too about the timeline. I appreciate that. Thank you.

Rich Landen: Other questions on clarity? We have been looking at this. We cannot see the forest through the trees. If there are terms or concepts or history that we need to explain, I would be happy to do that.

I do not see any so let us just open it up then to all general questions from the committee members. Either we have glazed over eyes or everybody is in perfect accord. Somehow, I do not quite believe either one of those extremes.

Denise Love: It is probably a little information overload and post-lunch combination.

Tammy Banks: Everybody is formulating all their thoughtful questions, which I know is forthcoming very soon. I just wanted to say I really appreciated the subcommittee's lens across the landscape, recognizing that we are one piece of the interoperability puzzle and also appreciate the RFIs that we received that really went across the landscape so we could think about how this fits within one universal roadmap so to speak. I just want to commend you and Denise for taking a broader lens and then diving into our swim lane so to speak in order to make this manageable. I know this is a lot of material, but it could be even more. But if we do not look at this across the landscape, it is just going to be very difficult for each stakeholder to manage moving forward in my opinion. I just wanted to say thanks for that.

Rich Landen: I appreciate the comment.

Again, with apologies, I know this is a ton of stuff to drop on you. I think maybe what we should do is move on and get to the next components of this afternoon's presentation while you continue to think about your comments. It may help you identify something if you take a look at what our thoughts are and where we the subcommittee has areas of consensus.

If you think about those as a hypothetical, if we brought those forward to you today or tomorrow, what would your questions be? What would your concerns? Is there anything in there that scare you or directionally are we looking fairly solid or are there things you would need to know before you can render an opinion? As you think about those, let us move on.

Denise Love: Let us ask Denise. I see a hand. Denise Chrysler.

Denise Chrysler: The area that particularly spoke to me is a broader view of return on investment and looking at not just the financial effect of particular standards and implementing those standards, but also the broader societal benefit.

Rich Landen: I will take that as a comment in support of the concept?

Denise Chrysler: Absolutely.

Rich Landen: Thank you.

Denise Love: Rich, I like that approach to concentrate just on where we are at at this point as a committee because of the months of deliberations. I think we did get to those touchpoints. The next challenge is as we broaden our lens, how does that fit? But I think that is where we are today, correct, and that is where we want some feedback on.

Rich Landen: Okay. Are we ready then to introduce our reactor panel?

Denise Love: Not quite. I am going to sort of broaden the lens a little bit. Denise and I are just going to review some of the collaboration that we have had with ONC and then we will move to our – Tammy will talk about – anyway, no. I will take it from here if that is okay, Rich. Thank you, Rich.

As stated, our subcommittee has acknowledged and sought to cast a wide lens on the broad health care ecosystem to really gather all the information we can before we finalize our Convergence 2.0 document. We want to understand what might be missing, what are the barriers to achieve our stated objectives in the Convergence document, for actionable recommendations, for specific federal agencies, states, localities, and industry groups to collaborate and support of convergence goals.

I am going to take a few minutes and talk about a couple of collaboration partnerships with ONC and HITAC. As we know, they are a key collaboration partner as the reactor panel that we will talk with CMS and state-based initiatives and again ONC.

Before we go on to the panel, I wanted to brief the committee on the fact that two of us, Denise Chrysler and I, participated last summer in the HITAC Public Health Data Systems Task Force. Both of us sat in on those meetings. The task force was charged with developing recommendations to inform HHS in response to the Executive Order ensuring a data-driven response to COVID-19 and future high-consequence public health threats.

Not only was the task force assigned with identifying policy and technical gaps related to public health data exchange and surveillance, but the task force was also tasked with identifying characteristics of an optimal future state for information systems relevant to public health and their use.

There was a total of 52 recommendations from the task force, which if you felt like the Standards Subcommittee recommendations were daunting, these were daunting as well. Twenty-two of these addressed infrastructure and surveillance issues, including standards. Sixteen were related to policy and funding through the 21st Century Cares Act. Six focused on improving engagement across the system. Two were related to strategic approaches necessary to address under-resourced needs, disparities, equity, et cetera. And six were cross cutting across the public health data systems.

The following slides – we are going to move really quickly, but I am going to call out 11 of those 52 that potentially overlap with our convergence work, and again, some from the public health emergency hearing we heard about earlier today and discussed earlier today. Some of these would benefit from

committee collaboration with ONC to advance a more holistic, interconnected, health care ecosystem in which public health is a full partner coming from the HITAC report.

The focus of the task force was really data exchange in a public health emergency, the need for data integration and program alignment for all conditions was recognized. And some of these recommendations touched on workforce training, equitable funding for infrastructure, sustainable funding as well, not just bolus funding, but sustainable, minimum necessary guidances, standards harmonization, transparency and guidance, and good faith data exchanges.

I am going to run through these very quickly and attempt to connect the dots as we look at merging clinical and administration systems. The first one recommendation of interest that I lifted out or filtered out was preparedness plan and data standards applied across the ecosystem during public health emergencies.

The next one that caught my interest was collection of complete demographic and contact information by providers and standards communities.

And 17. I might touch on Denise's expertise.

Denise Chrysler: First, the Network for Public Health Law is mentioned in this particular one. I did not ask for it to be. But it is because the task force recognize how critical law is as part of identifying policies that limit or prevent health departments from exchanging data with the clinical sector and especially, I am looking at issues that involve the need for data and especially immunization data during COVID to cross jurisdictional boundaries.

Denise Love: Thank you. Recommendation 21. Support states in establishing an infrastructure, meeting both local and federal needs for collecting both situational response and other data that support core public health data functions. That spoke to me.

Twenty-three. Again, reference patient matching across public health and health care systems. And though ONC is charged with that and probably funded to do that, I think it has some interest to our committee to track what is happening there relative to standards and other perhaps privacy and other concerns of this committee.

Recommendation 30. Advocacy. I think this is important in the sense of as we think about how to advance convergence and these recommendations, we need a robust and sustainable consistent funding to not only implement and develop and maintain routine and large-scale public health responses. Again, perhaps the committee could join forces and advocate for sustainable funding. This is Denise Love talking, but that caught my eye.

Thirty-five. Incorporate equity considerations into funding models for public health data systems, especially directed towards under-resourced communities. We hear that in our deliberations, and it very much came out in the Public Health Data Standards Task Force.

I may let Denise speak briefly to minimum necessary recommendation here on 37.

Denise Chrysler: This concerns developing and releasing best practices and guidance for applying the HIPAA minimum necessary standard to information sharing with public health authorities. Public health has the status under HIPAA so that if a public health agency is authorized to collect identifiable data, HIPAA permits clinical providers to provider that data, including an identifiable form. However, absent a mandate for reporting, the minimum necessary rule applies and that in the middle of a pandemic or other emergency is not a time that we are trying to figure out what minimum necessary means in that context.

Denise Love: Thank you, Denise. Next is 39. We get into data sharing. I might let you say a few words on that.

Denise Chrysler: This is a lot of what we discussed this morning and that is the recognition that government and its partners need necessary data, but also, we need to have policies in place to prevent inappropriate use, reuse, or access.

Denise Love: I think I am hearing some themes from this morning as well. And then Recommendation 43, payer access to public health reporting data to maintain complete patient health histories and facilitate clinical data exchange and sharing. That resounded with me as far as our committee has some interest at.

I think this is the final recommendation. Again, since we have a workgroup and we are concerned with standards and data elements around health equity, meeting community needs and updating to advance health equity as needed.

Again, these were things that we learned coming out of the Public Health Data Systems Task Force and having ONC on the panel that follows. I think we can have a discussion about perhaps some collaborative opportunities for coordination as we move along similar pathways.

Before we get to the Reactor Panel, are there any questions or discussions. Tammy has also another ONC touchpoint. But I see Vickie's hand is up.

Vickie Mays: I may be a little off base but one of the things I do not understand is almost all the recommendations intersect with CDC. In a public health emergency, there are also some other offices that we tend to need. For example, there is the – I think it is called ASPR, which is preparedness office. I think that there is again kind of depending on what it is, it may be that you need the Census to help you. They have a deeper dive and being to give you data sometimes to do estimates and can do the work faster. I just think that all of this – even though CDC has a public health agenda in a public health emergency, these other bodies are also working. I think we should kind of think who do we need at the table in an emergency is different than who we may need at the table for just regular handling of these things.

Denise Love: Right. I do not know exactly how to respond. I think my interest in looking at some of these recommendations touched on the fact that how we think about improvements in handling a public health emergency also should be the improvements that we build into the infrastructure writ large so that data sharing and some of the standards are built in before an emergency that put us in a better position to respond to the emergency. I do not disagree that in a public health emergency, you may

need a broader task force and I do not know who that might be, but ahead of an emergency would be nice to know who the swat team is that we pull in of certain aspects.

One of the recollections I have of 2002 Olympics in Utah was they built the emergency team ahead of the Olympics so that if there was an Anthrax – who are you going to call. Those people were already at the table and engaged long before any emergency. It was not reacting, but it was preparing of who is who at the table. I do not know how exactly to respond to your question. Someone else may have a better --

Vickie Mays: I am just suggesting that if we are going to take it up next – that was what ONC said. But if NCVHS is going to take it up next, the data needs maybe a little beyond what ONC would do. I am suggesting exactly that that we may have to think more broadly.

Denise Chrysler: May I respond a little bit to Vickie? Vickie makes a great point. I am thinking, for example, of the importance of data from CMS. This task force started with an extremely broad charge, and it was appearing that it would be impossible to take on that charge in the limited amount of time and it was narrowed very much to focus on the intersection of public health systems and clinicians and to specifically focus on immunization information systems, syndromic surveillance, case reporting and laboratory reporting. Vickie, for our purposes, as we are looking at HHS as a whole and all the important sources of data during a public health emergency, I agree with you and just pointing out this was a narrower charge.

Denise Love: Again, these were discussion points. I did not want to lose these particular touchpoints with ONC as we think about who else we need going forward at the table and where there is collaborative or partnership activities.

Unless I see another hand, I think I would like Tammy to talk about the next collaboration with ONC.

Tammy Banks: I have the pleasure to report that the ONC's Electronic Prior Authorization RFI Task Force will be initiated this week. ONC published a request for information today that seeks input from public regarding support for electronic prior authorization processes. In the RFI, ONC is requesting comments on how the ONC Health IT Certification Program could incorporate standards and certification criteria related to electronic prior authorization. I have the honor of being appointed co-chair with Sheryl Turney and my NCVHS colleagues Rich Landen and Deb Strickland will also serve on the task force.

Our task force charge is to provide input and recommendations in response to the RFI on Electric Prior Authorization to inform future rulemaking and other actions in this area. We look forward to reporting back on this progress of this important work and encourage all of you to review and reply to the ONC's RFI. Thank you, Denise.

Denise Love: Thank you, Tammy, and I am so pleased that you three are on and will be well represented for sure.

What I would like to do because we have some – again, in the spirit of broadening the lens and looking beyond HIPAA and just health care data, we have a panel put together that precedes a committee discussion later.

Again, we have increasingly interdependent environments. There are barriers to achieving our interoperability goals. I am really impressed with the panel and the panelists that I have talked to individually. We want them to share the perspectives on their initiatives and data systems and what they see from their perspective of what improvements might be needed, how we fill these critical data needs like alternative payment models.

In this panel, we have NAPHSIS, the National Association of Public Health and Information Systems. We have the Executive Director Shawna Webster and Jeff Greenland, NAPHSIS Senior Development Advocate, followed by Kate Sapra, CMS/CMMI, Center for Medicaid and Medicare Innovations, and their initiatives really – they are doing quite a bit and might inform our work plan. Again, I come up with alternate payment model capture and other challenges related to value-based purchasing. And then followed by Chris Muir, ONC. We have been talking about ONC quite a bit and understanding the plethora of activities, which boggles my mind. ONC is tasked with and what collaborative potentials are there that could leverage ONC and NCVHS collaborations and achievement of common objectives.

With that, NAPHSIS, I will turn it over to you, Shawna and Jeff.

Reactor Panel

Shawna Webster: Hi. Good afternoon, everyone. As Denise said, I am Shawna Webster. I am the Executive Director of NAPHSIS. I would like to thank the committee for inviting me back to one of your meetings. Always a pleasure to get to see the two Denise's and everyone else as well.

I just want to start with a general vital records update since I spoke to you all last August to set the stage for our reactor comments. Back in August, I reported that CDC funded vital records through what is called the ELC grant, the Epi and Lab Capacity grant, to move the National Vital Statistics System towards implementing FHIR. This 77-million-dollar grant that is $1.3 million per jurisdiction is the largest amount of money dedicated to vital records maybe ever. I went looking for another amount of money that had been dedicated like this one and I could not find it. Let us call it at least 30 years if not more. And given the importance of vital records for both the feds and the states and individual citizens, all of us individually, this kind of funding is long overdue. It was great news.

But unfortunately, COVID goes on. Vital agencies are stressed to the max and the majority of states describe themselves as not even close to being ready to start implementing FHIR. This money will be used for and will move us forward towards implementing FHIR. But it will take more than two years for sure. This was two-year funding period.

We need sustainable funding to fuel basic infrastructure improvement, workforce, and to implement new national standards; otherwise, at the end of this two years, we will have five states capable of sending FHIR messages and the rest will be struggling just to keep up with increasing demands on their data and a constantly shifting technological landscape.

I can discuss the particular details of how and why this work is very burdensome for the jurisdictions right now. But in the meantime, let me just sum it up by saying that jurisdictions are being expected to shift priorities to this new work while still having to perform their current work and already have multi-

year systems in development and cannot just stop in the middle or jump to the end. That is just not how it works, not without sustainable funding over a much longer period of time.

One of the things Denise and I talked about the other day was it is kind of comparing it to meaningful use. CMS spent about $35 billion, I believe, on health IT over the past 12 years. It took a pandemic the likes of which we have never seen before for Congress to spend $550 million on data modernization efforts in public health. And even though we are still in the midst of it, it already feels like attention is starting to wane on this funding need.

To Denise's point and one of the things she pulled out, several of the things she pulled out in her presentation, public health will absolutely never be a full partner in this realm if the funding does not increase to that kind of level.

Public health desperately needs a decade-long investment similar to what was spent on meaningful use to modernize its data systems and work towards true interoperability.

Just as an example, one relatively average size state in the Northeast just spent $8 million upgrading their electronic death registration system. That is just one state.

Overall, NCHS, for example, their whole program that purchases vital records information from the states, both birth and death, pays the states in total all 57 jurisdictions about $21 million. In one state, a new EDRS cost them $8 million.

The days of federal government buying vital records for a few bucks are just done. If we really want to make progress towards all of these goals, the current model is simply not sustainable. Meanwhile we still expect our citizens to pay anywhere from $5 to $35 for their own records.

I would strongly encourage the committee to weigh in on the data modernization initiatives and recommend that HHS support every effort they can to support the vitals aspect of this data flow and make it more of a priority for not just CDC, but for other federal agencies that also rely on vital records data because every part of every level of government needs access to vital records data whether it is for statistical research or fraud and identity theft prevention.

Each use case requires vastly different skill sets, technology, timing, and accessibility and the data saves a fed billions of dollars every year. Those use cases should be supporting and helping to pay for all of the public health use cases.

I know this is all a bit to the side of the standards discussion and the discussion about HIPAA. But what I am talking about here is really foundational. It must be addressed before vitals have the luxury of considering new standards. Even the current funding to implement FHIR is pretty burdensome on states who are already struggling. HIPAA just adds another level of complexity and burden even though vital record agencies are not in most cases considered HIPAA-covered entities.

To address some of the issues we have run into around HIPAA and some other areas, I have asked my developer, Jeff Greenland, to sit in on this call today and to talk about some of our recent experiences for becoming a HIPAA-covered entity for the systems that NAPHSIS owns and operates. You may have

heard me say the names EVVE and STEVE before on prior visits to your committees. EVVE is the Electronic Verification of Vital Events system that NAPHSIS owns and operates on behalf of its members that allows entities to verify or certify vital record documents, birth certificates. And STEVE is the State and Territorial Exchange of Vital Events. It is the system that delivers data both to our partners like NCHS but also helps states deliver data to each other on a real-time basis.

We have looked into the HIPAA coverage and have done a deep dive lately. I am going to ask Jeff to talk about some of that now.

Jeff Greenland: Thanks, Shawna. To begin with, HIPAA, as we are all aware on this call, I believe, definitely has a pretty big overhead as far as implementation and trying to get all of the pieces talking and the requirements met and that sort of thing.

As Shawna alluded to, vital records are not one of the HIPAA-covered entities. The amount of effort that is put into this especially from NAPHSIS point of view would require us and other jurisdictions to create compliance and security offices that of course are costly and require all the staffing and everything there. But since vital records are exempt, there is no really clear reason for this to be performed. The cost and the time investment involved is certainly excessive in this case for areas and departments that are already strained to the max. As we all know, especially from the pandemic, there is just not enough people to go around anymore. There is not enough labor to do the things that need to be done to help with these tasks and to respond to these emergencies. And taking what few people are remaining to go and ensure that compliance is there rather than actually solving the problems of sharing this public health data and vital record data for those that need it certainly is not the best use of time in order to meet our goals.

Something else that is worth mentioning is we also believe that NCHS is also not a HIPAA-covered entity and the fact that the jurisdictions may be sharing data with NCHS where NCHS is not covered also does not make sense necessarily that the jurisdictions need to be fully covered as well, again, being public health.

In my experience just as an anecdotal piece of information, it does seem that there is a large amount of funding and money and budget that is put towards the HIPAA compliance and effort even without meaning to be a covered entity compared to the amount of damages if that is the right word to use there, the amount of damages that could occur if some of that data was subject to a breach of some sort. There is a lot of pre-work in doing this. And the effort is just hard to justify the result or that ROI as we were talking about earlier.

My opinion on the matter really is that if we are talk about when HIPAA came out in ’96 or thereabouts, security and technology was primarily the challenge there. Being able to secure messages and such with the technology platforms that were available back then such as our modems and phone lines and all of that was definitely a challenge. It was a technology problem. Nowadays, technology does not really seem to be the problem with HIPAA anymore. It is really more of a people problem. The amount of social engineering and those types of breeches where staff already have access to data are able to share it and throw it out on the internet or those types of social engineering cases are much harder to protect

against anyway and the amount of effort put into HIPAA does not assist with that simply because a bad actor, as they are called, can do a lot more damage than faulty technology so to speak.

With that, I do not know if I have any other further comments unless you want me to expand on any other topics, Shawna.

Shawna Webster: No, thanks. I just wanted you to be able to provide your perspective there. Jeff has only been with us for a short time at NAPHSIS, but he has been part of our community for many years. He has seen and lived the vital records experience on both sides now. Thanks, Jeff, for your comments.

Unless there are direct questions now, I will turn it back to --

Denise Love: I think we might have some questions. I know I may have a couple circling back. But I want to be sure that we get the other panelists in there and then I would like to open it up for questions.

Could we have Kate Sapra brief us on some of the CMMI initiatives and some of the issues you are having.

Kate Sapra: Sure. Good afternoon and thank you to the Subcommittee on Standards for the invitation to speak today and for all of the work that you are doing to address this important topic. Thank you especially to the co-chairs, Denise Love and Rich Landen, for leading this effort.

My name is Kate Sapra. I manage the portfolio of state-based multi-payer alternative payment models at the CMS Innovation Center. I am speaking to the state-based experience today and not on behalf of all of CMS or the CMS Innovation Center. However, I do believe that many of the challenges and opportunities that we have faced with respect to data sharing in our state models are common across alternative payment models and I hope will be thought provoking and informative for the subcommittee's work.

For those unfamiliar with the CMS Innovation Center, generally referred to as CMMI, it was established by Congress in 2010 in the Patient Protection and Affordable Care Act to identify ways to improve health care quality and reduce costs in Medicaid and children's health insurance programs and to accelerate the shift from a health care system that pays for volume to one that pays for value.

The center develops and tests new health care payment and service delivery models to improve patient care, lower cost, and better align payment systems to promote patient-centered practices. These alternative payment models reward health care providers for delivering high quality and cost-efficient care.

To provide some context for the scope of alternative payment model adoption, MedPAC, the independent congressional agency that advises Congress on Medicare notes in their July 2021 data book that almost 70 percent of Medicare Part A and B eligible beneficiaries are in Medicare Advantage or an ACO, which is an Accountable Care Organization, or an ACO-like plan, meaning that one entity is coordinating the care of the beneficiary to reduce fragmentation, decrease cost, and improve quality of care.

CMMI recently undertook a strategic refresh and has set a goal to ensure that all Medicare beneficiaries are in this type of accountable relationship by 2030.

A key requirement for accountable care to deliver on higher quality and lower cost is that participating providers have the right incentives and the tools needed to coordinate care. Data, of course, is an indispensable tool. But the volume of data in health care can be overwhelming. Tools for analyzing and summarizing data into meaningful metrics are also necessary.

The inherent tension with data sharing and alternative payment models is balancing the need and desire to uphold the privacy of patient's protected health information with the goal of greater care coordination across providers, systems, and settings of care to improve health outcomes.

This challenge grows as we move further upstream to address the social determinants of health, which we know contribute greatly to poor health generally and to health disparities within populations. For example, as we strive to integrate health and social services to address health-related social needs, non-health care entities may receive protected health information. While this may improve care coordination, for example, of a diabetic patient receiving medically appropriate foods from a food pantry, it then places a strain on the social service provider. The provider by receipt of the PHI, becomes subject to HIPAA, including, for example, more stringent IT security standards. Upgrading software to meet HIPAA requirements may prove to be cost prohibitive and preclude the service provider's participation in these types of coordinate care activities to the detriment of the populations they serve.

Additionally, backbone organizations have emerged as central players in the efforts to coordinate health and social needs. However, these organizations may not meet the current definition of health oversight agencies, which can limit their ability to receive data central to their coordinating function.

Further, while there have been great strides made in the area of interoperability and the Gravity Project is working to establish standards for SDOH data, it still remains a challenge to share this data electronically as the way providers may capture or ask about SDOH needs may not align with the way another provider asks or captures similar information.

There are other challenges as we aim for more granular data on health-related social needs to inform whole person care. For one, these needs change regularly. As an example, a person may be food and energy secure one month, lose their job, and become food and energy secure the next month. These data needs have to be updated regularly across all systems that rely upon them to inform care delivery.

Additionally, they want to avoid duplicating data collection and adding additional burden to the health care system. For example, if the Medicare beneficiary applies for Supplemental Nutrition Assistance Program or SNAP benefits, ideally, that information would be pulled into a regional health information exchange and fed into the provider's electronic health record so that the health care provider would not have to query for food insecurity during their clinical encounter.

Unfortunately, proxy measures for demographic and social needs data, which could reduce burden on health care providers or provide insights where individual-level data are absent, have their own limitations.

Firstly, many of these proxy variables are at the neighborhood rather than individual level. While these data may indicate geographic populations that could benefit from additional assistance, they do not provide person-level information on specific health-related social needs.

Furthermore, many proxy variables are publicly reported in such a way as to prevent person-level identification. Statistical noise may be introduced into the most granular and therefore the most actionable levels to ensure individual privacy protections. However, this noise makes the data less accurate and thus less reliable for certain health-related applications.

Another challenge with proxy variables is that differences across states can introduce variability in the underlying constructs of the measures. For example, dual eligibility for Medicare and Medicaid is an obtuse marker of low income. However, depending upon state and Medicaid eligible rules, a person could maintain income, move across state lines, and lose or gain Medicaid eligibility. Their income has not changed. But our interpretation of their economic need based on this proxy variable has changed.

We also have challenges within the traditional health care setting as we strive to break down silos between physical and mental health care. One issue is around opt-in versus opt-out policies for data sharing. For example, health information exchanges seek to centralize all health data in one place. Some states require often consent for data sharing and others require patients to opt-out. Opt-out policies result in more information being available to providers within the HIE. However, there may be concerns that patients are not aware of the data sharing occurring and if knowledgeable about it, would choose to opt-out.

Similarly, many accountable care organizations or ACOs have opt-out data sharing policies that allow beneficiaries or members to request their data not be shared with this entity. While this respects the right to privacy, it hampers the ability of the accountable care organization to coordinate care for those individuals. If this occurred on a widespread basis, it could limit their ability to better manage the population.

Another challenge is around sharing data for encounters for substance use disorder treatment. Even if a beneficiary that has not opted out of data sharing, current federal regulations prohibit beneficiary-level SUD claims data sharing with accountable care organizations. We know persons with co-occurring mental and physical health disorders have poorer health outcomes and higher costs. Yet this particular privacy policy limits the ability of the accountable entity to better coordinate care for these individuals.

Finally, achieving health equity will require greater engagement of health care providers caring for the most underserved populations. These providers may be limited in terms of their financial resources as well as staffing capacity and ability to analyze data. Thus, it is incumbent upon payers to ensure these providers have timely, actionable, and comprehensible data. It may mean providing visual data displays rather than CSV files. It may mean providing technical assistance in coaching so that practices understand what the data mean and importantly how they can act upon it. Ideally, data would be aggregated across all payers so that providers with limited resources can access critical data in one location.

In closing, accountable care offers promise for ensuring patients have better coordinated high-value care. However, providers need tools, including actionable data to achieve this goal. Today, we have more data and more diverse data sources than ever before and a greater interest in integrating physical and mental health care with social services to reduce health disparities, improve health outcomes, and reduce cost. However, certain limitations around data collection, quality, timeliness, and sharing are limiting our progress.

Thank you once again for the opportunity to provide these observations.

Denise Love: Thank you, Kate. As I said, this is a listening session, and you gave us a lot to listen to. As we digest that, I will move on to our next panelist, Chris Muir from ONC. Thank you for joining us.

Chris Muir: Thank you. As was stated, my name is Chris Muir. I am the Director for the Standards Division in the Office of Technology within ONC. First, I also want to thank the committee for inviting me to be a part of this process today. I appreciate my other panelists and the challenges that they brought up.

I want to share with you some ONC's priorities and my initial thoughts on where our interests may intersect. I am starting off with public health. As you are all aware, one of the administration's top priorities is COVID-19 response and also making sure that the public health IT infrastructure will be able to better support future public health emergencies. In fact, Denise mentioned President Biden's Executive Order asking HHS to develop a data-driven response to this in future public health threats.

Currently, ONC and CDC are jointly developing a report to be responsive to that executive order. And it is focused on modernizing the public health infrastructure. And of course, we heard from Shawna and Jeff as they have described some of the challenges with the current public health infrastructure.

Denise also described the HITAC public health task force that came up as several recommendations for ONC and CDC to consider. Currently, teams from ONC and CDC are reviewing the HITAC recommendations and other inputs that came from the report. I do not have a specific timeframe for when that report will be released. But I think it could be helpful as that is released to review that report and to see how we can work together in addressing those priorities that come from that.

Also, another common theme was health equity. One of the themes on this call and what we have learned as we have been battling COVID-19 is that there are health and health care disparities. Certain groups were hit harder by COVID-19 than others. The administration takes this very seriously and ONC along with some of other HHS agencies are exploring a variety of ways to help address these disparities.

One area is race and ethnicity. ONC has adopted robust and flexible standards related to race and ethnicity. But now we are working with our federal partners and others to give better guidance on how to use the value sets and develop better tools to collect the data. There may be something in this area in which we can work together.

Additionally, or another example I should say, is sexual orientation and gender identity. We have been working with our sister HHS entities to come up with better ways to collect data on sexual orientation and gender identity. For example, we have added data elements related to these topics in ONC's United

States Core Data for Interoperability or we call it the USCDI, data standard for health IT certification and nationwide interoperability.

Currently, we are asking for feedback during the current draft USCDI Version 3 public comment period, how to better address to help those populations.

Additionally, we are working with HL7 on the Gender Harmony project. There are a lot of stakeholders involved in this project, including representatives from the LGBTQ community. This project will result in valid information documents that will define use context collections and also appropriate value sets. I understand that they are also going to be looking to update the FHIR resources as well.

We believe by properly addressing these data elements, and more importantly the information collected by those data elements, that is very important to ensure these populations receive better advice and better treatment of care. We are happy to explore ways in which we can work together in that area as well.

I think it was Kate that mentioned social determinants of health. Tightly related to health equity is SDOH. ONC has been interested in this topic for a long time and we have had various projects related to it over the years.

Kate mentioned HL7 Gravity Project. We are currently working with HL7 on that project. Kate mentioned some of the challenges for capture and exchange. There may be some opportunities to work together as well.

Administrative data. Rich mentioned the HITAC ICAD report that supported the convergence of clinical administrative data to improve the health ecosystem. While our primary focus most recently has been on COVID-19 response and public health and health equity issues, ONC continues to be interested in administrative transactions and how they intersect with clinical data.

Some of the things that Rich was mentioning earlier, addressing provider burden and advancing health care reform efforts. All of those are still completely valid and of interest to ONC.

Tammy mentioned the ONC release. The request for information on e-prior authorization today. We are trying to engage the industry's readiness for e-prior authorization to be included in rulemaking. Again, another area that may be worth exploring.

And then Rich also mentioned consumer access, which is another theme that I think ONC has always been interested in and something that we can pursue as well.

Pain points. I was asked to also mention some pain points. I will just mention one for the sake of time. As everyone knows, FHIR is the new hot standard in health IT and ONC is very bullish on this standard as well. But from our perspective, there is a lot of implementation guide development going on in relation to FHIR. But we would like to see more robust testing, piloting, implementation, and adoption of the implementation guides. It is really the second step of getting people to actually use the standards or where we see the gaps or the pain points in the current market.

I think I will leave it for now. The subcommittee did an excellent job on I would call their environmental scan and came up with a lot of potential things. Again, just appreciate being part of this process. Thank you very much.

Denise Love: Thank you. Thank you, panel. I would like to open it up for any questions or comments, the subcommittee or the Full Committee. What I heard is there is overlap and we have a good conversation going on with ONC in the form of the Prior Authorization Task Force and perhaps the Public Health Data Systems Task Force when the report is out and going forward.

I think my interest in this discussion was to be sure that we were not duplicating or missing some of the efforts going on in the larger ecosystem.

Rebecca Hines: Denise, Wu and Rich have their hands up.

Wu Xu: First, I want to thank all the panelists and also the subcommittee who organized it. It is really a lot of timely and important information. I want to make a comment on the vital records on Shawna and Jeff's discussion because the vital records are really critical and foundational data system for public health. It is not only for public health. They are also nationwide the identification base of the system linked with a lot of non-health agencies and systems. And also, they have the social determinants of health data in the birth certificates. Very important. Our committee has vital in our title. I really wonder – general comment. What is our committee's scope of responsibility or authority to help strengthening the vital record systems?

I am new to the committee. I am still learning. It looks like we are focused on the standards and the privacy. If we just took all this narrow scope, I want to talk about this modernization funding for the FHIR and through the electronic lab reporting, ELC grants. I think for our interoperability roadmap within the public health systems, we need a lot of interoperability's effort to make this happen. Especially now in the states, the technology services have been centralized within the state technology service department and also the – I think Shawna can say that. To my understanding for vital records, they have a few handful vendors to provide the service to all the systems.

I am thinking we may need to help vital records, the technology, the system issues. We may need to go above vital record systems, vital record office level like maybe ASTHO to get involved or communicate with the associate of the state, technology services association, and also like ONC, the FHIR is your priority, and you deal with the vendors. I think we need more national higher level, about CDC, to really help this coordination.

I really think any improvement we make on the vital records data will benefit beyond health. Like in Utah, I know there are routine data transactions with vital records with other agencies just in Utah. It is 15 plus. Also, the CMMI mentioned the social services, at least the Utah social services and health, the vital records, the data connects. There are very broad needs for timely, accurate vital record data sharing through FHIR technology. That is my comment.

Denise Love: Wu, what I am hearing is it sort of dovetails with one of the earlier slides and how we can work with ONC on the funding advocacy to boost it and sustain it more than a two-year bolus. Would that fit?

Wu Xu: Yes, and also within the CDC. Their modernization grants cannot just go to epidemiology program, separate vital records because I do not know how other states. In Utah, those programs are served by one technology service department, the vendors. You need coordination at least at the state health department level. You can get more efficiency on there. CDC already started the vital record funding through the ELCs. The ELC technology funding system. That is good. But I think what FHIR needs is beyond just these two programs. We need to really go to interoperability interpretation, a little bit higher at the state level. The ONC can play more role in that level.

Denise Love: You mentioned ASTHO. I had an email exchange with them. They could not be here for this discussion, but they have promised to follow up with us.

Wu Xu: They do have regular meetings with health officers at the state and territory level. It is good to have a presentation at level. Health officials at the state. Then they can coordinate it when they discuss the funding data allocation. They can do that.

With the interpretation of the Health IT at the state level, it is very hard for one public health program to promote more broader technology update innovation.

Denise Love: Thank you, Wu.

Rich.

Rich Landen: First question for Jeff Greenland and his clarification. Jeff, in your comments, you talked about the value versus the benefit of compliance with HIPAA. Were you focusing mostly or exclusively on the privacy and security or did you include the transactions and code sets in that compliance? Again, just clarification.

Jeff Greenland: Thanks for asking that. I do not know that I have -- I was really directing that towards either side specifically. I do know that the harmonization of the code sets, as was mentioned in some of the previous slides that you had, it is definitely a challenge in getting those values together to where they work consistently among records and among agencies for that matter, let alone among jurisdictions. That is definitely a challenge. It is one of those things in my experience anyway just creates – like it is a bad thing, but it creates more jobs because there are so many discrepancies between using those code systems and how things are reported and then how they are converted, for example, by a nosologist over to whatever the final code is. That amount of work is something that is extra and could be eliminated with a little bit more standardization and harmonization along those lines.

As far as the security and privacy side of things, I think that from a technology standpoint, those challenges these days are “very easy” to take care of. Most of the items that are standardized by HIPAA or other policies such as FedRAMP or FISMA or whatever. Those standards are pretty standard practice these days. Everyone has secure transactions for the most part and secure cloud services or secure data and transit secure data – all the good things that make security and privacy a good thing. But the efforts that come into social engineering are far less straightforward to prevent because any “bad actor” has access inside of that to do more damage than could be protected by most types of technology solutions.

Rich Landen: Thanks. One more question before – there are other hands up, I see. This one is directed to Shawna. Shawna, one of the concepts of the Standards Subcommittee is thinking about making recommendations for – we described as the concept of federal leadership as opposed to federal mandates and preemption. From your perspective, what would federal leadership look like to you?

Shawna Webster: Just generally or in the context of a public health emergency only?

Rich Landen: Generally. We are talking about – again, it is a hugely broad scope, so we are talking about the convergence of clinical administrative data. We are talking about federal mandates under the HIPAA transaction and code set rules. Very broadly.

Shawna Webster: I think vital records is maybe a perfect example of something that does sort of cross all of the normal silos that the federal agencies can put themselves into because it is so broadly applicable to all of these different use cases. Knowing a lot of the political folderol around do not pay at Treasury and SSA and its release of the public or the not public DMF or SSA sharing with other benefits-paying agencies, the data that actually belongs to the states. I think all of us have the best of intentions and support all of those different use cases to ensure that our federal government is not just sort of wasting money in all of these different areas. But I think vital records is an example of a data collection and delivery system that could be supported in a more coordinated way across the federal government so that it is itself supported sufficiently to do its job for the American people.

It is criminal to me to hear that SSA or NCHS are paying $2 or $3 a piece for records when we expect our citizens to pay $35. And the states are set up that way because they know they have to fund themselves. Most of them, the great majority of them are fee funded. They are not getting a line item in the state budget. And those that do get a line item, it is not usually – and maybe one case that I can think of is that an amount of money that actually covers their cost and expenses in a year. In that way, they are more like a DMV. They have to figure out how to fund themselves. We ask ourselves, is that really appropriate, given how important, how vital our vital records are, not just to the agencies and the administrative or the public health use cases that we desperately need them for, but for every person in this country that relies on them for getting their kid into baseball, getting their kid into school, taking care of things after a loved one dies? It is too important to make them have to figure out how to support themselves and underpay them at the federal level.

I think it is ripe. It is a ripe situation to use as one that can maybe cross all of the federal silos and really be more coordinated in how it is supported in this country.

Denise Love: I think in the interest of time, I am going to go to Melissa and then Denise.

Melissa Goldstein: Thank you. Thanks to all of the panelists. We really appreciate you joining us today and it has been very helpful to hear your perspectives. My particular question is for Kate. Kate, I found your presentation really interesting. The material you described seems to have a lot of privacy implications and security implications, particularly your discussion of opt-in and opt-out when my ears perked up. I am wondering how the agency, how your group is assessing privacy and security considerations as you make decisions, recommendations, and what processes you are going through and how you are seeking advice from privacy security experts, that sort of thing.

Kate Sapra: We follow all existing privacy laws and we do have data privacy and security folks on the staff at CMS and at the CMS Innovation Center. I am mostly pointing out this inherent tension between privacy and better sharing data to coordinate care as a place of consideration for the subcommittee.

Melissa Goldstein: Thanks. We do appreciate it. We are very aware of those ideas. Some of us think it is more tension than others. I was just wondering like how you go through the processes of making the decisions, the balancing. I am glad to hear that you guys are very cognizant of it. Thanks so much.

Kate Sapra: You are welcome. Thank you for the question.

Denise Chrysler: So much food for thought from so many people. I, like Melissa, really had my ears perk up when Kate was speaking because of how we address social determinants of health and how essential it is for multi-sector data sharing, thinking of clinicians needing assistance to address housing and food insecurity. But yet, I had never thought of challenges of data sharing that may pull community-based organizations that just do not have the kind of resources to meet this gold standard for the HIPAA Privacy Rule when it comes to privacy and security.

My interest was somewhat like Melissa. I was going through my brain and thinking are community-based services in that situation – would they be a treatment provider so possibly HIPAA would not get triggered or if there is an authorization, a written authorization that clinicians have signed to collect laudable organizations and help coordinate care. That would mean that HIPAA would not be triggered.

But I was trying to think. Is there any guidance that OCR or CMS has put out to share especially with these community-based organizations that are supporting services that are needed to address social determinants?

Kate Sapra: I should say, I am not aware of any. That does not mean that CMS has not put out any such guidance. Just that I am not aware of it. Typically, we defer all questions around legality, including HIPAA concerns to the participants. We do not offer any legal advice to our participants in general. I do think it is a challenge and one that we have not directly weighed into again to my knowledge.

Jeff Greenland: I just wanted to follow up on a few comments from Dr. Xu. I am here in Salt Lake City as well. Utah is definitely one of the if not the most, but one of the top three most advanced technological jurisdictions as far as public health goes in the country at least from my experience in working with other jurisdictions as well as Utah.

The challenges that you have outlined are – they are real and they are big challenges, as you mentioned. With Utah being one of the best ones, think of how much more challenging it is for the other 54 that are barely having any kind of technological supports. I do not mean to disparage any of those that might be represented by other jurisdictions on this call because I know they all work very hard.

One of the things that I have been aware that NAPHSIS has been doing coming from the vendor side of things and now being with NAPHSIS is that getting systems standards throughout the country in place is something that is very near and dear to our hearts and very important. It is a real need in order to have those standards in place so that everybody can coordinate and implement them in a way that data sharing and all those good things that we all know and love happen efficiently, effectively, and without a

ginormous cost burden on the states to implement these, let alone the trading partners. Having some kind of support from maybe a federal type of support in doing these types of things would definitely go a long way at least from my opinion and I believe I speak on behalf of a lot of the public health and vital statistics community.

Denise Love: Thank you. I think we are running a bit – we could go all day as far as I am concerned, but I do not think our new chair will let me. I think what the goals of this conversation was to validate a little bit of our convergence document and the work that we put into capturing earlier input from the listening session and being sure we did not miss anything. I think we are closer to understanding that.

There are a few follow backs that I heard from this discussion that at a future committee discussion or meeting, we might want to elevate as future work. But I think it is too raw right now to come to any conclusions. Does that jive, Rich, on where we are at as we conclude our discussion?

Rich Landen: I agree with you, Denise. It is a learning path as we, the subcommittee, move forward. Not only will we continue to update the Full Committee via the Executive Subcommittee Meetings. It is the normal part of our process although we have not really gotten far enough along to figure out exactly the format or the timing. We will do another reach out to industry as we start really crafting recommendations. Particularly with ONC, we have been working very collaboratively. I look forward to working with Chris and his colleagues just to compare and contrast how the HIPAA mechanism works vis-a-vie the HITEC mechanism and hopefully through some fruitful conversations, we can identify potential paths that are more efficient and effective, again, to use the HIPAA language for the industry implementers as we try and envision an improved network of bidirectional dataflow both for health and for wellness.

Rebecca Hines: I will just add that this committee has a new workgroup that is focusing on the data collection of SOGI and SDOH data. I heard, Chris, you talked about ONC's work and the addition of some elements in the USCDI. I think this is another area where I think our two workgroup co-chairs, Denise Chrysler and Vickie Mays, we may need to circle back with you, Chris, and your colleagues on that particular thread because we want to make sure we are aligned. I just wanted to point that out as well given this is a broad topic, but that seems to be something worth noting as we wrap up this session.

Chris Muir: Absolutely. Thank you very much.

Rich Landen: I think we can call it a wrap. Our thanks to the Reactor Panel and thanks to the NCVHS members. If the members have more thoughts or the Reactor Panelists, please email them to us and we will incorporate them in our deliberations as we move forward.

Again, just to set expectations, the subcommittee is hoping to come forward with recommendations for action at the next fall meeting of NCVHS. We will have some sort of public outreach between now and then just to get industry input. But the timing of that and the mechanism of that is to be determined.

Madam Chairman, back to you.

Jacki Monson: Thank you, Rich. We are scheduled for a 15-minute break. I do not know about all of you, but Zoom fatigue is real so we are going to take a full 15 minutes. We will come back at 4:03. Thanks, everybody, and see you in 15 minutes.

(Break)

Subcommittee on Privacy, Confidentiality, and Security

Jacki Monson: Great. Thank you. Maya is going to display the security letter. I just want to thank everybody in advance for all of their comments, thoughtfulness, edits, et cetera, that we got via email. We tried pretty hard to incorporate them all and turn a draft in hopes of hopefully getting consensus either today or tomorrow to get approval. That is really the goal that we are aiming towards. What I hope to do today is to actually just go through letter line by line. Rich, I would also like to get your input particularly because you had raised some concerns early on. I think we have addressed them but I want to receive confirmation of that if we have not and see what other accommodations we could perhaps make and then open it up for anybody else's feedback as we move through the letter.

Rich, do you want to – I would love to hear your thoughts first before we start divulging in.

Rich Landen: I have I guess what I would consider a major concern still, I think we heard more about that from Kate Sapra, and it is the letter essentially makes recommendations for more mandates at the same time that it is presenting evidence that many entities in health care do not have the ability to comply with existing mandates. That bothers me that we are doing both, adding more mandates and yet making allowances for non-compliance with mandates. I thought a lot about this over the last week or so, and I think we need to find a way to reconcile the two because from a purist standpoint, the argument would be if people are not going to be able to conform to the mandate, do not make the mandate.

But the pragmatic thing is that if we make a mandate, we will at least partially succeed because those who can afford to comply will or those who cannot afford to risk penalties will comply. But I think we need to somehow bridge that gap because it is creating issues. Kate was describing, when you get down small organizations, there is no way they can comply. I recognize we cannot say it is okay for small entities not to comply. But somehow, I would be more comfortable if we can reconcile the two concepts. I cannot see clearly how to do that.

The other issue I had is with the concept of doing away with the addressable. From my standpoint, addressable should probably be modified to eliminate the option of doing nothing. But I think we should maintain the component of addressable that allows a smaller organization to implement an appropriate step toward compliance, not necessarily being mandated to swallow the whole enchilada. But I did not see any provision for that keeping addressable in but pared down in the latest draft.

Those are my two comments. I have another one but it just concerns the use of the word Herculean. It sounds editorializing.

Jacki Monson: I think we removed that one I believe already.

Rich Landen: It is still in the latest draft that I looked at.

Jacki Monson: That is easy. I can come to consensus with you on that one and we can remove it.

Rich Landen: Those are my concerns.

Jacki Monson: I think on the reconciling the two differences, I do not see this any different than meaningful use. Meaningful use – we put forward a number of requirements. We really pushed the EHR adoption. We also had incentives so that small physician practice or a solo practitioner whomever that is considered small would have the opportunity to have it accessible to them an electronic health record via incentives.

It would be helpful because we have done a lot of discussion. We talked on Friday at the subcommittee meeting after your comments. I tried to as much as I could make reference to the meaningful use program and how we thought that was pretty widely successful although it definitely created security complications, which is why we are where we are. It would be helpful to know your thoughts on that and whether you see a difference or an issue with that. I can try to figure out how we can gain your consensus on this.

Rich Landen: You are flattering me. I am one member only and do not expect you to necessarily agree with you. I respect the process that the subcommittee went through. But since you asked, the difference is, I think, meaningful use is at its core – it is voluntary, number one, and number two, it carries financial payments to those who volunteer to engage in the program. HIPAA is not voluntary. It is mandatory and it does not include any financial reimbursement for compliance.

Jacki Monson: We have as one of our recommendations the idea of creating programs to support. We do not go as far as saying financial incentives. But that is a piece of our recommendation to replace not only legacy technology, but also those that we acknowledge cannot meet the minimum requirements because today they do not have the resources and/or they are not supported in getting the resources because if you are looking at it from a risk-based approach from a small organization, they are not necessarily going to invest in something that is not mandatory versus something that might be permissive. They have an option to decide whether that is risky to them or not.

I think what we are trying to achieve with this letter is raising the bar so that we are so that we are at least having the minimum-security requirement so the most vulnerable or easiest cyber attacker cannot get access to these systems and impact patient safety.

Maya Bernstein: Can I ask a question if other members are not weighing in right now? I think the attention -- my read of the attention letter, Rich, was that not to say that entities who are not complying cannot comply right now, but they are not responding. They are not complying.

I think there is some language in here as I recall that these are the articular minimums that were recommended are things that are cheaper, more available, more easily accessed by small and medium-sized entities than they were when the security rule first came out several years ago. And that those entities should be able to comply now but still are not. They are not in the habit of it or it is just not part of their routine.

I do not think we meant to say the way that you characterize it – I am interested to know if the committee – but that if the language is reading that way, then I do not think that is what the committee intended or the subcommittee intended. Maybe a subcommittee member can weigh in. But my read of it was these are things that are much more accessible now and people are still not doing them. What sort of incentives or help can we give people to come into compliance? There are some things that are not exactly – like the legacy technology is not particularly a HIPAA requirement right now. There are some things that are specifically HIPAA requirements and there are other things that would improve the security of the overall let us say health care – the whole system or even one entity system that are not being done and maybe they could use help with. Maybe we need to focus on the difference between what is in the rule and what is not in the rule or something like that.

Rich Landen: Maya, I like your question. I am also interested. Am I the only one reading it the way I am reading it? If so, that is a whole different story.

Jacki Monson: Melissa, do you want to comment, and certainly open it up to everyone else who has comments on either on what we are talking about with Rich or other comments or concerns related to the letter before we get into the specific details?

Melissa Goldstein: Rich, I am sensitive to the idea of can my eyes not see the way that you are reading it now because having been so involved in writing it. That is not the way that we have intended it. But if there is language that we could add or fix or alter to address your concerns.

I think you know that we all recognize that the security rule has always been scalable, and the idea was to scale as technology moves forward and as capability moves forward. But that we are in a situation now where cybersecurity is becoming an increasing issue and increasingly important and increasingly vulnerable. We do think that there needs to be a response from the agency and finding small ways, doable ways. “Cheap”, I am putting in parentheses. Not everybody is going to think it is cheap. But ways that are achievable I think to address the problems that we are facing with the full recognition that many entities are not following the rules right now. What do we do about that? What do we recommend? How do we address that?

We recognize that huge things are probably not achievable right now. We are looking for small things around the edges. If you have ideas of how we could adjust the language so that other – you cannot possibly be the only one that would react in a certain way to language. That is our goal.

Tammy Banks: I really support this letter because this is a critical topic right now. But I understand what Rich is saying. I am wondering, can we just add evaluation of? What levers out there are there to help the small practices, to help those who are not meeting because I am sure people are not meeting these intentionally? Are vendors not complying with the requirements? Are there more requirements that need to be put in place? Is that little piece that seems to be an unknown, even though there have been studies on this, just adding that into maybe this recommendation or add another recommendation?

Jacki Monson: Where specifically would you put that, Tammy? I think it is a really good thought and we are definitely --

Tammy Banks: I was so afraid you were going to say that. I was going really easy and just staying with the same evaluation. I always like to keep it simple. If you pull that and just put evaluate. Again, I was looking at the same recommendation. It may make it too long, but I was just thinking if you just put HHS and other appropriate government agencies to consider evaluating, and then the question is what. Evaluating why noncompliance and develop programs to assist. That is not the right language, but that is kind of where I was thinking. You could just plant the seed that they need to not just develop programs. Really find out why. That could just be doing through lit research because there has been studies. It is not at our fingertips.

Jacki Monson: That sounds good.

Tammy Banks: Does that help, Rich? I know where you are coming from and you are dead on. It is just how do we move the needle. What are the levers to make this easy? Like with EMR readiness, there are all these readiness centers that small providers could actually get the toolkit and help them implement. I do not think we necessarily have that in privacy and security. However, there are toolkits out there and maybe even a resource to support and help them implement that compliance plan, which when you have the template and the tools, it is not that difficult. But, again, some of this other stuff is more time consuming and challenging.

Rich Landen: I am liking the direction. I have no fundamental disagreement. In fact, I enthusiastically support the major themes, the major thrust of this letter. My concern is more sending mixed messages.

Tammy Banks: That is the point to move the needle. This is just too important now that all those weak links are huge holes of where we can lose the sensitive data and necessarily lose the trust because I know I do not want my data going through that chain. What are the levers to get us there?

Maya Bernstein: When you talk about evaluating, and I'd suggested some language in here that is not your language – you guys can see the screen, right? To what end? The subcommittee has said this is a need. Here is a bunch of literature and the notes that shows examples of failures that show why we have this need. Can you talk a little bit more about what that evaluation would lead to? What are you envisioning for what would the department do about that?

Tammy Banks: My answer is I would start with the lit search because there has been a lot of studies already done on this. But the point is whenever you are going to develop a program, you need to do a business need analysis to see what type of programs are actually going to help.

If that foundational research is already done by the department, that is great, and then they already know what programs need to be developed. That is great as well. But I would hate to just go on the assumption that there is not compliance and therefore you are developing programs to meet this ask because it is just too important.

Jacki Monson: I think it is a good thought. I think the challenge is there is literature out there both from Office for Civil Rights with corrective action plans, with the audits, and then CHIME and others have also done their own evaluations and all of that literature was available to us and some of it is actually said it in the footnotes specifically to support this recommendation.

Jamie Ferguson: I just want to say that I support the letter as is. I do not think any further changes are needed. I would point out that cyber crime and malware have risen to the point that it needs to be addressed more urgently. It affects small systems just as much as large systems. There are solutions that are available to everyone if you want to use them and implement them. I do not think it is impossible. I think that we are asking for systems programs. I like the letter as is.

Jacki Monson: Thank you. Other thoughts or comments while we think about Rich's comments and Tammy's comments?

Maya Bernstein: Do you want to go through it a little bit?

Jacki Monson: Yes, let us do that.

Maya Bernstein: Here is the summary of the four major actions.

Jacki Monson: Let us just go through each recommendation and then if folks have comments on the recommendations and/or on the specific texts including words, please let us know. If you can keep scrolling to the first one. I can see the bolded each one, but we do not have the text.

Maya Bernstein: Let us go to the text. Do you see what the first one is?

Jacki Monson: Yes. Our first recommendation is we recommend HHS strengthen the HIPAA Security Rule. The first one is making the addressable provisions of the HIPAA Security Rule mandatory. Rich, on this one, I think what I heard you say is you would rather not have it be mandatory, but instead evaluate based on risk or what are your thoughts around this.

Rich Landen: When I see addressable, I am thinking addressable allows three possible choices to the organization. One is to comply with the requirement as specified in the rule. The second is to not comply with the requirement as specified in the rule, but to institute some reasonable alternative. And the third option is to decide to do nothing. If my understanding of addressable is accurate, what I am suggesting is keep the first two, but delete the option to do nothing rather than doing away with addressable in its entirety.

Jacki Monson: Maya, could we technically do that where there really are three options under the regulations?

Maya Bernstein: The regulation does not specify how you comply with it. It leads open method by which an entity might comply with a security provision. It does not say you must encrypt – it gives choices about the particular implementation, so that we do not dictate technologies, for example, as technologies evolve. I am trying to figure out if there is a way – if it would be different to say you have to comply, but compliance means either the way it is in the rule or some reasonable alternative. I think that is accountable for in the rule.

Rich Landen: What you just stated, Maya, that would be ideal to me. That would be great with me. Either the rule or a reasonable alternative. My concern is that my understanding of the rule now is there

is a third alternative and that is to decide to do nothing. It has been a while since I looked at it. But if there is that third alternative, that is what I suggest we eliminate.

Maya Bernstein: What I was suggesting is by saying that it is mandatory, mandatory means you have to address it in some way, the way in the rule or a reasonable – I think that is already accounted for in the rule. That is why I was going to go look at exactly what the language is to say whether --

Debra Strickland: I would agree. If we are going to mandate it, it is just like HIPAA. If you are mandating it, you have to mandate it. And then it is an enforcement thing after that. If folks are not complying, they could have good reason why they do not comply. Then we need to an enforcement program that goes into place to put them into a 30-60-90-day plan or something like that. I think mandating is mandating. I think it is high time the industry can start to figure out how to do that with our technology that we have now.

Jacki Monson: Thank you. I think the only challenge, Rich, if we make it just addressable, is this going to move the dial is my question in the way that we need it to move. Because if people are continued allowed opportunity to select out whether it is through risk-based analysis or just that there is wiggle room in the regulation, they are going to do it and it is not actually going to change the current state that we are in just based on what we have seen, based on all the surveys and the evidence and the data that is out there.

That would be my only concern with getting to what you would like to achieve. I understand, but I do not want to lose the ability to actually make people meet the minimum requirements.

Maya Bernstein: Let me look at the language again. I am thinking about whether there is some modifier that you could put here that says that you have to have a – of the minimum things that we outline in the rest of this recommendation, they are listed individually the things that are important that are basic security requirements, and whether we could add some language that would give that idea of reasonable alternative. It is something that addresses these basics for certain that does not allow you to – it does not allow a covered entity to decide not to do it for whatever reason.

Jacki Monson: The question is what would those reasonable alternatives be?

Maya Bernstein: That could be up to the department. You do not have to dictate those or decide those. That could be – in your recommendation, you would say to the department either come up with some reasonable alternative or they could decide there is no reasonable alternative. But at the point where the department comes to revisit the security rule – usually the committee does not specify exactly how the department – gives a policy or a feeling of like this is the direction we believe or we recommend you should move in.

Jacki Monson: I am okay with that. Rich, does that get to what we were looking for?

Rich Landen: Not really. I've got up in front of me an FAQ from OCR. It says what is the difference between addressable and required implementation specs in the Security Rule? The answer is if an implementation specification as described as "required", the specification must be implemented. The concept of "addressable implementation specification" was developed to provide covered entities

additional flexibility with respect to compliance. In meeting standards that contain addressable implementation specifications, a covered entity should do one of the following three things. A, implement the specification. B, implement one or more alternative measures. And C, not implement either an addressable implementation specification or an alternative. I am just merely asking to delete C from that list of choices.

Maya Bernstein: Would you turn around – I'm sorry, Tammy, go ahead.

Tammy Banks: That is alright because Rich clarified my question. I was kind of curious. I would assume and, Maya, you will have to correct me about the enforcement provisions would be similar to a standard or an interpretation issue, which would then allow a progress report or a project plan on how to get compliant. But that is not your issue, is it, Rich? Your issue is the definition of addressable and so either state what provisions need to be mandator and be really clear or revise addressable definitions is kind of where you are going.

Rich Landen: Exactly.

Maya Bernstein: Kind of saying is that you want to eliminate the third piece. If – and talked about – instead of just making it mandatory, you want mandatory and alternatives, but not the ability to just be voluntary and I am not going to do it.

Rich Landen: Right. That is the same objective as making it mandatory.

Maya Bernstein: Right. But it gives that idea of your alternative middle ground. You can address it by either what is in the standard or by a reasonable alternative, but you cannot not do anything.

Rich Landen: Exactly. If I have a reasonable alternative, I can document it, and everybody is good. It can be audited. In hindsight, the OCR can form an opinion on it. But I do not have the option of ignoring it.

Debra Strickland: I think, Maya, you could just take out the word addressable entirely here and leave that up to the department how it does it and just say eliminate the possibility of not complying from entities or something like that so that we are not telling them to redefine a term but if you want to avoid that.

Rich Landen: Just put in A, B, and C in the chat for those of you who want to see the FAQ language.

Debra Strickland: Thank you. I do not want to look at it here because it would cover up the screen.

Maya Bernstein: Eliminate the choice of not complying perhaps.

Debra Strickland: There is better language than this. I am just thinking out loud.

Valerie Watzlaf: Should we also give a little background just like Rich put in the chat of what those three choices are first that might then lead to this?

Rich Landen: Maybe it is simpler just footnote the FAQ.

Debra Strickland: I actually agree with getting rid of that other option. How is doing nothing addressing? To me, it does not comprehend like you are not addressing anything if you are doing nothing. Why should that stay as an option?

Jacki Monson: I think the rule was designed for flexibility based on risk, not necessarily contemplate, that folks would choose not to do something. And the rule is pretty dated. It is 20 years old and most of what we have seen enhancements to is just the extension to business associates, the same liability as we saw for a covered entity. I think that is also part of the challenge with this is we are in a different security world than we were 20 years ago. Part of it is widespread adoption of the electronic health record among other things. Technology is a main component of how we take care of patients.

Maya Bernstein: I think it is also the case that you are exactly right about the measurement of risk. You have covered entities that were entirely paper based 20 years ago. They had to submit certain electronic claims. But they were either a hybrid paper or electronic. The adoption of – and the connectivity that we have seen increasing over the last 20 years changes the level of risk where some entities might have decided the risk was low and therefore, they did not need to do anything now. We have all this evidence, some of which is amassed in this letter that talks about how those risks – that landscape has changed significantly.

But I think to Debbie's point that that is right. At some point, people thought they could get away with doing nothing. It seems clear and I think the argument of the committee here is that the most basic kinds of security practices should be adoptable even to small and medium-sized entities are now more available, less expensive and so forth.

Who has some ideas for how this should sound?

Jacki Monson: Maybe eliminate from the provisions of HIPAA Security Rule that allow a choice not to comply, requiring either drug compliance or reasonable alternative.

Debra Strickland: I would support that.

Maya Bernstein: Eliminate provisions that permit the choice of noncompliance.

Rich Landen: I think we need to keep in the term addressable because it is a specific category of the rule's provisions. Maybe eliminate from the HIPAA Security Rule the --

Jacki Monson: Or should you change eliminate to evaluate the addressable provisions of the HIPAA Security Rule?

Rich Landen: I would support keeping and eliminate essentially what the FAQ calls option C, so eliminate from the HIPAA Security Rule, apostrophe s, addressable provisions the alternative to not permit the choice to comply. That is messy but –

Maya Bernstein: One more time.

Rich Landen: Eliminate from the provisions of the HIPAA Security Rules addressable category the choice to not comply. Then i.e., either requiring compliance or a documented reasonable alternative.

Margaret Skurka: I always like a shorter sentence than a longer one. The fewest words have a stronger impact, I think. While we are fixing that, I know I said this about the last letter we sent, the ICD-11 one, that they get so long and we work so hard and there is so much detail, but is the reader really going to read a 12-page letter? Tell me I am wrong.

Maya Bernstein: There is an executive summary in the front that just lists the basic recommendations. They are summarized here. And then there is detail.

Rebecca Hines: In the past what we would do is have an attachment or an appendix to a two or a three-page letter so that the people who are going to have to handle the disposition of the letter only have to read two pages, three pages. And the people who were going to actually read it for content, can then read the attachment. In the past, that is how we have handled it. You are welcome to do it however you would like. But I kind of agreed that shorter – the message should be as short as possible with the backup available as well.

Jacki Monson: It is far shorter than it started.

Maya Bernstein: I have sort of made some suggestions. It is a simple markup so you do not have to see all this mess, now it is all red, but this is how it would read. I can get rid of those too. It looks a lot neater now.

Jacki Monson: Yes, and then I think we will just have to probably modify some of the texts below, Maya, to reflect the changes.

Maya Bernstein: How are people feeling about these two lines here?

Margaret Skurka: I like it.

Maya Bernstein: I see some nods.

Jacki Monson: Let us keep moving then.

Maya Bernstein: We will fix some of the text. Is there anything that anyone wants to directly address in the text for the first recommendation or we will go on. We will make it match.

Each of these – those are sub things, right? Do you want to go through each of these, Jacki, or skip it?

Jacki Monson: Not unless there is any particular concern or a need for clarification. I would like to go to the next recommendation. The second recommendation is HHS in partnership with other appropriate government agencies should consider mandating basic cybersecurity requirements for any organization that is a recipient of federal funds.

Comments or thoughts on this recommendation?

Denise Love: I thought it was good.

Jacki Monson: Hearing none, let us go to Recommendation 3. Recommendation 3 is we recommend HHS further enhance communication and education about the HIPAA Security Rule and security threats and incidence.

Any comments or suggestions on this one?

Let us go to four, Maya.

Valerie Watzlaf: I think there are a couple of questions on that one.

Jacki Monson: Okay, Tammy.

Tammy Banks: I just had a quick – on the last paragraph of Recommendation 2, I think you put in hygiene. I would just strike that word hygiene under – it was before A.

Maya Bernstein: -- all the instances of hygiene. Do you not like that word?

Tammy Banks: No, it is perfect. It is just that in number two, you include hygiene requirements. I would just strike – if you keep going down. It is the next recommendation. I will send it to you. It is just in the one that you are not talking about the cyber hygiene requirements. You have it in again. It just confuses with that section. I think it would be just an easy strike to make it clearer. I can send it and you can think about it.

Maya Bernstein: I think this is it. I think this is what you are talking about.

Tammy Banks: I will doublecheck in the copy you sent.

Jacki Monson: Rich.

Rich Landen: I am at Recommendation Number 4, if we are ready to go down there.

Jacki Monson: Let us do it.

Rich Landen: My concern is that within the recommendation itself, we specify upgrading or replacing high-risk legacy technology. Yet when you read down through the concerns, that is just one of the concerns. That is just one of the potential issues. While I do not disagree with the legacy technology thing, I think the recommendation itself should stay broader. By that, I am suggesting we put a period after the minimum-security requirements. Then either use the high-risk legacy technology as an EG or we can eliminate that fragment of the sentence and just rely on what is in the narrative below the recommendation. In other words, I do not think we want to restrict the federal help that we are looking for just obsolete technology. I think it should any provision of the security that an organization cannot afford, be that resources or technology.

Jacki Monson: Jamie, did you have a specific thought on this?

Jamie Ferguson: Yes. I would support making that an EG.

Jacki Monson: I am fine with that too. I think we went back and forth on this one a few times and probably had that at one point.

Maya Bernstein: Do you want your EG to be in the recommendation itself or should it be part of the discussion?

Jacki Monson: It is in the paragraph below, so I think it is probably fine to just stand on its on like that and then we have it in the contextual example. I do not want to lose the example because I think it is a really important one. But I do not think it necessarily has to be in the text of the recommendation.

Maya Bernstein: I think this tribunal was meant to be tribal. Yes? I think this was meant to be tribal.

And then there is some mark up here that Jacki and I were working on, but I will just show you how it now reads. I think here in the second paragraph, it is called out as a specific challenge, a specific example. Is that, Jamie and Rich, what you were heading toward that we call out the legacy technology as a specific challenge? But the general discussion is broader than that.

Rich Landen: I am not suggesting any changes. But when I think of obsolete technology, I do not limit that to devices. I am thinking in terms of EHRs themselves can become obsolete.

Jacki Monson: I think we could probably add EHR to one of the examples.

Rich Landen: I am not suggesting that. I am just – for subcommittee edification.

Jacki Monson: I do not see any issue with just adding in as another example in the list.

Melissa Goldstein: We could put some other software systems.

Jacki Monson: Yes. I do not hear a lot about EHR technology being like it is – but it does not matter. We can specifically say that radiology, you name it, everything else could also be that so I think it is fine.

Rich Landen: And another tangent. FDA does classify EHRs as a device.

Jacki Monson: I think your edit was fine, Maya.

Denise.

Denise Love: We go to the recommendation in bold above. I want to nitpick a word that may or may not be important. HHS and other appropriate government agencies should consider evaluating the level of compliance. Do we want them to develop programs or assist with solutions because it may not be a program? Or maybe it is. And develop solutions or identify solutions to assist health care entities. If it does not fit, that is fine. That was just my nitpicking because it may not be a full program. It could just be technical assistance.

Maya Bernstein: We might call that a program internally.

Denise Love: That is fine. Sometimes I do not know if it is just nitpicky or if it improves it.

Maya Bernstein: Did somebody have a suggestion? Do you want to try to word that?

Lorraine Doo: You already fixed it.

Maya Bernstein: I unfixed it.

Lorraine Doo. It is just a very long sentence.

Maya Bernstein: Is that better? Whatever you call it, a program or whatever. The point is to provide assistance. Right?

Jacki Monson: I think that is fine.

Melissa Goldstein: What does with the greatest need mean?

Denise Love: The greatest noncompliance.

Melissa Goldstein: Can we just take out with the greatest need?

Rich Landen: I would not because I think what we are saying is we are focusing on the smallest with the least resources. We are not talking about large integrated delivery systems, non-rural areas.

Jacki Monson: We could probably say that in that paragraph below if we removed it from the recommendation.

Rich Landen: That would work.

Margaret Skurka: There is something missing in that sentence. We are evaluating – we are considering evaluating the level of compliance of what? We are evaluating the level of compliance and –

Jacki Monson: With the HIPAA Security Rule.

Maya Bernstein: So greatest need or greatest risk.

Rich Landen: Or greatest resource shortfall.

Jacki Monson: Greatest risk. That is the challenge that we are facing. We are all interconnected now. Whoever is the greatest risk is going to create the biggest patient safety issue to everybody.

Denise Love: The lowest common denominator.

Maya Bernstein: How much sympathy does the committee have for very large entities that do not do what they are supposed to do and have a very big risk versus small entities that may have less risk but less ability? Maybe that is something to flesh out. Or you could leave it to the department to decide. What is the rubric for deciding who gets this assistance, how to distribute this kind of assistance?

Jacki Monson: I think it would be okay. Although it is not – this is not targeted at small organizations. Large organizations have challenges replacing $500,000 radiology imaging machine that is 20 years old too, that does not have good security.

Maya Bernstein: This language kind of leaves – maybe that is fine to leave up to the definition of what the greatest need is who would be drafting or designing this kind of a program. Is that okay with you?

How are we on time?

Jacki Monson: We are still okay on time, I believe. Rebecca, public comment is in 15 or 16 minutes?

Rebecca Hines: Public comment is at 5:20, so it is in 20 minutes.

Maya Bernstein: How is the best way to use your time here? Rebecca made a suggestion earlier that you have a cover note and the detailed recommendations as an attachment or you could leave it as it is in a full letter like a letter report. We have done that before. That is just sort about format or presentation. But if you want to talk more about the specific content or examples or if there is something that is still --

Rebecca Hines: If you would like, I can find you an example and send it around.

Jacki Monson: Of the cover note?

Rebecca Hines: Of the approach to having the meat in an attachment with a shorter letter to the secretary.

Jacki Monson: That sounds good.

Rebecca Hines: Okay. I will search around.

Jacki Monson: Are there other comments, suggestions on the letter or any of the content?

Maya Bernstein: I think Jacki sent you all an email with this version of the letter yesterday. It is not that different from what is in your packet, but a little bit. We have made some adjustments. If you looked at that, it should be relatively familiar and it is marked up. You can see what we changed. If you have specific markups and you have time to – something sticking out that you want to send me tonight, I will put it together along with the other letter overnight, and you will have it in the morning. Do we have time for both of these tomorrow?

Jacki Monson: We do. My hope was to get as much consensus as we can today, which it sounds like we are – at least from what I hearing so far, is we are at that point. And then tomorrow afternoon, we are going to hear from two individuals who – one still works at CISO. The other one has transitioned off. They are going to share perspectives on cybersecurity, information security. They actually did a research report with HHS and CDC on the correlation between the challenges with the health care infrastructure, the current pandemic, and cyber-attacks.

Rebecca Hines: That is in their E-agenda book, Jacki. Everybody should read that if you have not tonight.

Jacki Monson: I hope we can hear from that panel and then bring the letter back to see if there are any additional enhancements, we should make based on what they tell us. And then I hope tomorrow afternoon we can get to a point where we can vote on this.

We have a little bit of time. We have about 18 minutes. Melissa, I do not know if there is any more to discuss on the PHE letter. It felt like we probably need to turn in another draft.

Melissa Goldstein: I think that is our plan is to turn another draft tonight. I am wondering, however, Rich and Denise, Tammy, from the discussion this afternoon, are there additional points that you would like to make that we should consider when we are looking at the letter again tonight? I see Lorraine has turned into a cat.

(Laughter)

Melissa Goldstein: There were some overlaps, some real overlaps this afternoon in the discussions, which, Rich, you had brought up earlier this morning. I am wondering if there are any additional things that you would like us to think about in a PHE letter, in the public health emergency letter, as we are looking at it again tonight in light of what people said. Or if you think of anything, that is just what I was wondering from after the discussion today.

Rich Landen: You will have to give me a few minutes to retool my thinking.

Melissa Goldstein: Absolutely. Denise, as well.

Denise Love: We were going to add a footnote to that report. That will help.

Maya Bernstein: Which report?

Denise Love: The HITAC Public Health Data Standards Task Force report. I have the link or I think the link was on the slide.

Melissa Goldstein: You had put it in, Maya. You had put a placeholder for us to put that reference.

Denise Love: My lazy response would be I will review it to see if there is an overarching statement that many of these concur or reinforce or support the ONC HITAC report footnote. But I will think about it a little deeper.

Melissa Goldstein: Okay. Thank you.

Wu Xu: Later on, I have a thought for one word in the recommendation. Develop data stewardship responsibilities would be used to define the data stewardship responsibility. It is better than develop because they are data stewardship responsibilities in the practice. Everybody is already doing that. But as a federal, you define what is the principle for that institution. Just a thought later on.

Denise Love: Could that cross reference our earlier report? I think NCVHS some years ago, did principles for data stewardship.

Rich Landen: That was in 2019. But that was specifically focused on curation and dissemination of terminologies, vocabularies, and code sets. It was a different focus than this. There is some overlap.

Rebecca Hines: My first year here, I remember my first year here I remember you all got it done in 2015 early and people said, Rebecca, we need help getting this thing disseminated. It must have been completed in early 2015. I could probably find the link on the website. I distinctly remember this document because it was one of the first things handed to me when I got here in mid-2015.

Denise Love: We disseminated that report through the NATO(?) membership. It was some years ago. It was the principles of data stewardship. We had folks encourage them to review it to see if their policies and practices were aligned. I do not what year. I could find it if you cannot find it, Rebecca.

Rebecca Hines: I am sending you the link.

Maya Bernstein: There are several of them. There is a stewardship one for community health data from 2012.

Denise Love: I think that is the one that I was referring to. But that could connect the dots. That might help Wu's comment.

Maya Bernstein: Is this the thing you are looking for?

Rebecca Hines: No. I got you a newer one. I just stuck it in the chat.

Denise Love: I remember a booklet with a nice cover.

Maya Bernstein: Yes, the toolkit.

Denise Love: Maybe that is it.

Rebecca Hines: That is what I just sent you. It was using the NCVHS logo.

Maya Bernstein: Most of the writing was developed by a graduate student of Leslie Francis of Utah.

Rebecca Hines: Just for future reference, if you go to the website of NCVHS, there is a tab called products. If you do not click on any of the sub, just click on products, you will get a reverse chronology of all NCVHS' letters, reports, and responses from HHS in reverse chronology from now back until when the committee. Click on products. Just click on that and then you have to go down and hit view all. All of them are listed in reverse chronology from the beginning of time when things were posted on the web. If you want to narrow it, there is a search.

You can also go to your own subcommittee page of the website. You all should feel like this is a huge resource for you because now that I have been here a little longer than a lot of you, which is scary to say, issues are recycling around that some of you are not aware the committee actually had two-day hearings on and letters to the secretary on. And some of the issues really have not changed like what Shawna Webster raised today. I sent you the link and the chat to that letter. It is a lot of homework, but you might want to just make yourself – take some time and look at the topics.

Maya Bernstein: You can also look here to see what happened before. For example, if you wanted to find things that came out Pop Health, you could see them here.

Rebecca Hines: But those letters are still on the products list, the letters, the work product of the Full Committee because everything that goes in terms of a recommendation is a Full Committee product.

Maya Bernstein: If you want to narrow, there are ways to do it. I usually – organization that I think it came out of – I never know quite which things are reports and which things are recommendation letters though. For example, these are the responses from the secretary.

Rebecca Hines: Or from another agency.

Margaret Skurka: Sometimes there are responses and sometimes there is not. Is that what I am seeing?

Rebecca Hines: Yes. There is supposed to be a response to everything, but it does not always happen, Margaret.

Margaret Skurka: Like our ICD-11 letter on September 10th.

Rebecca Hines: I believe there is one being developed for that.

Maya Bernstein: They are not always extremely timely.

Jacki Monson: Okay. I think we have all we need from the PSE perspective. Is there anything else, Rich or Denise, that you want to talk about related to standards? We still have a few minutes.

Rich Landen: The only thing I would ask is if any thoughts have occurred to any of the committee members since our discussion, questions about the direction of the recommendations or the work of the subcommittee that remains to be done, delved into further.

Jacki Monson: I think one overarching comment I have is I heard a lot of overlap with PSE. I think at some point there is probably – it is probably ripe for a discussion to talk about the synergies between those two groups because it sounds like the direction that standards is going is it is going to have a lot of overlap with privacy and hopefully, we will also have bandwidth given the letters moving forward that I just wanted to acknowledge that I think there is going to be synergies between the two groups and things that we could perhaps work on together and at least be involved in.

Denise Love: I agree.

Public Comment

Rebecca Hines: Jacki, if there is nothing left for the committee to discuss this afternoon, we can move to public comment. We actually only have 14 members on the public on right now. I just checked email and there is nothing in the box. Is everyone ready to move to public comment? We can have the public comment slide please. Thank you.

We are now in the public comment period. Greg, do you want to review the phone and Zoom options although everyone here – we have one comment already it looks like from an attendee. Andrew Tomlinson. Gregg, do you want to review the process to get unmuted?

Greg Richards: Sure. Can do. Hello, everyone. Thank you for joining us today. If you would like to make a public comment, you have two different ways to do so. The first is via voice. If you are on a computer, please simply hit the raise hand button. You can do this on the computer by pressing raise hand. Or if you are on a phone, you can raise your hand by pressing *9. Once called on, the host will send you an unmute request to unmute yourself to state your public comment. When you called on, please state your name, title, and organization. If you would like to have a text comment to be read verbally, you can submit one via the Q&A box at the bottom of your screen.

At this point now, you should be able to both raise your hand and submit Q&A. We do have one individual who is currently raising their hand. Andrew, you should have a request to unmute yourself now. Please state your name, title, and organization.

Andrew Thomas: My name is Andrew Thomas, and I am the director of Federal Affairs here at the College of Healthcare Information Management Executives or CHIME. We are incredibly supportive of the work that NCHVS is doing to strengthen the cybersecurity and cyber resilience of the health care sector. As part of your work in submitting a letter to Secretary Becerra, we would encourage NCVHS to review and then continue to advocate for expeditious implementation of public law 116321 previously known as HR7898 that would mandate the use of an industry standard cybersecurity framework or a set of best practices in order to receive relaxations on HIPAA breech penalties.

We think that this previous law and then the future rulemaking that would be based around the law will help continue to incentivize providers to adopt cybersecurity best practices, not only to protect themselves, but also to protect their patient data. It can help be a real carrot to push forward a more cyber resilient future. We continue to ask NCVHS to review that law and then continue to highlight to the secretary that it is important for the Office for Civil Rights to move as expeditiously as possible to move that into implementation. Thank you.

Rebecca Hines: Thank you. Anyone else have a public comment this afternoon for the committee?

Maya Bernstein: If CHIME wants to send us an email just to make sure I got it correctly, I will –

Rebecca Hines: It will also be in the transcript and the recording. You are certainly welcome to send an email to that address on the screen, NCVHSmail@cc.gov. We will also have it in the transcript, which we will have available in about ten days.

Anyone else have a comment? I will check the email one more time. I do not see anything in the box at the moment. Thank you, Gregg. This is where we play our Jeopardy music. Anyone else? We have 12 stalwart listeners here this afternoon. I think we are done. If you were trying to get in and for some reason were unable to, again, send your comment to NCVHSmail@cdc.gov or you can try again tomorrow afternoon. Thank you.

I am going to turn it back over to our chair.

Jacki Monson: Okay. I think we had a very productive and busy Zoom day. Thank you all for your time and attention today. We are officially adjourned, and I will see you all tomorrow.

Rebecca Hines: And remember we start at 10 a.m. Eastern, my friends. A little earlier tomorrow to accommodate our West Coast academic who needs to teach tomorrow afternoon. We are starting at 10, starting off with a two-hour expert panel. Great first day. I hope you enjoy a screen-free evening. Check your email first thing in the morning for revised letters. Thank you.

(Whereupon the meeting was adjourned at 5:20 p.m.)