National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary/DFO**
Debra Strickland	Conduent	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 Gonzales	CDC	Staff
Marietta Squire	NCHS	Staff
Susan Jenkins	ASPE	Staff
Grace Singson	ASPE	Staff
Presenters		
Name	**Organization**	**Role**
Kristin Cohen	Federal Trade Commission	Acting Associate Director of the Division of Privacy and Identity Protection

Stacey Gray	Future of Privacy Forum	Director of Legislative Research and Analysis
Lauren Riplinger	American Health Information Management Association	Vice President, Policy and Government Affairs
Cobun Zweifel-Keegan	International Association of Privacy Professionals	Managing Director, Washington, D.C.
Jerilyn Church	Great Plains Tribal	Chief Executive Officer
Abigail Echo-Hawk	Urban Indian Health Institute	Director
Kristin Ekelund	Government Accountability Office	Senior Analyst, Health Care Team
Kirk Greenway	Indian health Service	Principal Statistician
Heather H. McLane	Indian Health Service	Senior Official for Privacy
Tricia Roy	Government Accountability Office	Senior Analyst, Health Care Team

Call to Order/Roll Call

Rebecca Hines: Let us go ahead and get started then. People are still filing in. Good morning and welcome to Day 2 to our members of National Committee on Vital and Health Statistics and welcome to committee staff and members of the public in attendance with us here today. This is Day 2 of our mid-year meeting of the Committee. I am Rebecca Hines and I serve as Executive Secretary and Designated Federal Officer for NCVHS.

We have had some changes in the agenda, which we will review, which the chair will review shortly, but just to note that the updated agenda is posted. I will put a link in a minute in the chat so everybody can find that. Let us take care of that. If people need the agenda, there it is, the updated version.

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

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

Rebecca Hines: Deb Strickland.

Debra Strickland: Deb Strickland, a member of the Full Committee and member of the Standard Subcommittee, no conflicts.

Rebecca Hines: Denise Love.

Denise Love: Denise Love, independent health data consultant. I am a member of the Full Committee, Co-Chair of the Standards Subcommittee, no conflicts.

Rebecca Hines: And noting Denise Chrysler is not with us today for the record.

Jamie.

Jamie Ferguson: Good morning. Jamie Ferguson with Kaiser Permanent, member of the Full Committee and the Subcommittee on Standards, no conflicts.

Rebecca Hines: Margaret.

Margaret Skurka: Hi. My name is Margaret Skurka. I am Professor Emerita at Indiana University. I am a member of the Full Committee. I serve on the Subcommittee on Standards, and I have no conflicts.

Rebecca Hines: Melissa.

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

Rebecca Hines: Rich.

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

Rebecca Hines: Tammy.

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

Rebecca Hines: Val.

Valerie Watzlaf: Good morning. Val Watzlaf, Associate Professor Emerita with University of Pittsburgh. I am a member of the Full Committee, and I am also a Co-Chair of the PCS Subcommittee and I have no conflicts.

Rebecca Hines: Vickie.

Vickie Mays: Good morning. I am a Professor with the University of California Los Angeles. I am a member of the Full Committee, the Subcommittee on Privacy, Confidentiality, and Security, and I am Co-Chair on the Working Group on SOGI and SDOH and I have no conflicts.

Rebecca Hines: Wu.

Wu Xu: Good morning. This is Wu Xu, member of the Full Committee and no conflicts.

Rebecca Hines: Thank you, Wu. Let us move over to the committee staff, starting with Sharon Arnold. Good morning.

Sharon Arnold: Good morning. This is Sharon Arnold. I am the Associate Deputy Assistant Secretary for Science and Data Policy at ASPE, and I am also Executive Director of the Committee.

Rebecca Hines: Good morning, Susan Jenkins.

Susan Jenkins: Good morning. My name is Susan Jenkins. I work under Sharon. I am the Director of the Division of Evidence Evaluation and Data Policy.

Rebecca Hines: Good morning, Maya Bernstein.

Maya Bernstein: Good morning, everyone. I am Maya Bernstein. I am the Senior Advisor for Privacy Policy at ASPE. I work for Susan Jenkins and Sharon Arnold. I am the Lead Staff to Sharon in her role as the Executive Director of this Committee and the Lead Staff to the Subcommittee on Privacy, Confidentiality, and Security. I look forward to today.

Rebecca Hines: Good morning, Grace.

Grace Singson: Hi everyone. Good morning. My name is Grace and I am new with ASPE and I support Maya, Susan, and Sharon.

Rebecca Hines: And moving over to Lead Staff for the Subcommittee on Standards, Lorraine.

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

Rebecca Hines: Did I miss anybody? I am going to go ahead and bring up the agenda, Jacki.

Agenda Item: Welcome Remarks/Agenda Review

Jacki Monson: Let us review the agenda for today. First, we are going to kick it off with Vickie Mays giving us an update on SOGI and SDOH Data and Measures Definitions, Collection and Use Workgroup. And then we will have a briefing on the legislative developments in data privacy led by Melissa and Val. Take a break. And then we will move into tribal epidemiology centers: data access and privacy led by Vickie and Val. We will break at 3:30 for public comment. And then we will move into Standards Subcommittee to review the letter again, recommendations on modernization, adoption of HIPAA transaction standards. And then after that if we have time, we will review the NCVHS workplan and then close and adjourn.

Rebecca Hines: Thanks for those in attendance with the public, you are welcome to email any comments. We did get some emailed yesterday, which were provided to the Subcommittee. We will have instructions up on the screen this afternoon around 3:30. Note that it could be a little before or after, but we will try to have the public comments start promptly at 3:30 if possible, just given how the proceedings flow. And you can email comments to NCVHSmail@CDC.gov.

Jacki Monson: Thanks, Rebecca. Let us go ahead and get started. Vickie, do you want to kick it off?

Workgroup to Assess SOGI and SDOH Data and Measures Definitions, Collection and Use - Update

Vickie Mays: Thank you, everybody. I am happy to talk about the Workgroup and where we are. I think it is probably good to start with this whole notion of why the Workgroup is important and kind of what has led to this.

One of the things the Workgroup does is really reflect the priorities that we are seeing right now in HHS from the Biden/Harris Administration, who have requested that we address inequities as well as HHS where health and well-being inequities in particular are a significant focus in all of the departments and agencies.

One of the things we have seen is that President Biden has issued a number of Executive Orders, some of which are specific to SOGI, which is what I am going to focus more on today than the social determinants of health.

Just this past June, what you saw from Biden is that he noted that over 300 anti-LGBTQI laws have been introduced in the State Legislatures. This has just been in the past year. Many of them tended to specifically target transgender children and their parents, specifically banning access to certain kinds of medical care. Of course, we have all been aware to some of the school bands.

Biden's Executive Orders actually build on some previous orders on equity and calls for SOGI that have been under this notion of equitable health, access for all. He has asked federal agencies to address some of the discriminatory attacks against LGBTQI children and families by actually directing a lot of the agencies to protect families and children. In particular, for instance, HHS has been called on to safeguard health care and programs designed to prevent suicide. Biden's Executive Order supporting LGBTQI children and family calls for improved access to federal programs and in areas that cross into SDOH such as education, homelessness, foster care.

And particular for HHS, what the administration has asked is that there be some protection from attacks on access to health care and has really instructed HHS to release new sample policies for states on how to expand access to comprehensive health care, the LGBTQI plus patients.

What you will see right now is that probably every agency within HHS is working on this. And what you might imagine is that needs will differ by both the purpose and the context in which those agencies need that SOGI data.

What from the outside may look like chaos is actually control response to what is needed for particular agencies and that is where a group like NCVHS can be helpful because we kind of stand in a position where we looked at the overview of things. We try and step back and understand where there are gaps, what kind of policies, et cetera, that we might see to be able to recommend.

The Workgroup was really established for us to determine a little bit of how and where within our purview of data, particularly looking at things like privacy, confidentiality, security, and standards, that we can contribute to a fairly large and daunting task that has been given to the Department.

Let me turn now to the charge to the committee. Again, there are things in here, the charge, the focus, the approach, and the discussion. In the discussion, what I am hoping for is that we can hear from the Full Committee how you see these issues, ways in which you think we can be helpful and to offer us some direction. The Workgroup actually kind of where we think about it turns to the Full Committee for a sense of its direction. We carry out a lot of the work but we will be looking to hear from you.

This is to remind you of what our charge is. As you can see, this is a considerable charge. But again, we are going to do this in a way in which it is feasible, efficient, and reasonable. Part of what we have talked about in this charge is thinking about the methodological issues. The methodological issues are often those issues in which people are asking how should the question of the determination in SOGI – and also, what are the areas that we want to look at this data?

In the past, we actually talked about survey, administrative, clinical, vital records, and public health surveillance as being those areas. And we have thought about doing them separately. But what is very clear is you take a framework, if you think about the life cycle data, what happens in terms of data being corrected in a clinical setting, it morphs over to use in administrative setting. We often need people birth and death certificates as part of that public health surveillance. We are not going to do these separately. Instead, what you are going to see is that we are going to try and look at the life cycle of the data and SOGI and to see a long that path how all of this will work.

Another charge for us is to think both the SOGI and SDOH, which we will be doing a little bit later, to get some sense of what should be collected. I can say I would be guilty of this as a researcher. Given that we cannot have everything we would love to have, just try and figure out are there some minimums that should be done by everyone so that we have the ability to harmonize across data sets. That is going to be, I think, an important concept to think about.

In this issue of limited data that can be collected, we are going to have to think about people, not just what we want, but we are going to also have to think about how to do that in a context that the data that we get from people, we can trust the data and that people can trust us to protect that data.

Issues of collection will come up. What are the specific data elements? Again, what are the data standards? I think for those of you who were here yesterday, you heard some of that discussion for SDOH. We have the same thing in terms of the SOGI data.

Public trust comes up as important to us, not for any political reason, but if we cannot ascertain that the public trust us then we have to worry that the data that we are getting may not actually be as accurate as we want it to be. We have to create a sense of trustworthiness in order to get people to give us accurate data.

Remember, one of the things about this data is that it will change over time. Being able to have a relationship with people that can sustain us as people's status has changed and having them comfortable to share that into an electronic health record or even in terms of fixing things like their birth certificates, et cetera, will be important.

We want to have the Full Committee really think about some of the specific privacy considerations and I will talk just a little bit about those for use and linkage both in terms of SOGI and SDOH in various settings. In particular, we want to think about the privacy considerations for potential uses of SOGI as it begins to roll out. We do not want to stay stuck in – we know a way to collect this data in a clinical setting and not realize that in that clinical setting, there are many things that need to be evaluated, ways in which that data are shared all the way from thinking about – in privacy, all the way from thinking about what happens when a prescription is filled, for example, and you get the bill and the bill says what the prescription was for. That could end up outing a person. We have a lot to think about here particularly I think in the privacy and data quality realm.

As you might imagine, we could enter the world of SOGI and data and have it be everything from ethics to the whole nine yards. But what we really are trying to do and this is what the workgroup has probably been spending its time on is to know what are the issues, narrow our focus in ways in which it matches what it is that we do best.

There are three things that have come up in the linchpin in some of this is progress and perception of privacy. What comes up is for us to be able to talk about the purpose and the context of collecting this data. The reason for talking about the purpose of it is so that everyone is clear why the data is collected for health and well-being because at any time where there is a question about why are you asking us or there are challenges from jurisdictions as to whether or not this data should even be there, at the end of the day, this really needs to rely on the responsibilities that we have at the level of HHS as well as the

federal government overall for the health of the nation. We have many documents that talk about that. We have Healthy People -- now, we are on Healthy People 2030. But in the US, we are responsible for the health of all. In terms of purpose and context, I think it is important for us to lay that as a foundation.

Next is to think about this issue of privacy and perception of privacy. And – just privacy because that would talk to what it is we do to protect. But one of the problems that we have, which affects data quality and integrity, is the perception of privacy and the need for transparency, for example, of when the data is collected, the imagination of what can be – what will be done, what might be done, and coming up with the ability to think ahead for any of those violations and to know, for example, that we assure people about protection and confidentiality. That they have an understanding of how it works and what the boundaries are and when those protections may be superseded based on some kind of legal requirement.

Part of what we have seen – I am only going to give a couple of stories here in terms of this so that people have a sense of the range of privacy issues. For example, in the 21st Century Cures Act, one of the things that was done was that of trying to make data available to patients. Think about what happens for an adolescent who is transitioning, who is non-binary, any number of different statuses that they may feel are very vulnerable to them to acknowledge.

What happens is that for that adolescent whoever the parent or caregiver is that has legal responsibility for that person, they have access to that data but yet you have a provider on the other side that needs to know the data in order to be able to deliver health care.

There are some procedures in place. I think questions are are they good enough. Are people going to trust that we can protect it? How do we on an ongoing basis figure out in a record whether that is behind a firewall? If it is behind a firewall, how the providers will know to look? There are a lot of complex issues in terms of some of the privacy things that I think as we go through this that we will be trying to unveil.

Again, I gave the example of what happens sometimes when bills come in. There have been instances where bills have actually outed an adolescent. And also, there are jurisdictions. We are seeing an increasing number of jurisdictions that are deciding that you cannot talk about LGBTQI and that, for example, providing medical care such as transitioning affirmative hormonal treatments that those are in conflict with some of the laws of those jurisdictions. There is a case of a kid who wound up in the hospital because of an attempted suicide and while in the hospital was asked typical questions about medications, et cetera. It came out that the kid was on hormone replacement therapy. The child was actually removed from the custody of his parents and became a ward of the state because of the laws that were there. You can see the growing kinds of conflicts that are occurring that some answers are really much in need sooner rather than later.

That moves us to issues of data quality and integrity. Everything from thinking about terminology. One of the things that I provided within the Workgroup is just how the definition of being transgender from – I think it began back in 1995 until now and how changing times have resulted in flushing out that data. We have the same thing in terms of language that we use around gender identity, sexual orientation,

and the ability to be able to match that over time is important. But at the same time, the ability to capture new ways of thinking about these issues is equally as important. People coding have to have this constant update on ways in which to track this information.

The bigger thing is to think about whether or not people are going to share their data with us if it is not a transparency and a sense of confidence that they are being protected and that is where this issue of data quality also comes up, how much missingness we have. What is the error rate of this data? Can we write reports? It is kind of like that small population issue. Can we write reports and make recommendations to establish policies if there is a lot of missingness? When there is missingness, what do we do? Do we impute data using some sense of what we think the numbers are in the population? There are some difficult but yet intriguing questions that are here.

In the discussion what I thought be useful is for first the Workgroup members to talk about the issues as they see them from where they sit. And then the other is to talk about we thought that the best way to really do this, as I started off. Federal agencies have different uses. It is very hard for us to come up with this one framework fits all. But instead, what we were thinking about is developing two to three use cases in which we could follow the lifecycle of the data, point out how different people have different approaches that may work in certain contexts.

I am going to stop there. I am happy to start by answering any questions about what I said. But I would like to be able to throw it to the Workgroup members at this point for additional comments. Then let us open it up to everyone.

Denise Love: Hi Vickie. Thank you and thank you for your work on this. It is not an easy task. It is going to be a hard task for many years.

From a national perspective, I am coming at it from the states and the frontline workers collecting it. It is going to be messy for a while. But I really think nationally what I am hoping will happen is the experts in the national arena will really work on I think some framework, conceptual framework, not only definitions and some clarity of what equity is and what the risk factors are, defining use cases that are actionable for policy and government. It is not a clinical setting. It is a little different. You just have a lot of potential data to collect that is not usable. Some of the states are asking for some conceptual clarity and framework.

What do we mean by framework? Do we need to 12 data elements, or do we need 20 or are there some proxy measures or composite scores that represent the concept that we are trying to portray? And then on quality indicators. Some of the states that use the AHRQ quality indicators are saying how do we adjust for disparities and risk and quality indicators in these new frameworks and then how do we identify bias in the data. You touched on that with missing. But also, there is going to be some muddy data for a while. These are really analytic, heavily big lifts. That is, I guess, what I am pushing back to the national arena to really work on that will help the data quality at the front end because just collecting the data without seeing how it is used and can be used will just get us a lot of data. Thank you for your work.

Vickie Mays: Thank you, Denise. I think this issue that you are raising about the research that needs to be done. We had research in there, and I really thought best we turn it onto what is the ongoing research that we need in order to make sure that some of the issues that you are raising are attended to and that we can do better as we go along kind of thing.

Thanks, Denise. And thanks for the kind words. The Workgroup has been great at supporting this work.

Wu Xu: First, I want to thank you, Vickie, for your leadership. I have learned a lot just in the past few months on this Workgroup. I am glad we are narrowing it down to come up with some actionable use case approach. But I'm a doer, so I am always thinking, what is exactly deliverable. What can we deliver in time? I think even for use case, we need to have a clear scope of work. What are unique contributions to this huge national issue?

I really like the last discussion, put this nationwide need into the research recommendations. But we need to focus on what we can do uniquely.

Vickie Mays: Wu, can I ask you because when we were talking about this in the Workgroup and we were talking about use cases, can I ask you to do one thing is can you explain the use cases so that everyone here is on the same page, kind of what that notion is about and what you see the benefit of a use case approach? Then you had some ideas about what you thought they should be and now is a good time to share them if you would like.

Wu Xu: A use case is a very broad term in different settings can do different. I am thinking your true adolescent's interaction, collect data and treatment are excellent and that really were needed and most complicated case. If we do a clinical use case, we can just use pick adolescent interaction. In each step when data collect, we will help parents, so we make up the whole process by that. When you talk to all three, I think we can define one for clinic what we decide for another two. We can think about that.

Basic, you let the frontline people know when they have this situation. How can I do SOGI data collection, data use, treatment, privacy so they know all those steps in this whole process?

Vickie Mays: Thanks. Denise.

Denise Love: I have learned to never disagree with Dr. Xu. I totally agree with her. Wu, I get it. Could we also have a use case that is a little more state based as far as what is happening today? We have states that have – they are doing payment based on quality and population health.

I would add to Wu's wish list for a very well-defined use case on the clinical side. I would like a use case on the state side that is actionable as they pay incentives to providers to improve health – and they are using quality indicators and different measures to quantify that. What data do they need and what adjustments need to be made so that we really get at those disparities and incentives to reduce equity at the policy or payment level? I think you need a couple of both. That is just my argument.

Wu Xu: I want to add, Denise, a proposal but maybe not call it a state use case because the legal issue is really a major problem for state law, how do they do that. Then also for payer, they use the

underwriting. How do they pay? Like Medicaid, their policy impacts – Medicaid and Medicare policy impact on payment. We could come out a policy approach use case. We can discuss that later.

Vickie Mays: I want to ask a couple of questions while I have – particularly in terms of privacy being a little quiet here. I wanted to hear from privacy, kind of your thoughts about some of these privacy issues and where they seem to fall into the sweet spot of expertise that the committee has.

Melissa Goldstein: Hi Vickie. I will jump in here if I may. I think it is always important for us to remember that privacy sensitivities are not necessarily universal, and they are certainly very different from person to person and that when we are talking about addressing the need of a population, we need to be sensitive, that population includes a bunch of people but they may have very different needs and desires among them.

We do need to recognize that certain groups tend to have more vulnerable people as – than other groups or at least historically, we go according to the data that we have. We have to be careful not to stigmatize them as more privacy characterized. But we need to listen. I think that requires us to keep communication with individuals and groups going as we actively strive to, as Denise said, make strides over the coming years in gathering this data and helping both public health needs and individual needs and government needs and resources needs so that we can see where there are problems if there are any problems and where we can help and where this body can actually offer our recommendations for helping anything that pop up along the way. But I think communication always is going to be important, which is not our role and this advisory body's role, but it is a very important thing for us to keep because things change. Perceptions change over the years and among different people. New worries pop up. Some worries go away. I think this will be an ongoing problem.

We have two very active listening sessions that we are going to be doing this afternoon. It is super exciting from my standpoint. I think these are examples of things that change a lot that we are trying to keep up with the times and see how different populations and needs change. Essentially, it is not really a question. It is just a comment of something that I thought about as – been speaking this morning.

Vickie Mays: Thank you. I think that that is well placed before us to keep in mind.

Any other thoughts, questions, or comments? If not, I have one more. I have time, Jackie?

Jacki Monson: A tiny bit of time.

Vickie Mays: Okay. I am going to – I will pass because I do not want what I was going to ask to be done so quickly that we cannot and that was – I was going to really get a little bit more into the value of a use case approach. Most of us on here will know that. I will stop there.

Any other questions, comments? First, let me thank everybody for the support that we have had throughout. Just so it does not come to you as a surprise, we are going to be on a bit – we are going to have a summer holiday for the Workgroup because we have to get some people in place. We are on a bit of a pause. The idea is that we will start fully staffed come the fall. That time that you have on your calendars captured back. Have a great time during that hour and think of the Workgroup. I will stop there, Jacki.

Jacki Monson: Thanks so much, Vickie.

Let us move on to the panelist discussion. Melissa and Val, I kick it over to you to start that.

Briefing on Legislative Developments in Data Privacy

Melissa Goldstein: Alright. I will start us off, Val, and then please chip in as well. I want to make sure that we have all of our great speakers line up and ready to go this morning.

As I mentioned a few minutes ago, maybe one minute ago, there is a lot going on and a lot going on at state levels with regard to data privacy, a lot going on at the federal level with regard to data privacy, confidentiality, and of course, we heard yesterday about cybersecurity. And all of these issues are interrelated.

We thought it would be useful for all of us and for the public to have an update on what is going on on the big issues. Obviously, we cannot cover every state, even every federal bill. But we have a super star lineup today. I want to give a special thanks to Maya Bernstein, who has been the brilliant figure head working with all of these people and somehow convincing them all to come join us today. Thank you to Maya very much. We really appreciate your efforts.

I will describe – my plan is to just give you a rundown of who has joined us and your titles. And then afterwards – please when each of you speak, feel free to give more detail about what your current role is and about your background as you see fit, and definitely correct my pronunciation if I butcher your names. I apologize in advance.

We have Kristin Cohen today, who is the Acting Associate Director of the Division of Privacy and Identity Protection at the Federal Trade Commission, which we, in DC, affectionately call the FTS when we get into the alphabet soup of Washington, DC.

We have Stacey Gray, who is the Director of Legislative Research and Analysis at the Future of Privacy Forum.

Lauren Riplinger has joined us. She is the Vice President of Policy and Government Affairs at the American Health Information Management Association, otherwise known as AHIMA.

And Cobun Zweifel-Keegan. Cobun, please fix my pronunciation. I suspect that you might need to – who is the Managing Director in DC of the International Association of Privacy Professionals. I never actually pronounce it as IAPP but other people might. We will let you tell us about that as well.

I want to make sure that Val has some time to make some general comments as well and then we will launch into this fabulous panel. Go ahead, Val.

Valerie Watzlaf: Thank you, Melissa. You did a great job. I just also want to welcome the panel. We are so very excited to have you here. Thank you to Maya and also thank you to the panel for being here. We are very much looking forward to this presentation and also to the great discussion that I am sure is going to happen afterwards. Welcome. Let us get started.

Are we going with Kristin to start us off?

Kristin Cohen: Thank you to all of you for inviting me here today. Let me just start with my disclaimer. The views I express today are my own and not the views of the Federal Trade Commission or any individual commissioner.

I think that a lot of folks on this call maybe do not think of the FTC when it comes to health privacy. Obviously, when you think about the privacy, you think of HIPAA, and you think of HHS. I think when HIPAA was first passed, it made a lot of sense to cover the health data that was held by hospitals and doctors and health insurers. But I think over the last – now, it is decades but especially in the last few years, I think we have seen more and more how so much of our sensitive health data is really covered by entities that may not be covered by HIPAA. You see that with respect to health apps. You see these period tracking apps or other kinds of health apps, or you have connected devices or data brokers that are using our purchase history or our location data to infer sensitive health information about consumers and that is sort of where the FTC comes in.

We have a broad mandate to enforce Section 5 of the Federal Trade Commission Act, which broadly prohibits unfair and deceptive trade practices. We have brought dozens and dozens of cases over the years related to protecting consumers' privacy and security of their information. And many of those have been in the health area. And some have been with HHS. Sometimes there are entities where we have overlapping jurisdiction. We work really closely with our counterparts at HHS to make sure that we are really covering the full breadth of consumer health data.

As I said, the FTC is a civil law enforcement agency and the kinds of cases we bring are typically where we are saying that a company has engaged in a deceptive trade practice because they have misrepresented how they treat consumer's data or the way that they are securing or sharing the consumer's data causes a consumer injury.

Just to give you an example of the kind of cases we bring, a recent one was against a period tracking app called Flow Health where the company had misrepresented that it was keeping consumer's sensitive health information confidential. And in fact, it was sharing that data with marketing and analytics firms, including the fact of consumer's pregnancy. That is the kind of cases that we bring.

I wanted to touch – most of what we do is related to Section 5 of the Federal Trade Commission Act, but we also do enforce the Health Breach Notification Rule. This is similar to the rule that HHS enforces. But we cover vendors of personal health records that are not HIPAA-covered entities.

And the reason I wanted to mention this rule in terms of thinking about the landscape, the privacy landscape is that last fall the Commission did issue a policy statement about the coverage or how we view the coverage of the Health Breach Notification Rule. I think there are two really important points that the Commission made.

The first is that it views – basically, most health apps and health-connected devices to be personal health records that are covered by the rule. I think that is an important point to highlight.

A second issue that the Commission highlighted was that it views a breach of security as being broader than just a cybersecurity intrusion and that it covers instances where consumers sensitive health data has been disclosed without their authorization. If a company were to collect consumer's data and share it with an advertiser, a data broker, and they did not have the consumer's authorization, that would be viewed as a breach under the rule for which the consumer would need to get notice. And if they failed to do so, they would be subject to civil penalties.

Two more things. Another issue I wanted to highlight is that I think in light of the Dobbs' decision, I think we have been hearing more and more about this kind of data that is out there about consumers, data that you would not traditionally have thought of as health data but that is used to infer sensitive health information about consumers. Location data is a big one and these health apps.

As I said, sometimes this data is directly collected and sometimes it is inferred about the consumer but regardless, we, at the Federal Trade Commission, think it needs to be protected and that consumer's privacy needs to be protected.

The FTC issued a blog I think a couple of weeks ago that I authorized that was just highlighting that we intend to use all the tools that we have to protect this data for consumers. I just wanted to highlight that point.

We also gave a few examples of the types of issues that we think these data brokers and other companies really need to be thinking about when they have this kind of data, including when they basically falsely promise that the data really will be anonymous because often the data really cannot be anonymous, especially when you are looking at location data. That was one thing I wanted to highlight that the Commission is doing and on these important issues.

And the last thing I will mention is that there has been a lot of talk about federal privacy legislation, and I think there has been a lot of movement on that, which is great. But I did want to mention that our chair has said that the Federal Trade Commission is considering whether to issue -- put out a notice, an ANPR, to conduct a privacy rulemaking on commercial surveillance and data security practices. Nothing has been announced. It is just in the consideration stage. But if that were to happen that could have a broader effect on the privacy protections for this kind of health information.

That is all. I just wanted to thank you very much for inviting me here today and I look forward to the discussion.

Melissa Goldstein: Thanks so much. That was wonderful, Kristin, and extremely helpful.

I think we will move on to Stacey now. Stacey, if that works for you.

Stacey Gray: Sure thing.

Melissa Goldstein: Nice to see you.

Stacey Gray: Nice to see you too. Melissa, thanks so much. Thank you so much to the organizers for having me. I am Stacey Gray. I am the Legislative Director for US Policy at the Future of Privacy Forum. If

you are not familiar, we are primarily based in Washington, DC. We are a nonprofit thinktank with a global presence. And our specialization is essentially commercial privacy, consumer privacy. We work with the chief privacy officers of over 200 companies and work on a variety of foundation and grant-supported projects, including with NSF and Sloan.

And specifically, my job is to track the emerging federal and state legislation. I have been asked to give you all a brief overview of the state privacy legislation and laws that we have seen pass in the last few years. I am very happy to do so and to leave time for questions or take questions at the end of however we would like to run things.

I think what I will do is start off with just a very brief history in the politics of how we got to where we are today and then spend most of the time discussing the substance of what we are seeing in California, Virginia, Colorado, Utah, and Connecticut with respect to the scope of these laws and the basic consumer rights that are in the laws and a couple of other things like sensitive data and enforcement provisions.

But a quick history. Depending on how you calculate this, the United States has been working on comprehensive privacy law as far back as 1974. The original privacy act of 1974, one of the early drafts, applied to companies as well as government. And it was later taken out and amended to only apply to government entities. Now, we have the privacy act for government entities.

Again, as this audience very well knows, the United States has very strong sectoral privacy laws in areas like health care. We have HIPAA. And HIPAA is one of the federal sectoral privacy laws that does not fully preempt state legislation in the same field. We have also a large number of state health care and medical records privacy laws.

What we do not have is a single overarching or comprehensive information privacy law in the United States except now in the states, which I will get to in just a moment, that fills in all of the gaps and regulates and applies broadly to personal information regardless of who is collecting that personal information, how it is collected, what sector, or where it is from.

One of the major political points in this debate, for example, has been that we have such strong privacy protections around health institutions and medical records. But equally sensitive information when it is derived from mobile apps or websites or your browsing history is not subject to the same protections although very much subject to the FTC's broadly applicable unfair and deceptive trade practices jurisdiction, as Kristin pointed out, which has been, in fact, very powerful. But I will let her to speak to that.

That is what we have not had. That has really started to change over the last few years. In 2016, the EU passed the general data protection regulation, which is a very significant step forward. In the Obama Administration, there was a consumer privacy bill of rights that the NTIA spearheaded, the Department of Commerce spearheaded, which did not end up making it – passing into law but was a significant federal step forward.

In 2018, the thing that really made the state privacy legislation just kick off like rocket was the introduction and passage of the California Consumer Privacy Act. The California Consumer Privacy Act

was initially proposed as a valid initiative and then passed into law relatively quickly as a compromise measure for political reasons that I am happy to dive into in the State of California.

And when it was passed in 2018, it immediately became, because of the significance and the size and the population and the economic power of California effectively became a national privacy law. Companies across the United States for the most part are complying with CCPA at least in California and many of the large tech companies have extended those protections across all 50 states. It has really become a significant thing and is being analyzed globally in terms of emerging tech startup markets in other nations are looking to California.

One of the issues with the California Consumer Privacy Act though is because of the unique way in which it was drafted and the speed with which it was passed, one of the common complaints that you will hear from law firms and regulated businesses about the CCPA is that the drafting was ambiguous. The drafting did not align with what people were used to in the GDPR. There were some confusing terms. Very quickly, you saw efforts including from many industry groups to support similar but clearer from an industry perspective legislation in other states. To be a VHS to the Betamax, an alternative model to California. We very quickly in the years following 2018 saw legislation passed, introduced and passed in Virginia, Colorado, Connecticut, and Utah this year.

That takes us up to five states. California has amended the CCPA through an additional ballot initiative, which was passed by voters in California in 2020. The California Privacy Rights Act, which is a set of amendments to CCPA. And now we have comprehensive privacy laws in five states.

To speak now about what they are, what they do, what is in the substance there, what has been happening because it has been a pretty fast-moving landscape. I will just speak about scope, consumer rights, and some of the pieces around sensitive data because that will be relevant to this audience.

First in terms of scope, California and other states have largely followed this exactly, contains a fairly broad scope of both covered entities and data regulated. With respect to covered entities, California regulates all businesses, doing business in California. There is a small business threshold with respect to revenue. And other states have largely mirrored that with the exception of Colorado, which has extended its jurisdiction to include nonprofit entities.

This is a pretty significant step before because nonprofits include a lot of entities that are not traditionally accustomed to complying with data protection regulations and laws. Often have more charitable, less profit-driven motivations and business models and also impact academic research in a fairly significant way.

I mentioned Colorado because even though it is only one of the five states, this has been a pretty significant major trend that we have seen mirrored in federal legislative negotiations and debates. For example, I will not go into it but the current federal proposal moving in the House of Representatives would also regulate nonprofit entities. And that is, at this point, I think considered kind of table stakes for negotiations on privacy.

Nonprofits are now in scope and a lot of people are looking at these things for the first time. California and the other states have an equally broad I would say in all of those scopes of covered data. All of them

apply to personal information, defined very broadly to include essentially any kind of information that is related to an identified or identifiable natural person either directly or indirectly.

Now, some states do not say natural persons. Some states say resident of that state. But nonetheless, the scope of covered data applies to we will just say more than your name, your address, your email address, and sort of the traditional things we think about as personal information but would apply to things like device identifiers, IP addresses, persistent, unique identifiers, browser information, device information, network information.

This is all, I think, relevant because it is different from what has been the norm traditionally in the United States, what has been the norm under other sectoral privacy laws. For example, very much an aside, but HIPAA has a more flexible standard of what they would consider personal information versus de-identified information, for example. De-identified under the state laws tends to be a much higher bar, a much stricter standard that covered entities would have to meet in order to demonstrate that that information has truly been anonymized. A list of pseudonyms, for instance, with a key coded matching table used in medical research, would probably still be considered personally identifiable information under state laws. That is scope.

The core consumer rights in each of these state laws are also broadly similar. We have states not wanting to diverge much from each other. It is worth noting. There are a lot of concerns and rights in the industry about interoperability of different standards. For the most part, even though there are differences, they align in a lot of really core structural ways. Each state contains individual rights, consumer rights for residents of that state to request access to their data, receive access to their data typically in a portable and interoperable format, which is sort of a back door into portability but not a true portability right. It is just more of I would like to get access to my data in a portable format to be able to take it to other entities.

A right to delete that data subject to often various exemptions for when the data is necessary for various things. In some states but not all, a right to correct that data if it is inaccurate.

Additionally, based on California's lead, there is a consumer right to opt out of various business activities. In California, you will see it described as the opt out of sale. Do not sell my data. Companies in California have to even put a link on their website that says do not sell my data. You can click on it and follow the procedure for a request to that covered entity to not sell the data. Other states have largely this and have expanded on it for opt out – things like targeted advertising.

Finally, most states have codified additional higher standards for a subcategory of personal information called sensitive covered information or sensitive data, which is a category of higher risk or more intimate type information. Usually that includes things like health conditions, health diagnosis. Again, we are not talking about HIPAA-covered data but if it is collected by a mobile app, for instance. Health conditions, sexual orientation, race and ethnicity, religion, things that would be considered uniquely revealing about people if they were released or uniquely high risk. Sensitive covered data in most states requires affirmative express consent.

Now, not all these states have come into effect yet. The strong affirmative consent provisions that we see in Colorado, Virginia, and other states do not come into effect until 2023. California has a more flexible or lax standard for sensitive data. Instead of a right to opt in, it is a right to opt out abuses of sensitive data. But nonetheless, very significant I think for the health community, very significant for commercial research that these are typically not subject to many exemptions. This really can change things for any private entity or nonprofit processing any form of sensitive data.

Finally, just a quick word about enforcement because it has been such a major political issue. In almost all cases in the states, these laws are either currently enforced or they are set to be enforced when they come into effect next year by the state attorney general. That is the case in Colorado, Virginia, Utah, and Connecticut.

Largely speaking, folks in civil society and privacy advocates have been pushing very hard politically for stronger enforcement through private liability, civil lawsuit ability, and of course the business community very much opposes that.

For the most part so far, attorneys general are the primary regulatory enforcers of this law. And AGs, it might surprise you to learn, have really stepped up into the privacy debate in recent years, not just in this context but through wielding their own unfair and deceptive practice authority similar to the FTC to bring enforcement cases around data privacy, including where it affects health. I am happy to talk about that.

State attorneys general are the enforcers of most of these laws. Some AGs have also been granted additional rulemaking powers. That is at least the case in Colorado. The Colorado Attorney General's office has recently been soliciting public comments from all across the country about what kinds of rules and guidance they ought to be promulgate to supplement, further articulate, and provide guidance around the new Colorado Privacy Act.

In California, it was also the State Attorney General under the CCPA but with the enactment of the California Privacy Rights Act amending the CCPA in 2020, California actually went farther, did something very significant and established the first in the nation dedicated state privacy enforcement agency, the California Privacy Protection Agency. You might hear about that agency now as well. They have administrative enforcement and rulemaking power over the CPRA. They are actively engaged in that right now. We have actually draft regulations out that they are solicited comments on for the next 30 days or so. Really a huge deal.

At 10,000 feet, the United States is really catching up to the rest of the world. It is a very exciting time. I would be happy to dive further into any of the micro-details of any of the state laws if folks are interested.

Melissa Goldstein: Thanks so much, Stacey. It is complicated and interesting. I am sure we will have a lot of questions for you. Be prepared for lots of questions. Thank you.

Lauren, let us move to you, if this is a good time.

Lauren Riplinger: Yes. Absolutely. Thank you. I am going to share my screen. I have a couple of slides for folks. Really excited that the committee is thinking about this topic today given the share of health information that is generated outside of HIPAA-covered entities and just really the overall growing complexity around information sharing.

I want to spend a moment for a second talking about the importance of proving some of these privacy laws that are currently out there. And I think folks can all agree that the scope of health information has expanded. But to Stacey's point just now, the laws ensuring the confidentiality, privacy, and security of this information is still catching up. We see that with health-related discussion forums, genealogies, science, geolocation data that might denote information regarding a health care service you received or remote monitoring technologies that may be used for personal use as well as potentially being prescribed by physicians.

As my other panelists have mentioned, we are also seeing this increasing number of consumer-facing technologies that can access, produce, and manage health information but they are not covered by HIPAA. Oftentimes, they are bound by their own privacy practices in terms of how they can use that information. Unlike HIPAA, there might not be a prohibition on the – marketing of that health information if it is disclosed in the practices.

That creates a couple of questions. As we anticipate data flowing beyond the walls of HIPAA to accelerate how are we making sure that this information is being kept confidential, protected, and secured consistent with an individual's expectations.

Relatedly, what are the implications for HIPAA covered entities if data is shared and consistent with individual's expectations may not necessarily be a violation of HIPAA but that individuals still may feel like their privacy was compromised, which we know can erode trust. And the last discussion relates to SOGI data and SDOH data kind of talks a little bit about that trust factor so critically important.

At the same time as data flows in and out of the HIPAA regulatory framework, how do we make sure interaction with HIPAA does not lead to confusion and at the end of the day is implementable by HIPAA non-covered entities?

I will also add because I know this is an area of focus for the committee in the past is that in this expanding world of the data and data analytics, we see entities continuing to amass large data sets from sources both within and beyond HIPAA. And the assumption historically has been that de-identification protects privacy. But as these data sets are increasingly being combined to glean insights, there is a greater chance of individuals potentially being re-identified. How do we ensure that there are sufficient controls in place to prevent re-identification of the individual?

Finally, I will just add that the current patchwork of state and federal laws governing health information – that variability has made it difficult from our perspective for health information professionals who we represent to really navigate to ensure compliance. I think that is an important part of the conversation.

I will not spend too much time on this slide really other than to say it just kind of demonstrates and provides some data around the fact that individuals are increasingly sharing and generating health-related information beyond the scope of HIPAA.

My two prior panelists talked a little bit about this but this just kind of demonstrates the complexity of the current policy landscape related to privacy and some of the pieces that we kind of have to think about in the course of this conversation. It creates a larger question, which is how does the new federal comprehensive privacy law really fit into this landscape? We will talk a little bit about that in just a moment.

I think we also have to think about the policies that have been put out there in the last couple of years around increasing access, use, and sharing of information. Since 2011, HHS has been very focused on driving policy that increases access to the sharing of health information that is held by providers and payers but tied to that are also policies that really just overall seek to enhance the data sharing beyond the scope of HIPAA.

We have to think about the Promoting Interoperability Program, really encouraging providers to share data, the Interoperability and Patient Access Rule really focused on encouraging payers to share data. Of course, the 21st Century Cures Act as well as the Cures Act Final Rule. Again, sharing data more broadly.

But it is also thinking about some of the more recent policies with HHS and Congress as it relates to price transparency. This started with a hospital price transparency rule followed by the transparency and coverage rule. But it also includes things like provisions in the No Surprises Act, which includes provisions related to requiring providers to offer good faith estimates to patients regarding a scheduled item or service as well as requirements on payers to create an advanced EOB for their beneficiary prior to receiving service, which kinds of brings us to the federal perspective of the American Data Privacy Protection Act.

We have seen in the last two Congresses this growing interest in catching up with the states, as Stacey might say, to really develop a comprehensive privacy bill. And the conversations have really been focused on having a broad applicability of this legislation with the Federal Trade Commission really leading enforcement actions.

But tied to that, there has also been some intentionality of creating carve outs to federal laws that already protects some of this information and that includes HIPAA.

I want to talk a few minutes about the legislation that is on everyone's minds, I guess, and that is HR 8152. Earlier in the summer this year, the legislation was referred to the House Energy and Commerce Committee. It was marked up at the Full Committee level yesterday. It did pass overwhelmingly with overwhelming support I should say out of the committee yesterday as well. The chairman did offer an amendment in the nature of the substitute to basically replace the existing bill text. When I talked about it in the next slide, it is really reflective of this latest version that the committee approved.

I will also note that this is a bicameral, bipartisan legislation. We refer to it as the three-corner bill in colloquial terms. What that means is that it currently has the support of the ranking member of the Senate Commerce Committee, Senator Roger Wicker, as well as – of the Chairman of the House Energy and Commerce Committee. Congressman Frank Pallone, and the ranking member of the House Energy and Commerce Committee, Congresswoman Cathy McMorris Rodgers.

Some of the key sections in this legislation and I will not go into too much depth in the interest of time. But Title I really talks about the duty of loyalty, what are the data – requirements, including permissible purposes and prohibitive practices. It also includes provisions related to privacy by design.

Title II is specific to consumer data rights around consumer awareness and transparency as well as data ownership and control and the right to consent and object.

Title III is around corporate accountability, which really is specific to what are the responsibilities of the executives of entities that are covered under this legislation.

And finally, you have Title IV, which is around enforcement and applicability. This really talks about the enforcement to be done by the Federal Trade Commission, enforcement by the state attorneys general, the private right of action, preemption, and relationships of other federal laws.

Two key areas that are currently under negotiation, we will talk a little bit more about this in the next slide, is the federal preemption of state laws and the private right of action.

Taking just a little bit of a deeper dive, how does this specifically intersect with health information? I think first and foremost, it is important to note that this legislation addresses all data and not just health data. A lot of the motivating concerns that really brought this legislation together was concerns about how data is being used by data brokers and big tech companies. I will note that a lot of the nuances around health data are not necessarily entirely accounted for in the crafting of this legislation.

That said, I will say that health data is identified as sensitive covered data. It is subject to more protections, fewer permissible sharing of that data, which is an important consideration.

The legislation also carves out covered data subject to other federal data protection laws, provided that covered entity is deemed to be in compliance with data privacy and security requirements of other laws.

But this kind of creates an interesting question that folks are kind of pondering right now in health care and that is what happens if a covered entity under HIPAA is not deemed in compliance. Will it be subject to the comprehensive privacy law? I think that is a little bit of an open question right now.

I will also add that while the legislation does add protections generally, it does not resolve necessarily the issue for individuals that might have the same health data, but it has different protections based on whether the holder of that data is considered a covered entity under the legislation or not.

That said, a key element of this is that this legislation does seek to address a lot of the gaps in the privacy and security protections I talked about earlier, i.e. those applications that receive or generate health data but they are not necessarily covered by HIPAA. They more than likely would be covered under this legislation. I think that is something important that we need to recognize, given concerns in the industry about that information flowing outside of HIPAA.

I will also note that the legislation excludes de-identified data from covered data. However, the de-identification definition in the legislation is not the same as defined under HIPAA. That is very consistent

with what Stacey talked about at the state level. It does create this question of how this gap will be bridged between HIPAA non-covered entities and HIPAA covered entities.

I will also note the legislation addresses the current patchwork of state laws that govern data privacy and security by preempting many of these laws. Yesterday with the acceptance of the amendment in the nature of the substitute, the number of exemptions has further narrowed to the point that it is only two Illinois laws related to biometric and genetic information as well as the California Private Right of Action related to data breaches are exempt under this legislation. I think that is an important piece to keep in mind.

Other aspects that are addressed in this legislation include again enforcement by the Federal Trade Commission as well as a private right of action. Under the original bill text, it was four years after the date went into effect of the legislation that an individual could seek a private right of action. After some negotiations, the bill went under the amendment in the nature of the substitute was amended to – so an individual can seek those two years after the effective date of the legislation.

However, I will note that the preemption and the private right of action are still considered very controversial, and they continue to be debated even after this bill has been approved by the committee. You will continue to see those conversations go forward if this legislation moves to the House for a floor vote.

One other thing I would like to talk about is just what are some of the opportunities for further inquiry for this committee in leveraging your expertise. First, I think there is a need for a systematic evaluation of HIPAA. And what I mean by that is how does the American Data Privacy and Protection Act interact with HIPAA. I used this example before, but I think it is a good one. If a covered entity is found to not be in compliance with HIPAA, would it be found through not being compliant with the ADPPA? I think that is an important conversation to have in terms of what that looks like.

The second thing I think there is an opportunity for this committee is to think about and focus on de-identification to protect individual's privacy while enabling the data to be used to inform a learning health system. This includes exploring new models for de-identification as well as opportunities to bridge this de-identification gap between HIPAA and HIPAA non-covered entities.

Finally, I will add that as the COVID-19 pandemic continues, we need to continue to better understand how we can increase the liquidity of data for public health without jeopardizing the confidentiality, privacy, and security of an individual's health data.

Let me stop there. I have a couple of resources in the deck that would be helpful to this committee. But I am happy to answer any questions that folks might have.

Melissa Goldstein: Thanks so much, Lauren. That was great. Again, I already have a bunch of questions and I am sure others do to. I look forward to having time to discuss.

Cobun, we would love it for you to present now. I do not remember whether you have slides or not.

Cobun Zweifel-Keegan: No, I do not. I was just going to talk to you without slides. I will try to be brief so we can get to some questions and conversation. Thank you so much for the invitation to speak with all of you today. It is a privilege with this audience about general privacy developments especially on the same virtual stage here as my fellow distinguished guests.

I am the Managing Director for the DC Office of the International Association of Privacy Professionals. We do generally say I-A-P-P even though IAPP would probably be easier to say. People do call it IAPP sometimes.

IAPP is just for those who are not familiar with it, we are a nonprofit, global, professional association. We work to define, promote, and improve the privacy profession. Basically, we sit at the center of the people on the ground practicing data protection and privacy in organizations of all types around the world.

I am a policy lawyer. But IAPP is generally policy neutral. To us, that means that we do not weigh in on where standards and practices should go. But instead, we try to track and amplify this always evolving conversation that we have already heard a lot about today. We try to ensure that our 75,000 individual members are kept up to date on the norms and regulatory requirements that shape the work that we do.

I guess I am going to be covering the international state. We talked about state, US and now it is like everything else. That is a big scope. It is kind of hard to cover the global stage without launching into history. We already heard Stacey kind of have the same tendency I guess to go into a history of us about where these privacy regulations come from. I will just briefly do that as well.

Just starting decades ago with the Fair Information Practice Principles to OECD Guidelines and these other foundational documents that undergird an initial wave of legislative activity. First here in the US in the sectoral rules that Stacey mentioned, including the rules that cover government agencies and then some of the things like health care and other sectoral laws. Those were generally sort of – those first principles what helped to inform and create the rules as they were established. That conversation also began to happen on the international stage. What really kicked that off though was the European Union, as Stacey mentioned, first taking those principles and codifying them in an Omnibus Regulation that had teeth.

I think it is worth noting that the US and the EU differ a bit in how they approach data protection and privacy. It mostly boils down to a difference between considering privacy protections as flowing from fundamental human rights as the EU works to do at least versus flowing from more consumer protection law and the other historical recognitions that we have in the US like privacy torts.

In practice though the standards that come from those different origins have developed in parallel and are broadly similar. But the EU, as I said, was the first to put that real enforcement teeth behind data protection rules. What started in 1995 with the data protection directive became the General Data Protection Regulation or GDPR in 2016.

I think as Stacey mentioned, the GDPR had a major impact on the policy conversation in a way that continues to flow today. It really fueled the compliance programs of a lot of organizations both doing

business in the EU or just interfacing with others who do. It kind of pushed best practices forward at a faster pace than we had seen before in this community. That trend really – it kick-started it and it has just continued from there. The pace has not slowed, I think.

Many countries have adopted GDPR-style data protection laws since GDPR became into effect. We now have – there is well over 100 countries – comprehensive privacy laws on the books.

What those laws do – here, we are talking about again as Stacey mentioned the kind of consumer or individual rules of governing how data is processed, personal data, in particular. They tell you how you can collect, process, share personal data. They also create obligations on organizations to inform individuals about the practices that they have and to respond to various individual requests like to delete data and the other types of requests that Stacey already outlined in the state laws.

The one additional factor that is often part of the conversation in an international context is data flows, which is kind of broadly speaking, the freedom to transfer personal data that has been collected in one place about individuals in that country across borders to another country.

That conversation has been a complicated one. You can kind of divide the trends in two opposite directions basically. One towards restrictions that lead to more localized data either explicitly or sort of de facto and how the regulations are applied and another toward more open flows of data. You have probably heard about movement toward increasingly localized or balkanized data flows. Russia has explicit localization requirements. China is moving in that direction.

The EU takes a more bureaucratic approach to data flows. They open them up to jurisdictions that are deemed to have similar protections and otherwise require additional compliance obligations from organizations that are transferring to other jurisdictions, the kind of not preapproved jurisdictions. And that is where the ongoing negotiation between the US and the EU for a replacement to the privacy standards agreement. That is where that comes in.

At the same time, there is also trends toward opening data flows. I think it is this ongoing question of how all of that will play out. But a lot of that work includes building accountability structures around existing data flows to make sure that there is some level of foundational agreement there.

I think the best example is in the Asian-Pacific region. There is an idea called data free flow with trust, which I like that. I really like that phrase. Basically, it signifies that kind of rooted in these principles of mutual understanding between countries. We can establish uniform baselines and then provide for flexibility between countries as to what their specific requirements are if they go above and beyond the baseline. I think that idea was really advanced some when the US Department of Commerce earlier this year helped to move the cross-border privacy rule system, which was formerly an APEC, an Asia-Pacific Economic Cooperation program from that regional program into a new global forum, which will allow participation by a lot of different countries. That will be really interesting to watch that play out. Otherwise, the conversation about data flows is just continuing.

I think another good example that people are watching is the United Kingdom. After Brexit, the UK is overhauling its approach to data protection generally that will include data flows, it appears. It is kind of

signaling that it may pivot away from the EU approach. We will have to see how far it moves away from that approach.

There are other countries with existing privacy standards that are continuing to update those standards, not just for data flows, but in general. People are watching Canada right now. Costa Rica and Australia are also in ongoing updates.

As far as like privacy generally, data privacy protections, I think Brazil has – they now have an Omnibus set of privacy principles, privacy law that they are enforcing. They have just begun enforcement on that and that certainly caught companies' attention because it did expand on some protections.

As I mentioned, China is definitely on the radar right now because they are finalizing multiple sets of comprehensive privacy standards and strict data transfer requirements.

India is not far behind that they have had some hurdles that they are working in in terms of their legislative process. Other countries are also starting down the road right now to Chile, Indonesia, Paraguay are all kind of actively considering legislation at this moment.

And then the EU, never to be left behind, is remaining on the cutting edge I guess of regulation. One of the main themes of conversations that I track here in DC is around AI, the use of algorithms. The EU is definitely focused on thinking about how AI and other new technologies should change their regulations. The European Commission has an entire strategy on data and AI, which has led to a whole alphabet soup of proposed regulations at the DSA, DMA, DGA, the data act, plus harmonized rules on artificial intelligence. Those do not all focus specific. They are not privacy rules specifically. They do not all just focus on personal data. Some are more focused on anti-trust. They apply to different sets of entities. But they all impact that responsible handling of data in various ways. If you would like, I can talk more about some of those in details especially the DSA, which is the most on point one.

I guess I will just quickly mention. I do not focus on health or research data in those conversations in my day-to-day as much as like the specific issue. But that does remain an ongoing part of the conversation especially after the pandemic in this international context, trying to create interoperable standards around sharing of research information is an important issue that regulators are definitely aware of and I think there have been roadblocks that have come up in some of these contexts. But they have attempted to work through them. I think that is an ongoing issue.

I will just close by saying that the world's largest economy is closer than ever to comprehensive privacy law as Lauren told us about. We will see where that takes us. That has been keeping us in DC very busy this week. I am happy to talk more in detail about that or any of these international things that I mentioned.

Melissa Goldstein: Thanks so much. This was so fabulous. We recognize that you guys are especially busy this week, although you were busy last week too, but we really appreciate your sharing time with us today. We really do appreciate it.

Val, would you like to pose the first question while the other members of the committee come up with your questions. I would ask that you raise either your real hand or your virtual hand for those questions. Go ahead, Val.

Valerie Watzlaf: Thank you. This has been fabulous. Thank you all so much for all of your presentations.

I think as far as we are concerned, we would love to know what your perspective on areas and issues or advice to HHS would be timely and constructive. Are there specific ones that you could narrow down that you would like us to focus on specifically as we move ahead?

Lauren Riplinger: I am happy to jump in. I think my last slide is kind of some of those key areas. I think really understanding how HIPAA interacts with the potential comprehensive privacy law because a lot of folks have questions about that. What does that look like? How do I know?

There are also conversations about if I am an entity that I have a HIPAA line of business, but the rest is not covered under HIPAA, how do I comply with both of these and what does that look like? I think that is an important question.

I would also add, given the committee's work on the identification, I think it has a real opportunity. Stacey kind of touched on this a little bit. Is the current standard in HIPAA no longer sufficient? When we think about protecting the confidentiality of an individual or de-identifying that information if we are bringing those data sets together, we need to think about that. We needed to raise the boats so to speak to be consistent with – or what has been proposed. I think that is an important question.

Valerie Watzlaf: Thank you, Lauren.

Any others who would like to give their perspective on what we could focus on?

Cobun Zweifel-Keegan: I can briefly say something on that. In talking to organizations, I think one of the most impactful things regulators often can do or any agency is to help provide guidance whether official or unofficial about thinking through some of these issues whether they are flowing from regulations or just best practices. I think sometimes it is often the case inside organizations that people are looking to point to something to just help them figure out how to operationalize, how to have a roadmap to working through this. I think specifically what was already said about working through HIPAA versus not HIPAA-covered health data makes sense. But really anything toward helping to navigate the variety of issues in specific industries that might come up is really what was welcomed by the community, especially of privacy professionals working inside organizations trying to make sure that people do the right thing.

Valerie Watzlaf: Thank you. Thanks so much.

Stacey, were you going to --

Stacey Gray: Sure. One of the biggest issues from our perspective is that I think it is actually not being paying enough attention to, paid attention to enough is this question of what norms and legal standards are going to be around commercial partnerships and commercial data-driven research even when it is

not conducted by companies but sometimes when it is conducted directly by companies in partnership with academic institutions, health care professionals, and researchers.

If we want to have real-world data-driven studies in research, if we want to do evidence-based policymaking, there is a great deal of interest and there is even a great deal of external pressure to conduct social research, for example, to understand things like the effect of social media on mental health that requires the access to underlying commercial data, which is directly intention with privacy in many cases.

The Future of Privacy Forum is very supportive of commercial partnerships when done with appropriate privacy safeguards. But not everyone agrees with that. They do not necessarily want their Fitbit data being shared with medical researchers to try to make new breakthrough kinds of investigations. We need to start to understand those norms. We have to do it nationally.

There is also a great deal of interest and a bit of a market disconnect right now with private companies seriously investing in privacy-enhancing technologies because of the regulatory uncertainty, because as has been mentioned, because of the lack of a set of national standards and guidance around things like what does it mean to be appropriately de-identified. What does it mean to pseudonymize data to reduce risk and still be able to conduct socially benefit research? There is a huge promise in privacy-enhancing technologies. You see academic institutions like Carnegie Mellon with these robust certification programs being rolled out.

There are tons of privacy engineers now in the market but a disconnect with companies who are hesitant to invest and adopt because of the regulatory uncertainty. This is a place where a national entity working in collaboration with entities like NIST, working with the Federal Trade Commission can just do a tremendous amount of good.

Valerie Watzlaf: Thank you. I appreciate it.

I do not know how much time we have left. Melissa, I did not know if you had a question or if you wanted to open it up.

Melissa Goldstein: I do but I will open it up to the other members to the committee.

Maya Bernstein: If our panelists are available until 1:30, I think we have until 1:30.

Melissa Goldstein: About 17 or 18 minutes, it looks like. I will go ahead if no one else has a question. I think oftentimes at the state and the federal level, people in general even some lawyers who are not keeping up with everything on a day-to-day basis like you guys are, hear that there are sectors specific exceptions to, for instance, the state laws and to the federal laws that have been percolating over the past several years and think I am a HIPPA-covered entity. Now, I do not have to worry about that. Or I am not a HIPAA-covered entity, but it is sector specific, and I am a health care app so I do not have to worry about that. But that does not sound exactly true.

I would like for you to go over a little bit more specifically. Cobun, this does not – if this is from an international perspective as well because health data is covered from an international perspective, but it is a little bit even more complicated than this situation.

Kristin, I am sure you get 100 questions about this all the time. OCR does not cover us, but do use guys cover us? And what does it mean sector-specific exception under what is happening in Congress right now? FTC obviously has a broad purview now. But it seems like it would be even increased or changed a little bit under this. I am sure you guys are following this every day as well.

My question is how we could narrow this down in our minds to how much health care data within HIPAA, beyond HIPAA, genetic data, biometrics data, that one you mentioned like, what is the general sense about the sector that we are most concerned with. Of course, we are concerned in general, but most concerned with.

Stacey Gray: I can definitely start. I suspect Lauren may have views here as well. The best way to think about this is that the sectoral exemptions broadly speaking, but I will just talk about HIPAA as a good example of this, are for the most part, data driven exemptions rather than entity-based exemptions.

I do not want to say for certain because sometimes states get this wrong and they kind of mess it up. In some drafts of legislation, for instance, we will occasionally see entity-based exemptions that say HIPAA-covered entity is not covered. That is generally not considered an ideal approach because in some cases, Amazon is a HIPAA-covered entity. The intention of most drafters is not to exclude an entire covered business from the scope of the law because some of its business practices are regulated by sectoral laws. Rather it is the data.

Reading directly, for instance, from the California Privacy Rights Act, this title shall not apply to any of the following medical information governed by the CMIA or protected health information collected by a covered entity and governed by the applicable rules under HIPAA.

That means that entities that think of themselves as covered entities to the extent that they are still a commercial entity or a nonprofit under FTC's jurisdiction should be considering any additional non-HIPAA-governed, any additional commercial data that they may be ingesting or onboarding or purchasing.

Similarly, private entities even though they may in some cases be HIPAA regulated, should not consider that that is a sectoral carveout – they still have to comply with all of the state provisions with respect to the rest of the data. And then you get some real complications when you combine the data. I will not even try to be a legal counsel there. But that interplay is very challenging for covered entities.

It is also worth noting that politically speaking, it is not that – sometimes these laws are criticized. They are not really comprehensive laws because they contain sectoral carveouts. I would say not the case. This is primarily an issue of political and regulatory capacity. I have not spoken to anyone at the state or federal level that is interested in reopening and renegotiating HIPAA. Might it one day be a good idea? Perhaps. But I just absolutely have no capacity to do it. In the interest of passing a law, generally, you see carve outs. That is certainly the case for HIPAA. There may be other sectoral laws that are more open to negotiation like the Gramm-Leach-Bliley Act, but I will not go into that.

That is my two cents on the sectoral carve outs. Is that helpful?

Melissa Goldstein: Yes, very. Thank you, Stacey.

Certainly, open to comments from – Kristin, go ahead.

Kristin Cohen: I was just going to say I can speak a little bit to the current law. I just wanted to relay something I mentioned in passing, which is that I think the FTC Act does have concurrent jurisdiction with some entities covered by HIPAA. We have brought cases like against CVS and Rite Aid where OCR brought a case. We brought a case. I do not think that they –-

And I guess the other point is that we do try really hard to work collaboratively with our counterparts in OCR to make sure that we do not want to waste resources by everyone going after the same entity. But at the same time, sometimes we have different coverages of different data in the way that Stacey talked about. Sometimes an entity has a HIPAA-covered aspect of their business and a non-HIPAA-covered aspect of their business.

In terms of the sectoral carve outs and I agree that most of the time with these laws that we are talking about, it is data driven. I just wanted to highlight that in the FTC's case and some of this might change with some of these bills but just to make clear. We do have carve outs for the most part with respect to nonprofits and things like banks and also entities that are in the business of insurance, which can have some health data. We do have some entities that are carved out of our jurisdiction although there are specific laws that bring them into our jurisdiction and certain circumstances where there are certain bills, privacy bills that have given us some ability to look at nonprofits. That is not exactly sectoral but is more entity versus the data-driven carve outs.

Lauren Riplinger: Just to add to that. I know there has been a lot of conversations I mentioned over the deeming, if you are deemed to be in compliance with HIPAA. A lot of folks are saying what does that mean.

Kristin's point is a really important one because that has been one of the things where the committee has pushed back from folks who have said we want a specific carve out for HIPAA because you are giving the FTC jurisdiction under this legislation and the counter to the committee is they already have that jurisdiction to Kristin's point. I think that is an important point to recognize as part of this conversation.

Melissa Goldstein: Thank you.

Cobun, I just wanted to give you a chance to jump in if you wanted to speak to the international approach here.

Cobun Zweifel-Keegan: I would have to – I am trying to think if I have -- I think the same general rule applies I think overall in terms of how this is thought about. I guess there are three different things, three different important factors in thinking about whether a law is going to apply in privacy usually. We have covered two of them, which is the type of data and the type of entity.

I think also there is this – one of the main important things is thinking about the relationship between the individual, data subject, as the EU would call it, and the company or organization processing the data and that plays a role both internationally and, in the US, where we are thinking about – and under HIPAA and in other places where we are thinking about whether you have a direct relationship. You actually collect the data from the subject or whether you are under obligations to process it just in keeping with – as a service provider or something like that. I cannot come up with countervailing examples.

Melissa Goldstein: Thank you. That is super helpful.

We have two questions from committee members now. Vickie Mays and then Denise Love. Vickie, do you want to go first?

Vickie Mays: Thank you. There are two issues for me. I heard some really interesting comments about it. One is in terms of thinking about de-identification. When we marry the issue de-identification to technology, I sometimes think there is no such thing because people can give identified back. If people have very specific kinds of recommendations of what they think we should be thinking about in that realm, I would love to hear it.

My second has to do with – just before this we had a workgroup presentation about SOGI and social determinants of health. There, the privacy issue is particularly in terms of SOGI, are really concerning as we see jurisdictions kind of changing what we are supposed to do and how that affects health care. Again, I would ask. If you have any specifics like this, this is the time for your wish list for us. I would love to hear it.

Melissa Goldstein: Anyone want to tackle that?

Lauren Riplinger: I will say, Vickie, that we probably just need to think about it a little bit more. The SOGI issue and SDOH is a hot issue for our members. How do you ask for the information? How do you maintain the integrity? All the three issues you talked about in the prior session. You would have to think about it a little more to be honest.

Melissa Goldstein: Thank you.

Kristin Cohen: I do not know if this is quite on point, but I will just relay it. I think de-identification is really hard, as you know. One of the things we said back when we issued our privacy report in 2012 was that it was both about making sure that the data was de-identified to a reasonable level of competence but also having those policies and procedures in place to publicly say you are not going to re-identify it and require that any entities that have the data also sign on to those policies.

I would also say and this is somewhat related is that in the non-HIPAA context, I think sometimes we see companies who try to -- consumers feel okay about turning over their data by claiming that it is only going to be used in an anonymous way and that is often really not at all the fact that they have mobile identifiers or things like that that are just not at all anonymous and that can very easily be tied to an individual consumer. That was one of the things that we did highlight in the blog I mentioned and the fact that that really can be a deceptive trade practice. I think that is something that we are looking at

really carefully. I know that is somewhat different from the process of de-identifying data but I do think it is an important point about making sure that we are not claiming something is anonymous when it really is not.

Maya Bernstein: I did put a link to Kristin's blog post in the chat. I could put it there again if people missed it.

Cobun Zweifel-Keegan: I have a little weekly column at IAPP. I wrote about the FTC's blog post last week because I think it was an important signal to be drilling down on this point about – certainly, avoiding the word anonymization but also thinking really in a detailed level about what de-identification means. In that, I gathered some of the government guidance on de-identification from various sectors and countries. I noticed in doing that that a lot of it is a little bit dated. OCR has guidance on de-identification but it is from 2012. Updating that might be helpful in the modern setting because it really is a bit of an arm's race as becoming more capable of – and combining data. It changes how we need to think about what de-identification looks like. Updating that but also maybe if that is outside of your purview, which it probably is as a committee, just providing more of that, helping people think through especially issues around it is not just about people's names. It is about the ability to identify people and thinking through operationally what that kind of guidance looks like for organizations would be really helpful.

Vickie Mays: Will you make sure to share your blog with us?

Maya Bernstein: I just tried to look for it but I only found something more brief. I think I did not get the right link.

Melissa Goldstein: We have three- or four-minutes left. Denise, I want to make sure that we get your question in here.

Denise Love: This may be out of scope but Cobun kind of jogged something that I have been working on with states. We have the Trusted Exchange and Common Agreement or TEFCA for data exchange across our jurisdictions between covered entities and non-covered entities. It is pretty clunky right now. It is not very liquid data to be honest in at least my observation.

I guess it is for Lauren. Will the new laws or the new emergence of laws, how would that affect something like TEFCA for cross-jurisdictional exchange of data that is needing to be more timely and robust?

Lauren Riplinger: I do not even know where to start. That is a big question. We are still in some early stages with this legislation. The biggest sticking point is we do not have a four-corner bill yet. Until that happens, the bill is likely subject to change. Even if it gets out of the House, it might get stuck in the Senate because we do not have that agreement.

It is hard to say at this point given that if we think about TEFCA in a broader sense of having entities that are not covered by HIPAA, exchanging that data, I think there will probably have to be an evaluation of what those policies or that contractual agreement kind of stipulates of how that needs to be altered in terms of how that data is.

Sequoia has done wonderful work and I know that they are tracking this closely. I know that is not a great answer but I think it still remains to be seen.

Denise Love: Maybe HHS may be a guidance at some point – we were talking guidances because I am talking to a few folks on the ground. It may take a year to a year and a half to do all the contraction revisions related to HIPAA. That is not liquid public health data. That is not going to help us. I was a little discouraged when I heard that it would take just one entity working with HIE to be about a year, a year and a half in contracts.

Melissa Goldstein: Thanks Denise. Obviously, that depends from my perspective on the covered entity and the HIE and the lawyers involved. Not all of them will take that long I am hoping. I am hoping we can – work out there. That is great.

Val, do we have any closing times because I saw Jackie pop up. That means that it is time for us to go.

Valerie Watzlaf: It is 1:30. This has been fantastic. Thank you all so much for being here and sharing your perspectives. I think it was a great discussion. Thank you again. We really appreciate it.

Maya Bernstein: I might just add that if there is anything that you think that we should have that you can amend the record or add more materials, you want to send us a link to your blog post, I have them. But formally, we will keep that with the record for a couple of weeks. Feel free to do that. Thank you so much.

Jacki Monson: Thank you so much. We are ready to take a break until 2 o'clock. We will see everybody back at 2 o'clock. Thank you.

(Break)

Tribal Epidemiology Centers: Data Access and Privacy

Jacki Monson: Vickie and Val, who are going to kick off the tribal epidemiology panels.

Vickie Mays: Thank you. I think I am the start here and then Val is going to be stepping in as well. First of all, let me start by thanking our panelists. We have an excellent group of individuals. I thank them greatly for their time. One thing COVID has taught us is that everything takes longer so we are all super busy and COVID has taught us to also appreciate the time that we have.

One of the things I want to do is to make sure that you understand how much we appreciate your time by giving you a sense of the committee's interests and its commitment to this issue over time.

One of the things that we have done is we have a very long history of working on these issues in terms of the health data and health issues as they apply to American Indians and Alaskan Natives. I think back when I chaired the Population Committee, we used to have before the FACA rule changed, a representative from the American Indian Health Service and that was Edna Paisano in case anybody remembers here. Edna used to sit with us at one of our population health meetings and her voice was strongly and well-represented and we appreciated that. I think back in 2012 and you can find a lot of this

on our website. We held a session in which we talked about the issue of data quality in American Indian and Alaskan Natives. We held sessions where we talked about consent, de-identification, research regulations. I just want to thank you for being here because we want to be able to both honor the issues that are in our purview and to thank you for helping us to do our work better than we would do without your voices. Thank you very much for being here today.

What I am going to do is to actually turn this over to Rachel Seeger. Many of you did not see. We have all been sending little emails to Rachel to welcome her back because she was one of our former lead staff in the Privacy, Confidentiality, and Security Committee. She served with great distinction, which is why she is now with us now because she was actually bumped up and promoted as the head of Public Affairs and Communications for OCR. Given the expanded work of OCR under the President's commitment to equity and privacy, they wanted Rachel. Rachel is not with us here. But in terms of this privacy work, it really has her stamp on many of the things that we did.

Let me turn it over to her because what she is going to actually do is talk about one of our late colleagues, Sallie Milam, and really explain to you the depth of how this work is in our DNA and the Committee. Rachel, welcome back. Great to have you.

Rachel Seeger: Thank you so much for that warm welcome, Vickie. It is so good to be here with all of you and I appreciate you having me. I just want to keep my comments brief so you have the maximum time that you can have with the panel but a few words about Sallie and her passionate work in this space.

Sallie touched the lives of so many around her. As a member of NCVHS, she was just energetic and hard-working part of the PCS Subcommittee who always contributed with her thoughtful perspective on privacy law with a side of her famous good humor, wit, and cheer. She will be fondly remembered for her efforts in planning public hearings, developing recommendations, and other important work products. She was simply a joy to be around.

She leaves a lasting legacy of privacy work for communities all over the country and a network of linkages across federal, state, local, tribal, and private organizations. And those of us who were lucky enough to work with her and spend a part of our professional lives with her, remember her warm smile and effervescence. She was really one of a kind and so skilled at bringing people together. We are all here today because of her.

Sallie approached me in August 2020 at the height of the pandemic, and she was grappling with questions around data sharing with state health departments and she came to ne about a year later, again, still at the height of the pandemic with questions around tribes, tribal organizations, tribal epidemiology centers with respect to whether HIPAA-covered entities can disclose PHI for public health purposes without a patient authorization as public health authorities under law and if HIPAA-covered entities can rely on these organizations, minimum necessary determinations with respect to public health data sharing.

Sallie's research in this area of the law and looking at public health authority of tribes and TECs, especially in light of the COVID-19 public health epidemic, this has helped us pave the way for today's session.

Her memory remains a blessing to us all and I am so happy that you are all here together to take up this work. I am going to hand it back to you, Vickie. Thank you for your time.

Vickie Mays: Thank you, Rachel. Let me turn this over to Valerie to really introduce our guests. But I think you have a clear sense of why we are here to hear from each of you.

Valerie Watzlaf: Thank you, Vickie. I also want to just thank all of the panelists that are here. We are very much looking forward to your presentations and also the discussion afterwards and also thanks to Maya Bernstein again for putting this panel together. We really appreciate all your hard work on that.

I did not know Sallie, but I feel like I do because of all the wonderful things that have been said about her by so many of our colleagues and so many others.

I am going to introduce our panelists very briefly so that we have more time for our questions and discussion. Each of their bios are available too, on our website. And also panelists, please feel free to share more about yourself if you would like to during your presentation as well.

I will introduce the panel also in the order that they will be presenting. Our first person is Kirk Greenway. He is the Director of the Office of Public Health Service Division of Program Statistics and a principal statistician of the Indian Health Service. He will be joined by Heather McLane, who is the Senior Official for Privacy and the Privacy Officer also of the Indian Health Service.

We also have Kristin Ekelund, who is a Senior Analyst of the Health Care Team at the US Government Accountability Office or GAO. She is accompanied by Tricia Roy, who is also a Senior Analyst on the Health Care Team at GAO.

And then we have Abigail Echo-Hawk, who is currently the Executive Vice President at Seattle Indian Health Board and the Director of the Urban Indian Health Institute.

Our last person, Jerilyn Church, who is the Chief Executive Officer of the Great Plains Tribal Leaders Health Board.

Again, thank you so much for being here. If you can keep your presentation within the ten-minute timeframe, we would appreciate that. We are going to start off with Kirk and Heather.

Heather McLane: Wonderful. Thank you so much. Let me go ahead and share my screen.

Maya Bernstein: While you are getting that together, Heather, I just want to say a particular thankyou to you because I understand that your office was 123 degrees this morning in Texas. We are delighted to have you under the circumstance that you find yourself with the crazy weather down there. Really appreciate you.

Heather McLane: My office is hovering at about 128 right now. I just want to start real quick with an introduction of Mr. Greenway and myself. Mr. Greenway is the principal statistician of the Indian Health Service, and he has worked for IHS for 17 years. For the last ten years, he has been the principal statistician and prior to that, he was the senior statistician. He has also worked with Navy Medicine,

Aspen Naval Medical Records Repository, which is pretty nifty. He has an MPH in international public health from University of Alabama and a Master of Art from University of Chicago.

And then myself, I am the senior official for privacy at IHS and the privacy act officer, the HIPAA privacy officer. I have worked for IHS for 11 years. For the last six years, I have been the privacy officer. Prior to that, I worked in the Great Plains areas as the health information management consultant and privacy coordinator. I have worked with state government, the Medicaid program and audit program. I have also worked for an Alaskan Native own nonprofit health care organization. I have many degrees. I actually have seven degrees. I love education.

I am a Native Hawaiian and Alaskan Native. In addition to being Kanaka Maoli, which is what Native Hawaiian, how we refer to ourselves. I am an enrolled member of the Calista corporation. I am a descendent of both Maserculiq Corporation and the Cook Inlet Region, Inc, which is three of the 12 Alaska Native regional corporations that were created by the Alaska Native Claims Settlement Act of 1971. Data in IHS is very near and dear to my heart as well as protecting our patients and ensuring their privacy.

We are going to talk about the Indian Health Service and the tribal epidemiology centers within the Indian Health Service. The Indian Health Service is an operating division within the Department of Health and Human Services and we have the responsibility for providing federal health services to American Indians and Alaskan Natives.

And a little bit of trivia there. In the HIPAA regulations, the Indian Health Service is also called out as a health plan. We are a health plan and a health care provider.

We provide services to members of federally recognized tribes. Those services grew out of the special government-to-government relationship between federal government and American Indian and Alaskan Native tribes. The relationship between tribes in the United States Government was actually established in 1787. It is based on Article 1 Section 8 of the Constitution. And it has been given form and substance through numerous treaties, Supreme Court decisions, and Executive Orders.

As the IHS principal federal health care provider and health advocate for Alaska Native and American Indian individuals, we provide comprehensive health care services for approximately 2.6 million American Indians and Alaska Natives across the country who belong to 574 federally recognized tribes in 37 states. It is quite a few patients.

To learn more about the Indian Health Service, I always recommend people to go to the IHS webpage, the newsroom and review in the fact sheets what we call the IHS gold book. This is the history of our agency, the history of our relationship with our people. It is the most fabulous read. It is like history 101 in about 15 minutes. It is a great read. I always recommend it.

Our tribal epidemiology centers are funded organizations who serve AIAN. This is how we refer to American Indians and Alaska Natives. Tribal and Indian communities. They manage public health information systems. They investigate diseases of concern, manage disease prevention and control programs. They response to public health emergencies and then they coordinate obviously all of those activities with other public health authorities.

It is important to note that the Indian Health Service does fund tribal epidemiology centers. We have a very unique relationship with what we call TECs. Tribal epidemiology centers were authorized by the Indian Health Care Improvement Act of 1996. Its purpose of course is to enhance public health, support to American Indian and Alaskan Native communities, tribes, tribal organizations, and urban organizations. There are 12 tribal epidemiology centers, 1 for each IHS area or region. In fact, the Great Plains is here today. We are pretty excited about that.

One additional TEC serves urban American Indian and Alaskan Native populations. And UIHI is also here today. I am very excited for that.

The Reauthorization of the Indian Health Care Improvement Act happened in 2010. It acknowledged the tribal epidemiology centers as public health authorities. And the Indian Health Care Improvement Act directs the secretary to grant each TEC access to data, data sets, our monitoring systems, delivery systems, and other PHI obviously, that may be in the position of the Secretary.

I am going to stop here, and Mr. Greenway is going to take over.

Kirk Greenway: There is a 2007 Tribal Consultation. Believe me, we tried to get a detailed set of notes on it. We are still working on that. But out of that came a tribal epidemiology center data sharing agreement template. And a chapter strictly in health manual. It was designed to standardize all the data sharing agreements between the TECs and their area offices. We were trying to make sure they complied with HIPAA. It also gave access to de-identified data in the IHS epidemiology Data Mart.

There are 9 out of 12 TECs using it right now. Ten of them have signed agreements, those DSAs I was just talking about. It is not a live environment. We send encrypted drives through air mail. We give them out based on their preference. We would give them out quarterly, semi-annual, annual, whatever they need. It is basically a general – it is like our general data mart that the feds use, like me. It has not a lot of identifiers in it. Very little personal identifiers. I do not think there is any.

There are a few additional variables that were added or created to make the EDM easier to use than GDM. The techs always receive notifiable diseases or reportable conditions and that is based on the guidance we got from the 2007 consultation.

Heather McLane: Can I just interrupt? I want to be able to explain why this is – this is kind of a dance within the Indian Health Service. Many of our communities are so small that if the data was reported out incorrectly, you would be able to identify who these individuals are. An example of that – Birch Creek, Alaska, let us just say, for example, we provided information to the tech and the tech said COVID made its way to Birch Creek and four people have COVID. There is actually only four people in Birch Creek. It is very easy to know who in Birch Creek now has COVID.

In addition, we have other tiny communities like Clark's Point in Alaska. There is only one person between the age of 45 and 54. Everybody there knows who that is. Getting this data out in a way that protects that individual in these very tiny communities can be a pretty tightrope kind of dance, if you will. That is where you see our EDM does not have these additional most identifier.

Go ahead, Kirk. Sorry about that.

Kirk Greenway: No problem. The leaders consulted with us and told us that they were concerned at that point in time. I think we may have to revisit that concern based on feedback we receive today.

You should know that all the GDM data that we get is transmitted to the EDM and the Division of Epidemiology Disease Prevention in the Office of Clinical Support, Indian Health Service produces the EDM.

The data tables include de-identified patient registrations and encounters. The registrations include information about the patient, the facility the patient is registered in, otherwise known as location of registration.

The AI/AN status, whether or not based on the information we have received that they actually are AI/AN or not, and tribal affiliation or if no tribal affiliation, community of residence, usually, year of birth, generally, gender.

The patient encounter information in there includes diagnostic procedure, lab result codes, and descriptions, type of encounter where basically where they were seen. If they were direct, which is where they get seen by IHS, not in a tribal health program or if they are taking care of purchase referred care or contract, hospital, outpatient, public health nurse. We have subdivisions for the kind of provider.

If there are any questions, please feel free to contact me at this information here. Thank you.

Valerie Watzlaf: Thank you both so much. I appreciate it. What we will do is we will move on to our next presenters and then we will have questions at the end.

Next, we would like to have Kristin Ekelund and Tricia Roy from the GAO.

Kristin Ekelund: Hi. This is Kristin Ekelund. I am Kristin Ekelund. I am a senior analyst on GAO's Health Care Team, and I am joined by my colleague, Tricia Roy. We both have been analysts of GAO for nearly 15 years and worked on a range of issues during our time here, including some of the tribal issues that we are discussing today.

We are here to talk about GAO's report that was issued in March that examined the tribal epidemiology centers, which we will also refer to as TEC's access to data.

The first couple of slides – I think we can kind of really just go over very quickly. The first slide really just touches on some of the laws that were just discussed that created the TECs as well as granted them access to data, specifically, HHS data through legislation that was enacted in 2010.

And then the next slide we have here really provides -- gives a sense that there are 12 TECs. Each of these TECs are very unique in terms of their size, their structure, and IHS service area and the populations served. This map just gives you a quick sense of some of the variation in terms of their service areas.

Moving to the next slide, we just provided a little bit of information about the objective scope and methodology for our work. We had two reporting objectives for our work. The first was to describe TEC's access to and use of HHS and state epidemiological data.

The second reporting objective we had for our work was to examine the factors that have affected TEC's access to and use of these data.

To learn about these issues, we did a couple of different things. But the main things that we did was review a wide range of documents and we conducted interviews with not only CDC and IHS but all 12 of the TECs.

For our first finding in our report, really, we talked about two things. We talked about TEC's access to data. And really, what we found was TEC's access to the epidemiological data both from CDC and IHS as well as the states varied as of November. In our report in this section, we really – we talked on three key points where we see some variation.

First, we talked about that all TECs have access to HHS and state data that are publicly available. In the report, we provide some examples of the different types of data that TECs can access through publicly available websites or other means.

The second main point that we talked about in this section of our report was that TECs also had access to some non-publicly available data. But the types of data they had access to really varied. Here again, we provide some examples about the different types of data that TECs had access to and where we saw variation. From this slide here, you can see that ten TECs told us that they had access to CDC COVID-19 data for their service area whereas only six of the TECs had access to COVID-19 vaccination data.

And the last key point that we want to touch on in this section is that while all the TECs did have access to some non-publicly available data, they also all described challenges accessing data from CDC, IHS, and states. We, again, provide some examples in our report about the different data that they had access to, challenges accessing.

The second portion of our first finding is it really talks about what data or how the TECs use the available data. And here, we found that they conducted a range of analysis to support tribal decision making. In a report, we provide several examples of how the different types of analyses that TECs conduct.

And the last point we make in this section that we wanted to highlight is that TEC's access to data really affects their ability to conduct analyses. And when they do not or have access to data or when their access to data is limited, it can affect the types of information that they can provide their tribal leaders that is needed for public health support.

With that, I am going to pause here and turn it over to Tricia who is going to discuss the factors that affects TEC's access to and use of epidemiological data.

Tricia Roy: Hi. This is Tricia Roy. Thanks, Kristin. I am going to talk about what we found with respect to the factors affecting TEC's access to and use of data. As we can see up on the slide, we found that while HHS has some systems to share data with the TECs, its lack of policies, procedures, and guidance hinders

access. I am going to use the next few slides to discuss each of these factors in depth. We found four factors.

Moving to Slide 8, first we found that data sharing systems and agreements have facilitated TEC's access to data. The presence of data sharing systems like HHS Protect that has HHS' COVID-19 data as well as IHS' Epi Data Mart, which we just heard about, containing patient registration and encounter data, has facilitated TEC's access to data and many of the TECs have access to these and other data that the agencies make publicly available.

But we also found that TECs have been unable to access data, in some cases, where such systems and agreements have not been established or do not meet the needs of the TECs. For example, CDC officials told us that they were unable to share detailed data on nationally notifiable diseases like influenza and tuberculosis because they do not have a system that enables them to readily share that data.

Separately, we mention that not all TECs have been able to negotiate data sharing agreements with IHS and CDC as of November 2021. We heard that the agencies were open to negotiating terms of their data sharing agreements but several TECs told us that they had been unable to successful negotiate agreements or that had agreements that did not meet their needs.

Moving on to slide 9, another factor we found is that a lack of HHS policies, guidance, and procedures hindered TEC's access to data. Some TECs faced a lack of clarity about their authority to access HHS data. And specifically, we found that officials from seven TECs told us that some CDC and IHS officials did not recognize that HHS is required by federal law to provide data in their possession to the TECs.

Officials from five TECs told us that they were asked by CDC and IHS to submit requests for data as entities without any public health authority standing, for example, as researchers or as public citizens through a FOIA request. TEC officials told us that they must request data repeatedly and negotiate access each time. As of November 2021, HHS had not clarified the specific data points that TECs are entitled to access under federal law.

The second point we make in this factor is that CDC and IHS had also not developed guidance for TECs on how to submit data requests or establish written agency procedures related to responding to those requests as of November 2021.

The officials we spoke with at CDC and IHS told us that they believe they had been responsible to each TEC's needs. But officials from six TECs told us that the process to request and obtain data from CDC and IHS was unclear and inconsistent both within and between the agencies. We found that a lack of clarity and TEC's authority to access data and the lack of guidance and procedures to request and respond to those requests likely contributed to delays the TECs have been facing obtaining access to CDC and IHS data.

Officials from seven TECs told us that they had faced delays receiving CDC or IHS responses to their data requests and four of those TECs told us those delays had been significant over a year long. We have some examples noted in our report of those delays and some TECs noted that those delays affected their ability to serve their tribes.

The third factor I want to talk with you about on the next slide is that data quality and timeliness can affect TEC's use of the data. Officials from ten TECs told us that their ability to use CDC and IHS data was limited due to significant concerns about the data's quality or timeliness. For example, eight of the ten TECs that had access to COVID-19 case data from HHS Protect was that they were unable to use it because the system included incomplete and inaccurate data, including on patient's race and ethnicity as well as COVID-19 cases.

We have previously reported separately on CDC COVID-19 data missing race and ethnicity information. We noted in our report that CDC has taken some steps to address the completeness of data. But CDC also acknowledged that gaps remain and are likely to persist because the nation's public health system is decentralized and state reporting to CDC is voluntary.

In general, CDC and IHS officials noted that there are limitations with their data and the data cannot meet the information needs of TECs to fully realize their functions as regional public health authorities. Those officials told us that TECs would likely need to rely on data from a variety of sources, including states in order to fulfill their responsibilities.

When we talk with the TECs about this, five TECs told us that state data was useful for them in conducting some epidemiological analyses. But 11 of the 12 TECs told us that they either faced challenges obtaining data from the states or using available state data due to poor data quality.

Moving on, the last factor I want to talk with you about is that TEC's capacity, which is their resources and abilities can affect their access to and us of data. TECs told us that seeking access to data can require a significant investment of resources. And a number of them were searching for additional resources while we talked with them last year.

Officials from nine TECs also told us that having better access to data would enable them to use their resources more efficiently and thereby expanding their capacity to serve their tribes or conduct more impactful work for their tribes.

We also note in our report that CDC and IHS have programs aimed at supporting and enhancing the capacity of all TECs to serve their tribes. And the programs that they have provide funds and provide technical assistance to TECs and our report outlines those programs.

On slide 12, I have a list of recommendations that we made based on this work. Our first recommendation is that HHS develop a policy clarifying the data that are to be made available to TECs as required by federal law.

The second and third recommendation are that IHS and CDC both develop written guidance for TECs on how to request data. And the fourth and fifth are that IHS and CDC each develop internal agency procedures to document their process for reviewing TEC requests.

In our report, HHS – with the recommendations and will continue to monitor any actions taken to address them.

We are happy to answer any questions that you have about our work. Slide 13 includes some basic information about GAO and the link to this report is available on the first slide. Thank you.

Valerie Watzlaf: Thank you very much, Kristin and Tricia. We appreciate you sharing those results.

We are going to move now to Abigail Echo-Hawk to present. Do you have slides?

Abigail Echo-Hawk: No, I do not. Good afternoon, everyone. My name is Abigail Echo-Hawk. I am a citizen of the Pawnee Nation of Oklahoma on my father's side. I was born and raised in the heart of Alaska amongst the Athabascan people of Mentasta Lake, Alaska and I have had the honor and privilege of both living in very rural tribal community dependent on subsistence hunting and fishing, to where I live right now in the lands of the Coast Salish people in Seattle, Washington, working and operating an urban Indian health facility and overseeing the work of the Urban Indian Health Institute, which is the only national tribal epidemiology center focused on the needs of urban dwelling American Indians and Alaska Natives.

Right now, we know approximately 78 percent of American Indians and Alaska Natives live off tribal lands and about 70 percent of those live in urban areas like Seattle, Washington, and myself. We have migrated to these places for a variety of different reasons from the fourth simulation of the relocation programs to the fact that we have people who are from this land, living displaced in these urban settings when this is traditionally better lands. It was very important.

I want to kind of go back to the beginning presentations related to the Indian Health Service, specifically, thinking about where and how the tribal epidemiology centers came to be. The tribal epidemiology centers exist not out of the good will of the government but out of the advocacy of tribal leadership both urban and rural who recognize that American Indians and Alaska Natives were not represented either at all or appropriately within data whether that from the local to the federal level.

Through the advocacy of tribal leadership, there was a large push to the Indian Health Service to begin to fund tribal epidemiology centers or that started in 1996 to the 12 that we currently have.

The Urban Indian Health Institute was established in the year 2000, really recognizing that within these national data sets, within these state and county data sets, the urban Indian population was often left invisible. We were the Asterisk Nation, as has been defined by the National Congress of American Indians, always that asterisk down at the bottom that says we are not significantly significant. As a result, these tribal epidemiology centers, which I am blessed to work amongst the leadership of the tribal epidemiology centers are focuses and who we are governed by is tribal leadership. The other tribal epidemiology centers sit within tribal organizations. Boards of directors that are directly coming from the tribes in which they represent. They are directed by their tribes, and I am sure Jerilyn will talk about how they answer to their tribal communities and what is necessary and needed around epidemiology data collection and response to public health emergencies like COVID-19.

The Urban Indian Health Institute of course, is unique but we have a board that represents the urban Indian community and those urban Indian leaders who are across the nation and funded by the Indian Health Service. There are currently 42 organizations, operating more than 60 IHS-funded clinics across the United States that focus on the urban Indian population.

We also recognize that there are large areas of the United States, which have large urban Indian populations. But because of the chronic underfunding and the nonfulfilling of treaty rights by the United States government, the Indian Health Service does not have the funds in which to open up those clinics. We still work in those areas even though there is not an IHS-funded facility there.

When the Urban Indian Health Institute is searching for data – I was listening to the report that was just talked about. I actively participated in that. A lot of our struggles are represented in that. The struggles in the fight for data has been so essential to our tribal communities.

I am sure you are all aware. The upholding of our treaty rights is dependent on tribal members, not just tribal members who are accessing services on tribal lands, but tribal people calculated in census data, tribal people who are present within vital statistics. All of those numbers are used by the federal government to calculate the way that they allocate resources and services in the upholding of our treaty and trust responsibility to tribal nations and to urban Indians like myself. Simply because I am not on the lands of Athabaskan people of Mentasta Lake, Alaska and because I am not standing on the lands of the Pawnee Nation of Oklahoma does not mean that the federal government still does not have responsibility to me and every urban Indian as a result of our treaty and trust responsibility that should be upheld for enrolled citizens of tribal nations. That is what we are fighting for and what our data is used for.

We are consistently fighting against perceptions that we are not as good as or we are not as qualified as other state and county departments. We have consistently pushed for the recognition of our legal right as tribal public health authorities to access PHI that is held under the secretary.

I will give an example. My team and I were asking for data from the CDC related to STIs. That team actually tried to explain to us what epidemiology is. I can reflect back on the presentation that was just given by the Indian Health Service where they talked about suppression of data. We are experts in suppression of data. And in fact, the Urban Indian Health Institute and I know my sister TECs also hold a higher standard level of suppression of data than is upheld by the CDC in most states.

For example, the example that was given of four individuals in a particular community, we would never release such data. We are experts of these fields. We uphold our responsibility to our tribal communities for not only confidentiality, but what small populations' methodologies actually are.

I have to train my epidemiologists when they come out of school on what actual small populations data analysis is and how to do that in a way that does not only go with what I see as racism embedded within epidemiology, implicit bias that is embedded in the way that folks think about tribal epidemiology centers. We have not only the capabilities but the responsibilities as tribal citizen reporting back to our tribal governments and to our urban Indian leaders, for upholding of not only the confidentiality. Again, I will say we have the highest levels of suppression, to ensure confidentiality and that we do not identify communities or individuals impacted by whatever health data we are working in. But we uphold and ensure that as requests come from our tribal communities, urban and rural, that we are answering the needs of our communities.

When I get epidemiologists, I have to retrain them because what happens in school is that they are taught to work with large national data sets, and all they are taught to do is really to put down that we are not statistically significant.

We actually work across the country. I, myself, along with my team lecture in universities, in trying to make the way that small population data analysis is done, is done correctly.

We are fighting this implicit bias that lives within systems like the Indian Health Service, the CDC, who will try to explain to me what epidemiology is when I should in fact be the one explaining to them the way that they should not only be releasing their data but the way they should be analyzing it to ensure the proper representation of American Indians and Alaska Natives.

Also embedded within these systems is not only they are not understanding of our legal right, which is why it is so important, and I urge you to make recommendations to the Secretary that take all of the recommendations that came out of the Government Office Accountability report. Every single one of those need implemented. We need a timeline and the resources for that implementation to happen so that we can get access to the data that we need.

I will give you another example. In 2020, my team and I reached out and we are trying to get STI data. We asked for that STI data, and what we received from the CDC was they actually copy and pasted it out of their policy where that when it came to this STI data, they would only release that data to the epidemiology branch of the Indian Health Service and to "and they are required to not subsistent– they were not allowed to release the case reports or extended records listed in the NNDSS data outside of the IHS epidemiology program including not releasing it to tribal nations." These are the kinds of policies that have been put into place without meaningful consultation to tribal nations.

It was discussed that the data-sharing agreement with the Indian Health Service was created out of a 2007 tribal consultation. That is not adequate. Tribal consultation under federal law is to be meaningful. It is supposed to be consistent, and it needs to be accurate for the times in which we are in. A 2007 tribal consultation is not meaningful nor accurate at this point in time. In fact, while I cannot speak for all of my sister TECs, I do know that many of them have struggled, and some have not signed those data-sharing agreements because there is a waving of some tribal immunity within those agreements that the tribes are not willing, and the tribal organizations are not willing to participate in.

But this response that came from that 2020 request goes even deeper and more disturbing to me. In this response from the CDC, they asked that if we were looking to get this desired data, we would have to fill out all of their forms as if we were researchers.

And then also one of the things that they put in is that there is an agreement between the Council of State and Territorial Epidemiologists, who I am sure you are all aware of, and the CDC that allows the CDC to only provide raw and I am talking about STD data to the epidemiology branch of the Indian Health Service only.

CSTE is a nonprofit. CSTE holds no purview nor government-to-government relationship over tribal nations. In this document from the CDC they sent to me, any changes to these guidelines must be discussed with CSTE. We continue to see not only the non-upholding nor the understanding of a

government-to-government relationship between tribal nations, tribal TECs, who hold tribal public health authority and the legal right to data under the secretary's purview.

But we also see agencies like the CDC saying tribal nations have to consult with a nonprofit to determine whether or not we have access to data we have a legal right to. There is a need for standardization of an understanding and policies put in place across federal agencies, across HHS that uphold the treaty and trust responsibility of tribal public health authorities as defined under the 2010 Affordable Health Care Act. We need to be addressing the implicit bias that lives not only within the Indian Health Service, within the CDC, within other agencies that deem tribal epidemiology centers not as qualified as and not as good at doing the data analyses or the data collection or the data dissemination.

I will close with this example because I know Jerilyn Church, one of my sheroes in Indian country is going to be talking next. During the COVID-19 pandemic, we fought for data, worked with members of Congress. It took two congressional hearings, a letter from 26 members of Congress for tribal epidemiology centers to finally get data. We get that data. My team and I realize the data is of such poor quality that the report we were able to publish on that was actually one I title data genocide and the fact that the elimination of American Indians and Alaska Natives in these data sets directly resulted in my relatives' deaths, the deaths in my communities individually, the communities that Jerilyn works within, and the communities across this country.

As we talk about data modernization, recommendations should go forward to the secretary that tribal nations, tribal public health authorities, including TECs, should absolutely be included and resourced to be part of this data modernization, which we are seeing significant resources flowing from Congress. We need those resources because not only do we work in these secondary data sets. I partnered and worked across the nation. The Urban Indian Health Institute did the very first perceptions, beliefs, and attitudes around the COVID-19 vaccine. And what we have found was completely opposite of where HHS was directing their public health campaigns around vaccinations. We use that and actually it has been cited by the president as one of the leading reports on how to actually reach American Indians and Alaskan Natives who have been one of the most successful populations in the country and ensuring that our folks get vaccinated.

And then I heard from Jerilyn's team who reached out to me and said can you disaggregate that data for our region, share that with us, and then also share your survey tools so that we can use it, adapt it, and do our own. And that was what tribal epidemiology centers our power is. Not only did I give Jerilyn's team everything they wanted. My team was on call, and they were on call to us so that we could partner together for the health and well-being of our communities because we are the ones who know how to reach them. We are the ones who are being informed by tribal leadership. We are the ones pushing for and ensuring that our treaty rights are upheld for data access and we, as tribal communities, know what it means to apply our traditional cultural standards of public health to ensure our health and well-being. Until we get the data that we need, you are going to keep seeing us because we are going to keep fighting.

Valerie Watzlaf: Thank you so much for your presentation. That is excellent. I wanted to also let people know that the link to the GAO report has been posted in our chat and also your data genocide article is up there too. Thank you very much.

Our next presenter is Jerilyn Church. Do you have slide, Jerilyn?

Jerilyn Church: No, I do not. Thank you for the invitation today. When Maya told me Abigail was going to be on the panel, I was so pleased because she is a fierce warrioress on behalf of our TECs and the communities that we serve.

I am going to speak to you not from the perspective of an epidemiologists because I am not. I am an administrator. And I will tell you a little bit about the unique structure of our organization and that area that we serve.

First, I just want to say I was born and raised on the Cheyenne River Reservation. I am an enrolled citizen of the Minnicoujou Band of the Cheyenne River Sioux Tribe. I was born and raised there. I have had the privilege of working with the Great Plains Tribal Leaders Health Board now for ten years.

Our tribal TEC center is embedded within our organization. We have our epidemiology center. We have a number of other public health programs. We also run a tribal health clinic in Rapid City. It is in an urban environment, but it is a tribal clinic.

We have a wonderful crew of 340 employees who wear various hats and the staff in the TEC is a really important part of that who provide support to 18 tribes within our region that include North Dakota, South Dakota, and Nebraska. We have one-member tribe in Iowa.

Some of the challenges that we – we have known for years that there have been inconsistencies, barriers with tribal data. We have been delivering that message for a long time. But what COVID-19 did is really brought those barriers and those challenges to the forefront.

Because we serve four different states, we have varying levels of access even across the states. We are in the Midwest. We were also challenged during COVID with state governments that really downplayed the pandemic. In South Dakota, we had a governor that never encouraged mask wearing. Acknowledgement much less support when it came to addressing the pandemic in our tribal communities was minimal. That was a barrier in and of itself.

And then we had the usual challenges that we have had with Indian Health Service. I want to be fair to Indian Health Service in that in their effort I think to try to find a universal approach to a data sharing request not only from our epi center but from the tribes themselves, I sometimes felt as though they were trying to create this one-size-fits-all data sharing agreement, which may work – every area is unique. The Urban Indian Health community is unique, unique challenges and access to information that is going to look very different from Alaska, which is one state, and to the Midwest. I do not know if that is part of the problem or not.

With our area, we just had our attorney – just had a conversation yesterday with the area office of negotiating a data-sharing agreement. It has been really disheartening. It has been very disheartening.

Our tribes in the Great Plains – a majority of them are still direct service tribes. They get their care directly from Indian Health Service. They rely on the Great Plains Tribal Leaders' Health Board for a lot of technical assistance. They rely on us for advocacy. And in some areas, the tribes are a lot more maybe

independent or exercise their sovereignty for their nation on their own and have the capacity and ability to do that. Our tribes do not.

We have tribes that come to us asking for assistance for access to data that they are not able to get directly from Indian Health Service. We are standing beside them. I am trying to get this information that they are challenged to get.

For an example, just yesterday, our medical epidemiologists received a message from one of our tribal officials and Abigail is correct in that for our organization, our board of directors are the presidents, chiefs, and chairmen of each of the 18 tribes. That is who governs us. That is who guides us. That is who sets the expectations for us in what they hope that we can assist their individual tribes with.

She received a message yesterday of frustration from one of our tribal elected leaders who has been working for over a year to get specific COVID-19 vaccination information for their community from IHS. They know the percentage that was vaccinated but they do not know how to break that down by age, by gender, location. They do not know who has been vaccinated and who has not. They do not know who they need to reach out to, which communities to encourage vaccination or provide the education that they may need on the benefits of vaccination.

This issue was brought to light by COVID. But the issue of access to information is not limited to COVID. Another challenge that our epi team is faced with right now is a pretty serious syphilis outbreak. One tribe has been requesting information on syphilis cases so they can assist with the treatment and potentially a case investigation. We have asked the state for this information. The response that our epi team received was they wanted a written justification and additional details as to why they wanted the information, what they plan to do with it. As public health authorities, these are not the kinds of barriers that we should be faced with. IHS freely gives their information to the states but that information does not get back to the TECs.

I also want to say that it is not just the TECs that are public health authorities. Tribes have that inherent sovereign right to operate also as their own public health authority.

There are just these disconnects. In some cases, in terms of policy within IHS and CDC or other agencies, if there were some universal guidance and directive, I think that would be helpful.

But I also want to be cautious about the fact that every tribe is a sovereign nation. They may want to utilize their TEC differently than another. Those nuances have to be taken into consideration. It is very complicated and there are multiple fronts in which we are trying to access information in order to respond to the needs that our tribes are looking to us to provide for them.

I really appreciated the GAO's report. We have been knocking at this door for a really long time. Because of the work and the effort that the GAO extended to the TECs and the interviews they have done, I am just so grateful that this conversation is beginning. I am not the expert. I am charged with giving our tribal epidemiology center the tools and the resources that they need to do the jobs that the tribes are asking them to do. Whatever advocacy that I can do I will do that. The real experts were not available for today. I think that there needs to be more conversation. I really hope that this is the beginning of resolving some longstanding problems within the tribal epidemiology centers. Thank you.

Valerie Watzlaf: Thank you so much and thank you to all our panelists. We all appreciate you being here and just providing your different perspectives.

I have a few questions. Vickie, I want to send it over to you to see if you have anything and then we can open it up to our committee.

Vickie Mays: Like you, I must say thank you for this presentation. This is what helps us and inspires us to head in the right direction. Thank you very much for your time.

I have a couple of questions. One is I would really like to get a sense. The GAO report is out. It sounds like for some of the panel was the feeling is that its implementation or dissemination or something is a little too slow and that that needs to be lifted up.

But I would also like to get a sense of beyond what you saw in the GAO report, are there any other things that you think would be important to do particularly as they relate to either data security, data privacy and confidentiality, data standards or data access and use. Those are the big buckets for us that we do our best in. We cannot do everything, but we can do those well. If you have any comments, I would love to her those.

Abigail Echo-Hawk: When it comes to standardization of data, that is definitely a huge concern. We will see in our report around data genocide is that there are very few standard definitions of American Indians and Alaska Natives despites efforts from tribal communities in ensuring doing that. When we get data sets, it is very often very difficult for us to discern where American Indians and Alaska Natives are. There are some states, for example, who still include us with Pacific Islanders and Asian communities. Those data standards are definitely something that need to be upheld and enforced. We know we have the OMB standards. They are not really implemented in the way that they should. They are definitely a starting point. They are definitely additions to that that could also be used.

In addition to that, we are seeing a call for and an understanding of what it means to collect tribal affiliation, how that tribal affiliation is used, and how to do that in tribal communities – hearing that tribal consultation is done so that the way that tribal affiliation is used is done appropriately. It is definitely one of the areas, particularly as we come to the urban Indian community where folks very often and I will say this specifically to research and other folks who are looking at data be like we do not have to consult with the tribes because this happened off tribal land. We can release this data. We can do this research. We can gather information.

And what we found is it is providing an opportunity for continued harm for data sovereignty to not be upheld and definitely beginning to use the words and all the things that you were just talking about of the upholding of indigenous data sovereignty. There is both an international push and a national push right now for the upholding of data sovereignty. I just want to explain that. Tribal sovereignty is the treaty and trust responsibility, what is called a dependent nation within a nation, the government-to-government responsibility that tribal nations have and uphold. Indigenous data sovereignty is under that. It is not a separate thing. It is part of tribal sovereignty. We need to have that indigenous data sovereignty upheld and as it is starting to be used in federal spaces because now, I am starting to hear it

being used is we need to create the definition and ensure the real true definition of that is what is being used. It really is, again, falling into and directly related to tribal sovereignty.

But if we could get a standardization use across the nation of American Indian and Alaska Native how that is collected, we would have data sets that are currently right now completely unusable. We would actually be able to use them. In fact, my sister TEC, the Northwest Portland Area Indian Health Board, does incredible work on linkages. They have done some linkages for national data sets such as SEER, vital statistics where they have found up to a 40 percent racial misclassification rate of American Indians and Alaska Natives. They are either not classified at all or they are misclassified as white. They are put into another category or the definition in which they had fallen under was wrong. They have actually been able to get to their tribes more meaningful data through these data linkages. But that is a lot of work and it is very expensive.

As we think about data modernization, particularly for American Indians and Alaska Natives, we need to have common definitions that stretch not just across one agency but all agencies.

Vickie Mays: Thank you. Val, let me do just one more and that is to give IHS a chance to respond to the GAO report.

Heather McLane: This is Heather. I can say that the IHS responses are contained in the GAO report. I would highly recommend reviewing those.

Valerie Watzlaf: You said that your response and your recommendations are in the GAO report. Is that what you said, Heather? You kind of broke up.

Heather McLane: Yes, I should not have said recommendations. I should have said the response.

Valeria Watzlaf. Response. I am sorry. I might have said recommendations. I apologize.

Heather McLane: I might have too. My brain is heating up.

Maya Bernstein: Heather, I understand that you cannot say anything that is not already public, but since that is public, are you able to summarize the main points of what IHS said in response to GAO? We prefer to have you do that than GAO.

Heather McLane: We were asked to refer individuals to the GAO report.

Maya Bernstein: Does GAO want to summarize since it is in their report?

Tricia Roy: As I mentioned earlier, we had concurrence on the recommendations that we made in the report from both IHS and CDC, which when we obtained concurrence, we then continued following up. We always follow up, but we kind of expect to see action related to the recommendations. We will continue to follow up until we see those recommendations being implemented.

As you know, the process for us as we – the first time we generally receive a response, a specific response about additional actions after the report is issued is in that 180-day letter. We have not yet reached that timeframe yet.

So I do not have any information other than what is available in the report, which someone just mentioned is page 31. I am close to that area right now in the report. I have no information other than what is posted in the report. But I know that there is concurrence and in general, we consider that to mean there is some action being taken at some level and we will follow up on that as time passes.

I know initially – Vickie, you mentioned that there may have been a delay. I would not say that there has been a delay. I just do not know what action has already been taken because the normal channels require that – generally, we are informed of action after 180 days.

Vickie Mays: It sounds like we still have some waiting time to see what is what. Hopefully, everyone heard that and there is still time to make those comments.

Let me just say one thing and then I am going to turn it back over to Valerie to open it up to everyone and that is we do have attendees. There are several people out there whose names I recognize who I think may have comments like Yvette Roubideaux and others, who have been working in this space for quite some time. Please feel free to put your comments into the Q&A and if time permits, we will either read them in the record or try and call on you or if time does not prevent, we at least will see what those issues are.

Val, maybe we should open it up to the whole committee now, as well as members outside of just Privacy, Confidentiality, and Security.

Valerie Watzlaf: Are there any questions from the Full Committee? Wu.

Wu Xu: I want to thank the entire panelists. It was wonderful presentations. Some of these are eye opening to me. I want to follow up on Vickie's question. What else did the GAO report recommendations not include. I recently retired, before the pandemic, retired from Utah Department of Health. Before I retired, I worked maybe two years with Arizona TEC to reach agreement, gave them not only academic data, also maternal and child health statistic data, help them build the indicators. I feel that the recommendation you presented in the slides, the three recommendations, is really on the point for what I experienced. First, have a clear policy guidance from the federal, state, really understand the TEC are public health agency. We should treat them as other state public health agencies. That is the first hurdle we got in Utah.

Then the second was the procedure issue. That is mutual training, understanding each other as a state. What type of data request we need? What is the language we use? We take time back and forth to fully understand each other.

Third, barrier challenge. I did not see in your presentation. It also takes time for us to finalize agreement. Is the requirement of data protections, security? How do you handle the data privacy issue? That takes a very long time for us to really understand each other.

And also, in one of your earlier slides, you mentioned data transaction has USB drives. I think the secure translation - transmit data become a barrier at that time. But I think after the pandemic maybe since changed.

Some of you mentioned the data modernization needs. I wonder. Is the CDC public health infrastructure – I think they grant eligible grantees that include TECs. I do not know how your TECs try to get some funding to really modernize your system. Those are my comments.

Vickie Mays: That is a really great question which if anyone on here – one of the panelists can say how their data modernization is funded, it would be great to know.

Abigail Echo-Hawk: I can speak a little bit to any kind of data modernization. Truthfully, there has been very little investment in that. Under the public health emergency, under the packages that have come out from Congress related to responding to COVID-19 crisis, we have seen an increase of resources to tribal epidemiology centers. Not very much of that is going to directly improve the public health data collection infrastructure, which is why my recommendation is to ensure that tribes, tribal organizations, and urban Indian communities are part of and receive resources from these data modernization packages.

We are seeing some data and other than overseeing this at my agency, I do not know that the Indian Health Service is investing in some overhaul of their data collection systems. I will say that the data that my team and I have access to, the Epi Data Mart, is pretty unusable. It is really not good data. We definitely struggle with getting meaningful analyses out of that data set. There is definitely modernization that needs to happen. I know IHS is doing some investment in that.

But as always, the Indian health care system whether it be through IHS or direct funding that goes to tribes and urban Indian organizations is woefully underfunded. We are continuously advocating for the upholding of treaty and trust responsibility, which was just upheld in 2021 Supreme Court decision that says American Indians and Alaska Natives have a legal right to quality health care. And that means fully funded health care.

We are definitely looking for some investment in policies particularly across the CDC and the states. We need methodologies that correctly capture American Indians and Alaska Natives such as ensuring that there is oversampling and resources for oversampling of Native populations. That is something we struggle with. And correcting racial misclassification also tends to be an incredible issue. And truthfully, only one TECs are going to be the most successful in doing.

We need some cross-agency protocols. We do not have cross-agency protocols on data sharing and how data is shared to tribal epidemiology centers and tribal communities who are looking for access to that data. It is definitely an issue to see the siloing of HHS and how that affects not only – I know that is not – I love seeing Dr. Yvette Roubideaux on here because she has worked with lots of other communities of color who are also looking for that disaggregation of data, more commonly data sets that could be shared and can be merged. There is a struggle with that across the nation. This is where we find solidarity with other communities of color. Dr. Yvette Roubideaux has been doing a lot of that really good work through the National Congress of American Indians. But we need to do more to ensure usable data across the nation. Right now, our public health surveillance systems are not adequate.

Vickie Mays: I wanted to do a follow up – two things that are very specific to us and that is vital records particularly in terms of birth certificates and death certificates. You talked about racial misclassification. Do you have any specific acts in terms of vital records?

And the second is one of the things that we have also taken up is this issue of social determinants of health and SOGI. In particular, we are focused right now on SOGI. Do you have any concerns about privacy and vulnerability issues in terms of the collection of the data within Alaska Natives and American Indian populations?

Abigail Echo-Hawk: Related to specifically to vital statistics is there is a common saying in Indian country. You are born Native, and you die white. We have seen that evidence out of the, again, the incredible work that both Indian Health Service has done and partnership with CDC in doing some linkages and corrections for racial classification.

What we see is a lack of standard across different states on who are the ones who actually classify, and what are the trainings required for those who classify folks both at birth and even more so at death. We know that there are funeral home directors and coroners who have no idea and who will look at a person and decide based on their own visualization identification of race, which is not real, determine what race they are instead of talking to the families. There are a lot of recommendations that have come out on how to do that.

We are definitely seeing states begin to implement training recommendations and requirements for folks who classify these kinds of – and are the ones inputting these records. It would be really great to see what we could do with that on the federal level and the recommendations particularly as funds flow to the states for these kinds of resources to ensure that these training standards and ensuring that there is some accountability for the way that these records are collected is done. Right now, it has been handled by particular states and some states are much worse than others.

In regard to confidentiality, we are always concerned about confidentiality. The tribal TECs published a paper on COVID-19. The very first on the rates of COVID-19 and early on in the pandemic. I will say that I almost withdrew my entire team from that paper because there was going to be a release of records that I felt could identify a particular community and a particular family. Again, the tribal TECs have a higher standard of suppression and our responsibility to community in terms of confidentiality. The engagement of tribal communities on what that is and all of the TECs have different levels of suppression. But I will say they are always – I have not seen them be at a higher level than pretty much any other state, county, or federal agency. Consultation on that, meaningful tribal consultation on confidentiality, suppression standards, aggregation of data to adjust for small populations really is something that needs to be discussed and some standards established as these kinds of efforts move forward.

Valerie Watzlaf: Would others like to respond as well like Jerilyn? I do not know.

Jerilyn Church: Like I said, my perspective is really coming from an administrator standpoint more so than our epidemiology experts who were not able to be with us today.

One of the questions or one of the resources that IHS referred to was their data mart. Our TEC has the authority to access and use the data mart. But what we do not have is the adequate – the server, the infrastructure to be able to full utilize it. That speaks to the need and the lack of infrastructure to really take our work to a whole new level.

IHS is working towards moving from RPMS to another health information system. We think it is important that whatever they come up with is able to support and speak to public health infrastructure so that we can – they can respond not only to the individual needs of our community members that we are serving but also be able to respond appropriately to the public health needs as well.

One of the things our team is working on right now is a little more robust response and recommendations to put forward. That will be coming from us.

Valerie Watzlaf: Thank you. Anyone else has a response? Anyone else have additional questions for the panel? I think we have about nine minutes.

Could I ask a question and excuse me if I am not making this clear enough? But I had a question about the data sharing agreements, which seems to be good for some that can get them and then not so good for others that cannot. Since the TECs are part of the public health system, do they even need to have a data sharing agreement to receive data from the CDC or IHS, particularly if it is a public health emergency? Or is that something --

Heather McLane: This is Heather. If I can -- during the pandemic, we have had many tribes that have reached out directly to areas offices. Because most of our tribes have not – prior to the pandemic, many of our tribes have not had an official mandate. Under HIPAA, there are public health authorities. There is an official mandate. Many of our tribes did not have an official mandate within their constitution or resolution that they were in fact a public health authority because many were depending on their — we did work with many tribes on – they did their resolutions that they were a public health authority. We went all the way up the chain.

We started at the area office and – leadership for us to be able to disclose the data that tribes were requesting. We simply asked them to send us a letter, i.e., we exercised our public health authority and were indicating that this individual is our contact person, and we would like that group to have all of this data and this is our public health activity. We were trying to do that in line with the HIPAA regulation. At first, we had a quite a bit of confusion. But as time went on, those tribes were in fact getting the information they were requesting. We have worked or attempting to work with some TECs that are requesting additional information outside of the EDM. Right now, it has kind of been on a one-on-one basis as opposed to using a more standardized one size fits all. I hope I answered your question.

Valerie Watzlaf: Do states go through the same process because then why would it be – I am just trying to understand why it would be different for the TECs.

Abigail Echo-Hawk: On behalf of my TECs, what we do is with the states that we work with closely, I have data sharing agreements in place with states across the nation with large urban Indian populations as we work on a state-to-state level with them to establish data sharing agreements and some of them it is not data sharing agreements. Some are okay with and we do not have to negotiate as hard because they

recognize what public health authority is because they do the same thing with their counties. It is really varied state to state.

When it comes to the CDC and having access, for example, to state-level data, some of the arguments have been that the CDC has data sharing agreements in place with the states. The CDC has to uphold what the states say in regard to the sharing of that data. There have been arguments around that and how we work through that. We have overcome a lot of that.

The other thing is it is related to some of these data sharing agreements is I have the same question you had. Why do we have to sign these data sharing agreements? Very often, they are the same ones that you would give a researcher, for example, versus a public health authority. We are definitely fighting for it. Again, the policies and the standards that are recommended in GAO report are so important so that there is a standardized approach to that because different divisions of the CDC will tell me different things.

In regard to some of the data sharing agreements that have been written for TECs, some of the things that exist in them are things that I am not willing to sign. For example, very often, they will say that they have to review our analyses prior to us releasing it. For what purpose? To me, that is where I see the embedded systems if they do not believe we have the same expertise or ability in terms of analyses. At some point, they are wanting us to withhold things that do not reflect well on a colonial government that is perpetuating health disparities in our communities.

My team and I are very cautious about what data sharing agreements we do sign. Sometimes we do it because it facilitates, and it moves things faster and we can get the access that our communities needs because that is what matters to me the most. Others I know it is just the wrong thing for us to do because we are upholding and perpetuating a system that for my predecessors, for the folks who come after me, I do not want them to experience. We are doing the best we can with all of these barriers. But the question is why do we have to sign them?

Valerie Watzlaf: Thank you, both, Heather and Abigail for your response. I appreciate it.

I do not see any other questions. Vickie, do you have anything else? We have three minutes.

Vickie Mays: I was just going to say that I think one thing that I want to make sure gets emphasized is the infrastructure because I have worked with different tribes, nations, pueblos, et cetera. And sometimes you have to be careful about sending PDFs because when we work with a clinic, for example, there will be one computer and it needs to be used for something – I think we underestimate what the ability to use also requires with it. I just want to make sure that any comments about need –

For example, you need to worry quite a bit about the census data and yet census data often is required to be used in a secured DAC and if you are not at one of the universities that has it, it is almost like it is impossible to do it and yet you are about to face this differential privacy issue, which will for the sizes of some of the tribes, communities, et cetera, is going to be really difficult.

I am wondering if there are any very particular resources – we only have a minute or so – that you think are necessary to make your ability to use and access data.

Abigail Echo-Hawk: I could speak for my organization. Again, investment in the infrastructure. We are blessed that we are in the Indian urban settings. I will say that one of the things we struggle with is exactly what Jerilyn was talking about. Some folks when it comes to what IHS has used – they use the IHS EMR system. Others are using different EMR systems. When we try to do a pool of data sets, for example, I do not always have the servers, the infrastructure, the things that I need, the software sometimes to take the first data sets and be able to merge them together.

While we have seen investment in tribal epidemiology centers under the work that was done around COVID-19, we have seen a lack of investment and infrastructure. I will say the same for tribes. We see such a huge investment in broadband right now because tribes did not have internet. We are at a very basic standard that I think folks in the United States are completely unaware of. While I am blessed to work in the urban settings right now, I used to work very deeply with more than 150 tribes across the country and that was some of our biggest struggles is that they had a dial-up connection still.

Vickie Mays: Thank you very much. Val, let me turn it over to you to close us out.

Valerie Watzlaf: This has been just wonderful, very thought provoking. I am just so glad that – I think we all are so glad that we could bring this issue to the Full Committee. We just so very much appreciate all of you for being here and for sharing your perspective. We very much appreciate that. Thank you. Thank you so much. You are getting applause as well. There they go. You are getting a lot of applause too. Thanks again.

Jerilyn Church: I really appreciate Abigail. She is just at the forefront of advocacy in this space. I am just so grateful that you have the right people at the table here.

Valerie Watzlaf: Thank you to Maya for doing --

Maya Bernstein: I just feel so privileged that you guys made the time to be here with the committee today. I know all the committee members really appreciate it and particularly that I asked you without very much notice at all and these presentations were fantastic. To my colleagues at Indian Health and GAO and to our tribal representatives, I am just so pleased and appreciative of your time – and expertise. Thank you so much.

Public Comment

Rebecca Hines: With that, we have time now for public comment. If anyone – we have one phone call listener and then everyone else is on Zoom. The instructions for public comment are here on the slide. For those in the audience on Zoom, you can raise your hand to have your audio unmuted or use the Q&A to request an open line. For the phone person, press *9 to request an unmute. You can always send an email to NCVHSmail@CDC.gov.

We did receive one comment this morning, but I see now we have one live one. Could you please open up the line for Dr. Yvette Roubideaux? You are unmuted.

Yvette Roubideaux: Can you hear me?

Rebecca Hines: We can, and we are delighted you could join us today.

Yvette Roubideaux: Thank you. I am really grateful for having heard about this session with the tribal epidemiology centers. Thank you so much for hosting this. I can attest that this has been a longstanding issue and it is time to fix it.

My name is Dr. Yvette Roubideaux. I am the Director of the NCAI Policy Research Center. NCAI is the National Congress of American Indians. It is the oldest, largest, the most representative national organization serving the broad interests of tribal nations. Our work is to protect and defend sovereignty for our tribal nations. I am also a former director of the Indian Health Service, but I am not speaking in that capacity today. But I do have a lot of history that I recall on this issue.

When I was back as the IHS director, it was so exciting that the Indian Health Care Improvement Act was reauthorized. In particular, back then, I was so excited to see the tribal epidemiology centers in law deemed to have public health authority and finally to have the authority to access federal and state data and other public health data. It is a little bit disappointing to see that they are still having problems. Now, it is 12 years later.

At the time, we did have tribal consultation on the implementation of the Indian Health Care Improvement Act. I do not know what that 2007 consultation was. But there was more updated consultation on it. Tribal nations wholeheartedly support their tribal epidemiology centers to have this public health authority and have access to the public health data that they need to help these tribes as sovereign nations. Data is important for policy. Data is important for programming. Data is just really critical especially in a pandemic. It really was sad to see all the struggles of tribes and the tribal epidemiology centers trying to get access to data. It was frustrating for me because – there is a law that says they have access to it. That was very frustrating.

I really feel like it is time for the Biden Administration to fix this. It has been far too long. It has been 12 years. But the Biden Administration with all of its work and executive orders on tribal consultation, executive orders on equity, data, and all of the initiatives that are related to this issue, it is time to fix this. The tribal epidemiology centers are more than capable of being public health authorities and handling this data in appropriate manner. It should not be a question anymore.

I agree with Abigail. There is a lot of unconscious bias around the capabilities of the TECs and that has to stop. This administration can allow it. The situation is this is 2022. There are very qualified and talented epidemiologists in these tribal epidemiology centers. I trust them. I know that they are doing a great job. They are ready to serve their communities better through getting access to the data that they need. I would encourage HHS to actually use them as teachers for all the data people in HHS who are still to this day not utilizing data on American Indians and Alaska Natives in the most effective manner. And the TECs have incredible experience and expertise to share.

I feel like it is just time to get this work done. It would be a really great outcome for the Biden Administration to solve some of these critical data access and quality issues. It is really time to do this work. These tribal epidemiology centers represent the tribal nations in their region. It was really important to note the comment about tribal nations are on their boards. They are directed by sovereign

nations. That gives them much more authority than a random organization that wants to look at something related to American Indian and Alaska Native data.

There are a lot of issues. I have lots of concerns about the 2020 Census and lack of access for small, rural – populations. I have concerns about the inaccurate use of just the American Indian and Alaska Native alone data. Ten years ago, people said these are the real Indians. These are the people who checked that box. The people in the combination category are not really Indians. But it is 2022 and tribal citizens are in the American Indian and Alaska Native combination data. It is not accurate to say that American Indian and Alaska Native alone data is the true data. There has to be some new guidelines about analyzing data and including the in-combination data. Abigail mentioned great strategies that the TECs have for small analyzing small data.

Anyway, I just want to affirm that tribal epidemiology centers are serving our sovereign tribal nations. We have already had the consultation where the tribes supported their public health status. The law has been passed for that. I would suggest that there by a list of priority action items for the next year or two through the end of the Biden Administration. And how about we all celebrate in 2024 all the progress in ensuring that the tribal epidemiology centers have their rightful place with all other public health authorities? Thank you for the opportunity to comment.

Rebecca Hines: Thank you for your comment. Anyone else? Can you please open the line for Margaret Egan please?

Margaret Egan: Good afternoon. Can you hear me?

Rebecca Hines: Yes, you are live.

Margaret Egan: Thank you. I am Margaret Egan. I am the General Counsel for the Great Plains Tribal Leaders Health Board. I was on that call that Jerilyn mentioned yesterday, negotiating the data sharing agreement between IHS and our TEC. I just wanted to fill in a little bit more detail on that.

What we are trying to do – this is our second data sharing agreement. We are trying to establish linkages, those linkages that were mentioned earlier, so that we can establish an American Indian registry in our area to correct racial misclassifications in our state databases. We have those linkages with the state system set up. But I do not know how many rounds of negotiations we have been through with this DSA because it started before my time. It has been difficult.

I just want to contrast with a couple of examples. For example, no DSA was required with the South Dakota Department of Health when they just gave us access to their system. They recognized the TEC as a public health authority. In Washington, I know the Department of Health gave the TEC their direct access, log-on access to their system and all that needed to be in place was a standard access agreement.

What we are trying to do with the data is just standard public health practices. We are not trying to access PHI and do anything untoward with it and yet we cannot get our DSA in place to do those standard public health practices or at least right now at this moment, we are in – our bottle has been stopped up.

We have speculated. Maybe the area is nervous because their data is not very high quality and they do not want us to see it and we know that the Data Modernization will speak to that if that is an issue. We know that the RPMS system that IHS works with is not a certified EHR. But again, that modernization effort really needs to have tribes at the table to address some of these things.

I just wanted to note that it is really important to understand that epidemiology – I am a GDMPH, so I have some training in epidemiology. We cannot do epidemiology without each other. It is the study of populations. We need partners or we simply cannot accomplish the most basic public health goals. Epidemiology by definition does not exist in a vacuum. We need each other to improve health to even understand what is going on with our populations. We want that data so that we can use it as the TEC for the area and so that we can give our member tribes information about their people so that they can then address health needs in their tribes.

It is all I had to say about that and thank you.

Rebecca Hines: Thank you for taking the time to comment. We appreciate it. Any other live audio public comments? We have one written one from this morning that I would like to read. That would be a good segue back to the next agenda item.

The comment this morning was on social determinants of health from Michelle Gesture(ph.) who wrote, there is a lot of great work on data standards for both social determinants of health such as the SIREN Gravity Project and sexual orientation and gender identity data. We have spent almost two years leading an evidence-based and stakeholder-driven process to develop improved data standards for demographic data, including sexual orientation and gender identity data. We mapped the data standards to existing codification structures, LOINC, SNOMED, ICD, FHIR to enhance interoperability. Happy to share with this workgroup so they do not have to start from scratch. Note, these data standards are more for clinical settings but appreciate Vickie Mays' comments that data may be different depending on context and setting, e.g. whether public health surveillance versus clinical setting versus administrative setting.

Any other comments? We have another comment from Nicholas Hill. Can you please open his line? You are unmuted.

Nicholas Hill: Thank you so much. Can you hear me?

Rebecca Hines: We can. Can you state the organization you are with please?

Nicholas Hill: Yes. Sure. I am with the Great Plains Tribal Leaders Health Board and the Great Plains Tribal Epidemiology Center. My comment is I have about a 25-year history in public health, mostly which has been in epidemiology and informatics. And what I have seen time and time again working at a state health department setting is that both federal and state-level resources are not often either sufficient or maybe perhaps the best way to phrase this is maybe the right resources may not exist to address local-level needs and threats and things like outbreaks. We have seen that time and time again I think with COVID as well.

I think that is the justification for ensuring that things like systems and policies would be updated to allow health data to flow in a decentralized model to essentially those at the local level that are the public health authorities that have the need to know who can respond because they are the right resources and/or may need to be funded to receive them to improve the health and well-being of the communities and address those threats that I mentioned. But bottling it up at various nodes, data centralization nodes is probably not the best answer based upon my experience.

I have seen partnerships that form with local-level resources in times of great need affecting what most higher-level agency public health authority could accomplish. I think that is sort of the justification to do that and I think that also really makes the case for the data modernization initiative and all that goes with that that there needs to be of course we know serious funding with all the right partners, and I think tribal nations need to have a prominent seat at that table especially in the health disparity – to address the health disparities and address health equity of course. I will just stop there and take questions if you have any.

Rebecca Hines: Thank you for your comment, Nicholas. That was very helpful especially given that data modernization is on the table as a high priority right now.

We will wait another moment. Any other comments? Nothing has come in by email. We appreciate those of you who provided feedback to the committee. Jacki, over to you.

Letter of Recommendation

Jacki Monson: Okay. Let us pivot back to standards to the letter that we worked on yesterday. I am going to turn it back over to Rich and Denise.

Denise Love: Thank you, Jacki. Rebecca, is it easiest to post a clean copy and have me go over the edits that we made?

Rebecca Hines: Ready to go.

Denise Love: Tammy and Rich, you are welcome to chime in. There was no substantive or any changes to the first page to the front matter. It is still the standard language.

The next page. We added some just context wording for the bullets in the recommendations that follow. Just some clarity there in that first paragraph to describe the context and the rationale.

Throughout we made changes to “should” and “needs to”. That language carries through the document. We just tried to soften that HHS “should”.

Rebecca Hines: I just want to just chime in a quick second. For those of you who got the letter this morning, this edit came in after that letter went out because Rich Landen’s internet was down. These got added on after the version you got by email last evening just so you know.

Denise Love: Thank you for clarifying because there has been a lot of back and forth and I was not sure when that came through. Thank you.

Keep scrolling slowly. And then we added fast for FHIR. We spelled out FHIR in the last paragraph on the previous page based on a comment that clarifies for reader wherever that FHIR is. We spelled that out.

Go to Recommendation 1, the top one. I think the main other change there was just the reordering of the bullets so that the example of multiple standards approach was put on the bottom instead of the first. But the language itself did not change.

We did take – on Recommendation 2, again, the bullets were reordered so that the example was put not first but last. We took out the bullets of installed base, protected, business imperatives are met, upgraded costs are minimized. That is in text later in the description in the letter instead of a bullet and the same for we point to the ONC standard version SBAB prop P process is in text later. We took those bullets out.

Recommendation 3. We tried to capture what we heard yesterday. I will just pause a minute and say we changed just a few things.

Recognizing ONC's existing authority to facilitate the coordination of social determinants of health data standards' efforts across HHS agencies and offices, the examples, NCVHS recommends that HHS expand ONC's authority to include a formalized public process to – I think we put to include non-federal entities, again, private health and health care systems and State, Local, Tribal and Territorial Governments, and to align national standards with evolving and complex national and local reporting and information needs.

Then the bullets changed in response. Again, that "should" was taken out. The public process needs to include alignment of the data reporting requirements in federal programs and agencies. We used examples of HRSA and SAMHSA. And in federally funded data modernization investments in order to advance health equity in all jurisdictions.

Rebecca Hines: There is a comment that we have included twice in the actual recommendation statement. We need a suggestion I think, to streamline that.

Maya Bernstein: My suggestion would be, if I may – I recognize I am not a member, but my recommendation is break this into two sentences. You want to say recommend that HHS expands ONC's authority to include a formalized public process. That process would include --

Denise Love: Okay. I think that is fine. I then take out to.

Tammy Banks: And then the "and" is not needed there because the action is to align. I put in and out three times.

Denise Love: It is tricky.

The first bullet tried to get at that data modernization investments instead of public health grants.

The second bullet. Again, an important function of this process is to support - and the ongoing work was put in on data content, structures, and formats between diverse data sources, and establish a process to

request modifications and propose new standards for missing use cases. The concept of it is just not a one and done. This is an ongoing back and forth process to keep the standards updated for evolving uses.

The third bullet –

Rebecca Hines: Denise, Vickie's hand is up.

Vickie Mays: I just want to make sure I know what is a missing use case? How do you know to say it is a missing use case? I kept saying, do I know?

Denise Love: Okay, -- for use cases or --

Vickie Mays: Because I was not sure --

Denise Love: I will make a confession. I have seen this so many times I missed that.

Vickie Mays: That is okay. I thought I did not know something, and I wanted to know if I had missed learning something from you all. I am fine.

Denise Love: The secret use cases. Okay.

Rebecca Hines: I am wondering whether use cases –

Rich Landen: I think this point is really well-taken. I think what we really mean here is additional or new use cases so taking out the – meets the bill.

Rebecca Hines: Is new okay, Rich?

Tammy Banks: New or revised. Right?

Denise Love: Could we put emerging use cases? Things are moving --

Jamie Ferguson: How about specific use cases?

Rich Landen: Unmet use cases.

Tammy Banks: New or revised like the standards, what is coming –

Jamie Ferguson: I would just say for specific whether they are new or old.

Denise Love: Okay, but I think the concept is to have the back and forth so it is not just promulgating a standard and going away but having the content and structures and formats respond as modifications are requested by the locals to go up and then come back down with some examples.

Vickie Mays: Can you fix that because I think if we say propose new standards for specific use cases as the need arises, or something like that? That is a fix that you want to see. I understand what Jamie is

saying about the specific. But it is kind of like you are trying to make this a standard way of doing this to answer these issues.

Denise Love: Or in response to user needs or applications.

Vickie Mays: In response to needs.

Denise Love: Okay. It is more than business need. We have measurement needs that are broader.

The last tweak bullet is again, taking away the "should". We bring in this technical assistance. Provision of this process – that looks weird. We have provision twice.

Rebecca Hines: It is a 10 p.m. editing error.

Denise Love: Yes, it is. Because my version says technical assistance to state, local, STLS, and frontline workers.

Tammy Banks: It is a redundant because I know I deleted it at one point. Get rid of the provision. It probably needs to include --

Lorraine Doo: I sent edits for this one earlier, but they did not make it through.

Denise Love: Were they substantive edits? There were so many edits flying around between last night and this morning, I do not know which ones they were, Lorraine.

Lorraine Doo: Yes.

Denise Love: The concept here is technical assistance and tools to national and local and frontline health care workers. The tools. Some examples. EHR for testing purposes and a centralized repository of SDOH definition and formats and other activities needed to accelerate and improve new standards implementation and the integration of SDOH capable of supporting subpopulation and social risk analytics. Vickie, I think that was in response to just saying data. We wanted to expand the vision of that.

Lorraine.

Lorraine Doo: I think we were trying to make it two sentences so it would not be quite so long. Do you want me to try and pull that up? It was the same thing. They just made it two. Do you want me to try and find it and put it in the chat?

Denise Love: Sure. As long as it is not substandard.

Lorraine Doo: Not at all. It just made it into two sentences.

Denise Love: And then four. There were not too many changes. But Tammy, do you want to take that one?

Tammy Banks: Basically, it was the same thing as Denise was saying. What we did is we took the bullets that related to the action of the recommendation and put it in this part of the letter. Anything in regard to context or background was moved into the second part, which talks about the rationale and criteria.

The only main change is one of the key points that we had dropped was in order to streamline and facilitate the regulatory impact and fiscal impact analysis required as part of CMS' rule development process, the framework needs to include as many of the data elements as possible that CMS needs to complete its analysis. The intent of this recommendation was to bring value to the CMS rule development process as well as bring value to the standard development organizations and also industry stakeholders as they determine their priority roadmaps. I think that is the main change. I thought there was one more if you want to go down just a little bit. I guess that is. Review was added based on our conversation yesterday as well.

Rebecca Hines: Jamie Ferguson's hand is up.

Jamie Ferguson: Can I ask us to go back up to the fourth bullet on Recommendation 1 please? I would like to suggest a minor change to remove the characterization of more complex, less complex, bigger, smaller just to simplify that because I think that the FHIR-based APIs are not necessarily less complex. They are perfectly in many cases better for larger organizations for other reasons. Maybe as pointed out in the ADA's public comment letter would be to allow some stakeholders to use the API standards while other organizations could use the X12 standards.

Lorraine Doo: We had submitted that earlier too because that was not in the in the ADA letter. ADA wanted to use FHIR but they did not have that comment specifically.

Rebecca Hines: Will you want to put the option to use or just leave it as allow?

Jamie Ferguson: Just to allow some to use. I would take out less complex. To use API standards. In fact, it would be based on HL7, not like HL7. While other organizations could use X12 standards.

Participant: Take out complex too just to be consistent.

Jamie Ferguson: Yes.

Tammy Banks: Use the X12 standards.

Rich Landen: We could. My concern is that by doing that, we have taken out the rationale as to why two standards is better than one. The current policy is one and only one standard. Can we find a way to put in – I think, Jamie, you made a statement about alternative technology that could be an advantage unto itself.

Jamie Ferguson: There are many reasons why some stakeholders would find the FHIR-based APIs better. It is lower labor cost, more availability of workforce, lower testing costs, technical tools compatibility. There is a list. I do not think we need to go to the list here personally.

Rebecca Hines: Rich and Jamie, it sounds like you have a difference of opinion as to whether that level of detail is warranted.

Jamie Ferguson: Or maybe that goes in the rationale section down at the bottom of the letter.

Tammy Banks: Could we add based on business needs maybe? I am trying to think how to pull in Rich's point.

Participant: The problem is it could be the same business need.

Jamie Ferguson: I think if we have a rationale section then let us not put the rationale in the summary.

Rebecca Hines: Okay. So I do not make everybody dizzy, I am going to stop share because I am going to fly down to number four in the rationale section and I am going to re-share. Where would you like this?

Jamie Ferguson: Actually, it is recommendation number one, I believe.

Rebecca Hines: I am sorry. Close your eyes. Here we go.

Denise Love: There is a part about technologies have evolved significantly.

Rebecca Hines: But Jamie's point about the resource costs. Is that in here?

Jamie Ferguson: I do not know. Could you scroll down a bit please?

Denise Love: Go down to the last paragraph there. This is the ADA example.

Jamie Ferguson: This does not say I think here about the – it does not mention workforce availability. It does not mention lower labor costs or lower testing costs, things like that, which I think are things that we have heard about discussed.

Rich Landen: Jamie, I am thinking that thought should probably go in the middle of the paragraph above that where we talk about public inputs suggest that when adopted by regulation, new technologies, e.g., API FHIR could be more effective and efficient and then the next sentence to list the advantages that you described.

Rebecca Hines: Jamie, if you want to put this in the chat, I can just --

Denise Love: Rebecca, do we need to spell out fast health interoperable twice?

Rebecca Hines: No. It is already – we can take --

Denise Love: We do that in the first time. I do not know that we need to do it again.

Rebecca Hines: Right. That is exactly right.

Rich Landen: Just one of those closing parenthesis should be deleted, Rebecca.

Denise Love: Can we say some entities may – or just go into the advantages of FHIR and list those that Jamie --

Jamie Ferguson: I put something in the chat that we could consider.

Denise Love: Okay. Can you copy from --

Rich Landen: Rebecca, I would start the sentence with the advantages of FHIR or some stakeholders.

Denise Love: Does that get at the rationale, Jamie, that you were looking for?

Jamie Ferguson: It does. Thank you. It puts it in the rationale section.

Rebecca Hines: Denise, where are we now? Where do you want --

Denise Love: We are going up to the background and context of the rationale for recommendations. This just has the same recommendations worded with a little more discussion around each one of those. There was very little change in Recommendation 1 in the discussion in the revisions. You can scroll down. We kept that as is and then we just did some tweaking there.

Recommendation 2. Again, scroll down a little. We added the two – or one comment, the installed base. A bullet in the very last sentence, third paragraph. The installed base. Where is that? Under Recommendation 2. By allowing. This last sentence. The installed base is protected. Business imperatives are met. Upgrade costs are minimized. That was a bullet. It was just pulled out of the first mention of the recommendation into the rationale.

You can continue. We could say the same at the very end here, the very last sentence under SVAP. That was a bullet. We just pulled the bullet – go up above Recommendation 3. This last – we point to the office of ONC and referenced the SVAP, standards version advancement process, as a success story and a potential model. That is not new wording. That just came out of the first bullet on that first page or second page. That is not new. It is just in a new place.

Under Recommendation 3, we will align with our tweaks with the “includes”. Again, nothing was changed overnight from the rationale and the discussion. We referenced the listening session and the panelists that confirmed that collaboration and coordination of harmonization is needed. I will not read that word for word. That has not changed.

The second paragraph has not changed. Building on collaboration and momentum that HHS has already established to develop new standards for – Vickie’s missing use cases are showing up again. We may want to put that missing out and put emerging use cases again in that last sentence. I have to go back to what we – I want to be consistent with what we said.

There was no change here. The entity could provide national leadership and tools and testing.

Rebecca Hines: I think this is left over from yesterday’s live edit. Can I just delete that?

Rich Landen: Label it a Hanging Chad and eliminate it.

Denise Love: Thank you.

Vickie Mays: Go back up to that paragraph where we just eliminated the hanging Chad. I am going to tell you that I am struggling just a little bit and I think it is because maybe the sentence needs an edit but I do not know how to do it because it is really long. This entity and I am lost as to making sure I understand which entity could provide national leadership and establish a series of actions and tools to achieve its objectives for cohesive process and common basis standards – those series of actions. I do not know what those are. I am kind of lost. If I need to be someplace else. I just do not know the series of actions that you are referring to. Maybe you should tell the person or give a hint in a parens or something.

Denise Love: I think it is a process that we want expanded. The existing process out of ONC we want expanded.

Vickie Mays: -- to say the existing process in ONC could or should be expanded. This would then provide national leadership or something. I just do not understand the sentence because it is just referring to something and it is not --

Rich Landen: If I may, Vickie. I think the recommendation is for an expanded charge to an existing ONC program so would language – this expanded ONC charge to replace this entity.

Denise Love: We say that in the recommendation. The HHS expands ONC's authority to include a formalized public process that would include federal entities and state, local, et cetera.

Tammy Banks: We are talking about the public process --

Rich Landen: Instead of two, put could. Replace could.

Denise Love: Vickie, a series of actions is confusing. Maybe a centralized – what the testifier said is a go-to place, a centralized place for people to go either to learn what the standards are or to request modifications to standards plus tools and documentation.

Vickie Mays: That is so much clearer what you just said. I could not figure out what it was supposed to --

Denise Love: Instead of series of actions. A centralized source or a centralized location.

Vickie Mays: A centralized entity which could provide. We have too many provides already. A centralized entity.

Denise Love: Location and process.

Rich Landen: In some of the drafts, we use the term venue rather than location.

Vickie Mays: That is so much clearer now.

Denise Love: This is why we have these talking heads on my screen. It is really hard when you are sitting at your desk late at night --

Vickie Mays: I tried last night but I did not understand it enough.

Denise Love: I am really appreciative of your input because it helps. This is a hard one to get to. Common base standards, facilitate harmonization, develop needed tools. We give some examples.

Vickie Mays: The only thing we leave out is we did not put the private health stuff in there. It is up above. If you do not want to repeat it, that is fine.

Denise Love: I put across federal, industry, state, local, tribes, hoping it got everybody.

Vickie Mays: Maybe industry gets it. Okay.

Denise Love: And then there is one more just closing statement that testimony indicated that state and local authorities would be eager to adopt the work of – maybe put this entity or the collaboration may be too big as I look at it now. To avoid the cost and effort of developing local and nonstandard solutions for their health-related data reporting needs.

Rebecca Hines: Would it be instead of eager to adopt? To adopt the work of --

Denise Love: This entity or the process.

Rebecca Hines: I think you put a formalized public process above. I think that was the phrase --

Denise Love: -- seems kind of cryptic too.

Rebecca Hines: Adopt the work of this formalized public process –

Denise Love: To avoid.

Rebecca Hines: That is great. Big improvement.

Rich Landen: Either it is a solution or delete the "a" and use the plural solution.

Denise Love: It is solutions.

Rebecca Hines: That is great. Much stronger.

Denise Love: Tammy, I will let you wrestle with four that you know.

Tammy Banks: Four was not much change. It was just changing the recommendations to match what was up above. And then I believe the same three bullets remain that were there before.

Denise Love: And then we have Jacki's name at the end. That has not changed. And the appendix we did not revise.

Tammy Banks: We just updated the recommendations with the language that was there before, but I believe we have three comments to go back to the first set of recommendations. Vickie had a word change and then Lorraine provided the separation of that one recommendation.

Rebecca Hines: I do not need to do that. It was just splitting a sentence. I can handle that in a little bit. I do not need to take everyone's time. It does not change the meaning.

Was there any other substantive change here, Tammy?

Tammy Banks: Vickie, you wanted to change a word.

Vickie Mays: I just added the social risk and social vulnerability because we are really being pushed to do that in the health care setting. Social risk is about the individual who might be unhoused and then the social vulnerability is the homelessness. We are just starting in the UC to have both of those.

Denise Love: That is under three?

Vickie Mays: No. It is in Lorraine's. It was to fix that sentence.

Rebecca Hines: Which recommendation are we in?

Vickie Mays: Lorraine fixed this sentence.

Rebecca Hines: Where did you want to change social risk?

Vickie Mays: You have to take the sentence from Lorraine, which breaks it into --

Rebecca Hines: We will just take the time to do that then. Thank you.

Denise Love: She is going to split that last one.

Vickie Mays: Yes, she did. It is in the chat, Rebecca.

Rebecca Hines: It is hard to get out of the chat but I am working on it. Just give me a second. I am just going to make a whole new bullet point here.

Denise Love: And then Vickie, that adds social vulnerability.

Rebecca Hines: Where do you want social vulnerability? I do not see where.

Vickie Mays: It is social risks and social vulnerability analytics.

Rebecca Hines: Thank you. I appreciate your patience. I was a little slow there.

Denise Love: Rich and Tammy, did we hit the changes except, for number three, which was a lot of wordsmithing, were not substantive to the letter. It was more of a re-configuration of some of the bullets into rationale and changing "should" to "needs to". Those were the main changes. And then, again, three, getting those words to mean something because there are so many words that needed to be massaged as we just saw. But those were the main changes.

Rich Landen: And, again, I apologize for my internet difficulties yesterday but thank goodness we have a very engaged and well-informed subcommittee. My thanks to Denise and Tammy for spearheading this

effort last night to assimilate all the comments that we got from the subcommittee and then to do the cleanup of what admittedly was a somewhat coarse draft when we looked at the three different places where we had listed bullet points with overlap and not well harmonized. Again, that was due to the last-minute churning because of our meetings with CMS and ONC earlier this week. Apologies to the committee. I think we have everything incorporated now into the letter.

I would like to propose to the committee that we put it to a vote subject to the usual things about final editing and formatting, cleanup, not substantive changes. Motion then to turn it over to the chair for a motion to accept and approve the letter of recommendation.

Jacki Monson: Before we take a vote, I just want to make sure because Vickie, Melissa, Val have not had the opportunity so much as the Standards Subcommittee has to review this. I just want to make sure from the three of them that they are comfortable with this and feel like their questions and concerns have been answered.

Valerie Watzlaf: I am fine with it.

Melissa Goldstein: I am fine with it too. I think that there are areas that could be smoothed out but I think that that can be done after today without changing the actual substance.

Vickie Mays: I read it last night. There is just to me just smoothing things. I am not a standards expert. But what I am expert enough in is just smoothing. We did a lot of that today. I am happy to either – I do not know if I am supposed to make the motion or second the motion. I will do either one that you want.

Jacki Monson: Let me just check in with Wu quick. She is the last one.

Wu Xu: I am fine.

Jacki Monson: Okay. Ready for your movement.

Maya Bernstein: Motion, I think, is the word you want. I just want to make sure that you understand that the language of the recommendations themselves cannot change after this. We have wordsmithing to do, everybody has to be agreed that that language is exactly as it is going to be. The exposition can change if it is not really substantive. But just a reminder to take a look – one last look at it before you vote.

Melissa Goldstein: We do not have the document to take a last look at it, Maya.

Rebecca Hines: Is there a request to bring it back up?

Maya Bernstein: Can we put up just the text of the recommendations? Gather it in one place.

Rebecca Hines: NCVHS recommends that HHS update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Recommendation 1.

Melissa Goldstein: Does that mean guidance? Does that mean regulations? What do you guys mean by policies?

Denise Love: Regulations and policies. Both.

Rich Landen: If it goes to regulation specifically, not to guidance, but it is a policy change. There is nothing in the enabling legislation that says there can be only one standard or there needs to be more than one standard. It is a CMS policy right now that there is one and only one standard per use case, if you will.

Melissa Goldstein: I consider that just clarification. That can be made underneath Recommendation 1 in the guts of it or it could be left up to the secretary to decide what policy means.

Rebecca Hines: Right now, it says in the committee's assessment, HHS needs to ensure that regulations allow. This gets to your point, Melissa.

Melissa Goldstein: That is fine.

Rebecca Hines: Is that adequate?

Melissa Goldstein: Yes.

Rebecca Hines: Okay. Recommendation 2. NCVHS recommends that HHS --

Vickie Mays: Can someone answer – never mind.

Maya Bernstein: If the committee does not have that question but I was trying to back up Melissa's --

Melissa Goldstein: I think all that the language requires, Maya, is that someone does a check to make sure that the regulations allow multiple standards. That is all it asks.

Maya Bernstein: My confusion was that is a regulatory change, not a policy change. But like you said, there is a discussion --

Melissa Goldstein: I think that the recipient of the letter can make that decision because that person theoretically has the purview.

Rebecca Hines: Are we good with Recommendation 1?

Recommendation 2. NCVHS recommends that HHS enable HIPAA-covered entities to support one or more versions of adopted standards for business functions.

Melissa Goldstein: That is just the same issue. If you guys are thinking of policies – it could just be guidance explaining that it already is there, the ability. But if you do not care how it is done --

Denise Love: We wanted to leave that to CMS if I recall some of the conversations.

Rebecca Hines: Lorraine, is this adequate enough, this language in the bullet point, to explain what the committee means by this?

Lorraine Doo: They will understand. You have had conversations with them so you know where the national standards group is on this. But it would be regulatory.

Rebecca Hines: Very good.

Rich Landen: Melissa, maybe a little bit more clarification. No new standard. No new implementation guide can be used unless it is adopted by CMS. This is not a guidance thing. This would be enabling CMS to promulgate to go through new rule making to put up a second standard as allowable under HIPAA for the same use case.

Melissa Goldstein: Thank you. It nitpicks before. Data standards. I put a little bit up. If you scroll up in the chat, I recommended some language here. The second sentence says that process would include. I thought it might be a little bit more differential to say we recommend that the process include sort of like --

Rebecca Hines: We had it that way but when we split it into two sentences, it changed.

Melissa Goldstein: Instead of that process, can we put we recommend that the process include right there? Would that be okay for everybody?

Denise Love: I am fine with it. NCVHS recommends that a formalized public process. We also recommend. Is that what you are trying --

Melissa Goldstein: That would be fine. I just thought it looks a little prescriptive to say this is what it could include.

Maya Bernstein: I am confused. I am not a committee member. But does ONC not have the authority to have a formal process? It sounds like we are suggesting some advocating of some legislative change. Do they not have some authority to do this already?

Denise Love: As I understand, they have authority. We are asking them to expand their scope, right?

Rebecca Hines: In discussions with them, they actually said this would be helpful.

Vickie Mays: Then when we say we also recommend this – I don't know. It is getting hard. We would also recommend the expansion of that authority. Is that the way to say it? We would also recommend the expansion of that authority to include.

Denise Love: Again, I do not know if it is a regulatory or what. But it is the scope – I want the scope of what they are doing to be expanded.

Vickie Mays: Jamie has his hand up.

Jamie Ferguson: I did not want to interrupt that discussion because I had a different question about this.

Vickie Mays: I thought you were going to answer this. That is why I wanted to hear.

Jamie Ferguson: I do think they already have the authority. But if this would be helpful for them to exercise that authority then we should say it.

Rebecca Hines: That is what was communicated.

Rich Landen: ONC's current charge from the Secretary is the scope is limited to the HHS offices and departments that we have listed here. Our recommendation says, hey folks, that is good, but you need to expand it beyond HHS offices and agencies. I am getting concerned that in our desire to split this into two sentences, we are losing our focus on what our recommendation really is.

Rebecca Hines: I agree. I actually think it was much stronger as one sentence.

Jamie Ferguson: I also think it would be stronger. We do recognize ONC's existing authority. But we do not need to lead with that. All the other recommendations start with NCVHS recommends that. This one should too. The recognition of their authority can go elsewhere. I do not think it needs to be in the body of the recommendation personally. I think – the whole first part of that first sentence.

Rebecca Hines: That was kind of a request. We were trying to honor a request.

Denise Love: What do we lose then if we just go right into NCVHS recommends that HHS expand ONC's existing authority to include blah, blah, blah? Do we lose anything?

Tammy Banks: Denise, the way I read this is we are recommending the expansion to the public process, and we are breaking out the part of who would be a part of that public process and that is what that second sentence is. Can't we just say the public process – use the same language but does the public process include all these entities.

Valerie Watzlaf: You do have that down below, right, the first bullet. You could move it down there, right, if you move the second sentence– below.

Tammy Banks: That is the programs and agencies. That is not the same – we include – federal – it is because it is the federal agencies, which CMS, ONC, and then the non -federal. So you are separating stakeholders when you divide this --

Jacki Monson: What is the purpose of this recommendation? What are we actually trying to get to because it feels like we are telling ONC what they are already doing?

Denise Love: They are not reaching down to the local jurisdiction.

Jamie Ferguson: We are telling them to expand what they are doing because most of the reporting requirements on hospitals, for example, come from local and state authorities that are not included in the ONC process.

Denise Love: It is a real disconnect.

Jacki Monson: If that is the case then why wouldn't we just cut it – why wouldn't we just start with NCVHS recommends, which we have in the second part?

Rebecca Hines: My thought was use this material and this is a re-write of the recommendation so this is a re-write. Here is what we have so far. NCVHS recommends that HHS expand ONC's existing authority. I think we should say to facilitate coordination.

Participant: We do not want to lose that SDOH.

Vickie Mays: It is – very specifically and that should be there. Yes.

Rebecca Hines: Existing authority to facilitate the coordination of social determinants of health data standards' effort across HHS agencies and offices to include a formalized public process.

Rich Landen: To me, that starts to get murky.

Vickie Mays: Murky how? What is murky?

Jacki Monson: Are we expanding their authority or are we expanding their activities?

Vickie Mays: I thought they did not have the authority to work in this space. So it is activities but with authority.

Denise Love: I do not know legally what the authority reads as. I personally think it is -- Rich and Tammy were on the phone. I missed that call. Is the scope of their activities under that authority? I do not think there has to be a legal change to their authority. But the scope of it needs to incorporate social determinants and administrative data and programmatic data at the local and other agency levels.

Rich Landen: As we understand it, their current charge, which comes from the Secretary, so we are not talking legislative or regulatory, only includes agencies within HHS. Again, this recommendation is asking the secretary to expand his charge to ONC to include state, local, tribal, territorial, and the other entities that we – health systems that we in our discussion yesterday decided to add.

Denise Love: Should we then instead of authority, put charge? Expand ONC's existing – charge. Just put expand their charge.

Tammy Banks: We wanted authority. You may want to leave it unless there is a big reason. Why change the – requested us to use?

Denise Love: I think that gets it all in.

Tammy Banks: One other way I think you can make it short too is we are talking to include a formalized public process to align national, state – include involving and complex national local reporting information needs. Then make the second sentence – we can go NCVHS recommends. This includes non-federal entities and then put that as a second sentence. And then that will put what the – the actual charge for the public process next to each other. Would that make it easier to understand?

Rebecca Hines: Is that what you are saying, Tammy?

Jamie Ferguson: I think it makes it more complex. To me, that is less clear. And although I hate long sentences, in this case, I think it would be clearer if there were just a single sentence like all the other recommendations. NCVHS recommends the authority be expanded. A formalized public process that would include.

Rebecca Hines: Now, you are saying do not split it to say that would include.

Jamie Ferguson: Despite the fact that I hate long sentences, in this case, I will go against that rule. Just like that.

Rebecca Hines: We were right before, I think. I think it was actually fine the way it was.

Jamie Ferguson: That is just me.

Rebecca Hines: I think we are in wordsmithing territory.

Jacki Monson: Can I ask one more question probably for the staff to the committee? ONC has their own federal advisory committee, right, that is not our scope. Are we going beyond our scope by what we are recommending here?

Denise Love: I am going to take a stab at this. I think this is the heart of ICAD, the convergence of clinical and administrative data. This is really where the rubber meets the road. As we heard at the hearing, it is not working very well to cross fertilize the data sets. Your question is good. But I think it is in our charge to elaborate with the clinical and bring in some of the statistical and administrative together. That is my take. Others may have a different take.

Rich Landen: Absolutely agree with you, Denise.

Rebecca Hines: We have periodic sometimes quarterly discussions with them to ensure that we are coordinated and aligned, and they were in alignment with us. This was welcomed.

Jamie Ferguson: I think that this also – these data are important for the vital health statistics, not just for the EHR records that ONC focuses on.

Denise Love: At the hearing, we heard – I wrote down fragmented system like three times, three different of our panelists. And they wanted a centralized place to come together and whatever that entity was. We were pleased to have that conversation with ONC to build on what they are already doing and just expand it.

Rebecca Hines: I hate to say this, but it is almost like this is two recommendations because this one talks about including the non-federal entities and this description talks about getting your act together across the federal entities. But I guess it includes both. This is much closer to where we were yesterday. I think we have sort of gone around and come back.

Denise Love: It has been a challenge.

Tammy Banks: Is everybody comfortable with this?

Vickie Mays: Yes.

Tammy Banks: Is there any other – do you want to through Recommendation 4 as well or was there any questions on any other pieces of the recommendations? Melissa, I do not know if you had any additional questions.

Melissa Goldstein: I am reading.

Maya Bernstein: While she is doing that, can I ask -- I am going to have to explain what happened here to my leadership. Can someone just summarize briefly, how it came that ONC asked us for this – Rich or Denise, can you help me understand how this happened?

Rebecca Hines: Can you remind Maya, that we coordinated and co-chaired the ICAD Task Force, this committee – so that she knows that and can report that back up because they may have forgotten that fact.

Rich Landen: Building on ongoing collaboration and recognizing that there is a line between ONC HITAC and ONC's responsibility on the EHR side, and NCVHS' charge around health data. There is ongoing collaboration. I would not couch this as they asked us, but we are saying as our processes have evolved coming out of – building on the vision in ICAD, we came up with this recommendation and in our ongoing collaborative meetings on collaboration. We bounced these ideas off of both OBRHI, and in a separate meeting then with senior leadership, not the National Coordinator himself, the senior leadership. And they were receptive. I will not say – I will not categorize either as having agreed to or committed to anything, but they gave us the indication that these were ideas that were compatible with their own mission and objectives.

Maya Bernstein: That is really helpful. Thanks so much. I was just confused. Rebecca said that they had asked for this a couple of times. The committee of course can advise the secretary and so within your – anything within the subject matter scope that you have. You can advise the secretary on any of the agencies – departments. That is okay. I do not have a problem with that. I just did not understand how it came about. Thanks for the reminder.

Rebecca Hines: Maya, they asked for specific wording changes. I just want to be clear that I did not make that up, which is what you are implying. They asked for specific wording changes in our recent discussion with them, which is different than the process Rich just described.

Maya Bernstein: Denise, were you saying something there?

Denise Love: Back to the hearing where this all started, the panelists were asking for a centralized federal or national federal entity with "teeth". That is where the – who would that be, what would that be. This led us to conversations we heard that ONC has this process in place and has the charge for the HHS so it evolved to that locus. If you wanted to play it safe, you could say ONC or other entity designated by the secretary. But I think we are getting too deep there. I just do not want to do that. But that is where it started.

Tammy Banks: If I can just add because I also said that we gave them our recommendation. And just like we have the same conversations. What are the word choices that would be more palatable to understand the recommendation? They gave us those word choices. Of course, we had a choice to use it or not but obviously want to make sure that is clear and understandable. It was not – they asked. That is what the recommendation was in order to make it understandable for what we were trying to achieve. Suggestion. Is that a better word?

Melissa Goldstein: I have some very quick questions. Readiness means time. Is that correct?

Rich Landen: Readiness in the context of standards means more in the sense of ripeness.

Melissa Goldstein: I am trying to figure out what that means in terms of – you have asked – no scanning.

Rebecca Hines: Let me put a page break here temporarily.

Melissa Goldstein: I need the language of the recommendations because that is what we cannot change. Okay.

Rich Landen: Readiness implies a degree of maturity rather than a temporal focus.

Melissa Goldstein: The language says that you are asking for them to tell to outline how to develop and report a quantifiable estimate for readiness. What does that look like? A time guideline or what does that quantifiable estimate look like for readiness. That is my question. It is a dollar.

Rich Landen: Readiness is a term of art in the standards world and ONC not for HIPAA but for its electronic health record certification program and the ISA, the – help me out with what the acronym stands for. The standards advisory. It is a whole process by which ONC gives what one of the former national coordinators called a heads up to industry about what standards ONC is considering adopting in future years. It is a glide path about when a given standard might be tested enough, developed enough and mature enough for a large-scale implementation as opposed to pilot testing, alpha testing, beta testing in that sense. ONC has a very – I think it is now probably an eight-year-old program that describes standards readiness. It is not a new thing. It is a concept that ONC already has in place.

Jamie, can you help out there?

Jamie Ferguson: Yes. Thank you. I was just going to say in the meaningful use program, the ONC had more than one set of quantifiable measures for standards readiness. We do not want to prescribe which one they should use.

Melissa Goldstein: Jamie, should the word be estimate or measure? That is my question.

Jamie Ferguson: I think it is a set of measures.

Melissa Goldstein: That is really my question because I do not know what a quantifiable estimate would be for readiness unless they have a grade. That is what I am struggling with here.

Jamie Ferguson: In fact, we might say instead of quantifiable estimates, we might just say measures.

Rich Landen: That would work.

Melissa Goldstein: I understand that this is wordsmithing, but I am focusing on clarity actually. Because that covers all three: readiness, cost, and overall adoption value.

Rebecca Hines: One of the issues is that nobody thinks some of this stuff is going to be anything but estimates. Measures is fine. We have to – implied in that is when we provide data for the measures, they are going to be estimates.

Tammy Banks: You are looking at the measure or the outcome of the measure and the estimates are what occur based on the measure. Either works.

Rich Landen: Any other questions on language for Recommendation 4? Are we ready to call the question Madam Chair?

Jacki Monson: I believe so. Do I have a motion?

Rich Landen: Waiting for Vickie.

Vickie Mays: I was wondering.

Rich Landen: I thought you wanted to do the honors.

Vickie Mays: I thought it was going to be somebody from your committee. I was trying to be quiet and sit on my hands.

Tammy Banks: I will be the first. I will make a motion to approve this so Vickie can second it.

Vickie Mays: Okay. And I will second it. That is what I thought.

Jacki Monson: All in favor please raise your virtual hands.

Denise Love: With grammar modifications as needed. Do we need to add that?

Rebecca Hines: One, two, three, four, five, six, seven, eight, nine. Margaret and Jacki, your hands are up? Margaret. Or you can turn your camera on and raise your virtual hand, Margaret. Your real hand. We have one, two, three, four, five, six, seven, eight, nine, ten. We do have ten members who have voted in favor and one who appears to be off screen. We need 10 votes and we have 10.

Maya Bernstein: You need to ask for people who are opposed or people who abstain.

Tammy Banks: I will text Margaret. Maybe she just stepped away.

Rebecca Hines: We can either wait or –

Jacki Monson: I think we need to wait --

Rebecca Hines: We have a quorum. We have ten. If Margaret is with us, it is just like Denise Chrysler is not with us and cannot vote. Even though she is logged in – we have 10 active members, and 10 active members have all voted. We need a minimum of ten. We have the ten. There are no other members available to ask right now whether they abstain or disapprove. I think we are okay. But if anyone has a different assessment, please speak up. We have ten votes. That is what we need to approve the letter. The letter is approved.

Jacki Monson: Congratulations, Rich, Denise, and the Standards team.

Maya Goldstein: Congratulations you guys. A lot of work in this.

Denise Love: It was in a really short period of time.

Melissa Goldstein: I like these new floating emojis.

Jacki Monson: It feels like flying emojis because they kind of just fly across the screen.

Maya Bernstein: Jacki or Rebecca, can you remind us of what the process is from here on this letter?

Rebecca Hines: Yes. The process is that next week we will get it onto letterhead and confirm with the chairs of the Standards Subcommittee that the smoothing edits are acceptable and then send it to Jacki Monson, who is our chair, to approve application of her electronic signature at which time it will be submitted to HHS.

Maya Bernstein: Thank you.

Jacki Monson: Rebecca, are there any other items for discussion. We obviously do not have time to cover the workplan given that we are almost at the top of the hour. Is there anything else we need to address?

Rebecca Hines: Not to my knowledge.

Jacki Monson: Hearing no other business --

Vickie Mays: I have my hand up. I do have a real mouth if I can't get the virtual, so I am okay. I just have a question about the panel today in terms of on the tribal group. Is there a point at which at least in the Executive Committee or something that we can follow up on what we might want to do, or do you want that bounced over to PCS to say? I just think there was a lot there and I just want to know kind of how we work with it.

Jacki Monson: I think we can do both. I think we can add it to the Executive Subcommittee discussion. I think we can also discuss it at Privacy, Confidentiality, and Security Subcommittee.

Rebecca Hines: In lieu of having a Population Health Subcommittee, it will have to go to the Executive Subcommittee.

Vickie Mays: Thank you. My hand is going to go down.

Jacki Monson: Melissa, is your hand up for fun or you have something?

Melissa Goldstein: That was me just – my Hanging Chad. Sorry.

Jacki Monson: No problem. I just did not want to ignore you like I did Vickie.

Okay. Any other items for discussion or business to discuss? Hearing none, thank you very much for your time over the last couple of days. We have had lots of robust discussion, productive time, and I look forward to seeing you all soon.

Margaret Skurka: I ran out to get my mail and I am back. There was a vote I missed.

Rebecca Hines: Yes. Thank you, Margaret. We are fine. We had ten votes and we needed ten votes. With you not being present, we went ahead and – the committee approved the letter. Would you like to add a post hoc approval or abstention or disapproval of the letter?

Margaret Skurka: Approval, for sure.

Rebecca Hines: Okay. I guess we can post hoc say there were all 11 members present who approved the letter.

With that, I just want to thank everybody, thank the staff, thank the members for all of your effort and the contract logistics team. I think this was a smooth meeting. We had lots of moving parts. This is really team sport. I just want to really sincerely thank everybody. This really is a group effort.

Jacki Monson: Absolutely. I want to echo that especially with the short staff that we know you are all facing. Really appreciate all the extra time that you are putting into this to make this go. Maya, thanks for all the work on the panels that we had, and just really appreciate our contracted staff on running the show with Zoom. Rebecca called them helping us with all of the challenges with Zoom. Thank you so much.

Maya Bernstein: Thanks, everybody, for your help – engagement on the panels for the last couple of days. It was a big lift. I really appreciate everyone's participating, your asking questions. That really made it work great. I have gotten a lot of private emails. It was great that you asked us to do those things.

Jacki Monson: All right. Thanks so much and have a great rest of your day.

(Whereupon the meeting was adjourned at 5:00 p.m.)