# National Committee on Vital and Health Statistics

Transcript

June 17, 2020, 10:00 a.m. – 5:15 p.m. ET

VIRTUAL

## SPEAKERS

| NCVHS Members | | |
|---|---|---|
| **Name** | **Organization** | **Role** |
| **William W. Stead** | **Vanderbilt University** | **Chair** |
| **Sharon Arnold** | **DHHS** | **Executive Staff Director** |
| **Rebecca Hines** | **NCHS** | **Executive Secretary** |
| Alexandra Goss | Imprado/ DynaVet Solutions | Member |
| Debra Strickland | Conduent | Member |
| Denise Chrysler | University of Michigan School of Public Health | Member |
| Denise E. Love | Individual | Member |
| Frank Pasquale | University of Maryland Carey School of Law | Member |
| Jacki Monson | Sutter Health | Member |
| James J. Cimino | University of Alabama at Birmingham | Member |
| Lewellyn J. Cornelius | University of Georgia, Athens | Member |
| Margaret A. Skurka | Indiana University Northwest and Principal, MAS, Inc | Member |
| Melissa M. Goldstein | The George Washington University | Member |
| Nicholas L. Coussoule | BlueCross BlueShield of Tennessee | Member |
| Richard W. Landen | Individual | Member |
| Vickie M. Mays | UCLA | Member |
| **NCVHS Staff** | | |
| **Name** | **Organization** | **Role** |
| Susan Queen | HHS | Staff |
| Maya Bernstein | ASPE | Staff |
| Lorraine Doo | CMS | Lead Staff, Standards |
| Rachel Seeger | HHS Office for Civil Rights | Lead Staff, Privacy |
| Amy Chapper | CMS | Staff |
| Natalie Gonzales | CDC | Staff |

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| Kate Brett | NCHS | Staff |
| Marietta Squire | NCHS | Staff |
| Geneva Cashaw | NCHS | Staff |
| **Presenters** | | |
| **Name** | **Organization** | **Role** |
| Sharon Arnold | ASPE | Associate Deputy Assistant Secretary for Science and Data Policy |
| Brian Moyer | NCHS | Director |
| Paul Sutton | NCHS, Division of Vital Statistics | Deputy Director |
| Chesley Richards | CDC | Deputy Director for Public Health Science and Surveillance |
| Helen Nissenbaum | Digital Life Initiative | Director |
| Mark Rothstein | Brandeis School of Law and School of Medicine at the University of Louisville | Professor |

**Welcome/Call to Order/Roll Call**

Rebecca Hines: Good morning and welcome to the Summer Meeting of the National Committee on Vital and Health Statistics. A warm welcome to members of the public. I hope you all are well and safe. I am Rebecca Hines, Executive Secretary and Designated Federal Officer for the Committee.

A special thanks to our members and staff today. We appreciate many of you are doing double-duty with added responsibilities within your organization as a result of the pandemic. We are grateful that you are able to participate today to bring your expertise to the Committee's work.

Let us take care of roll call. Bill, would you like to start off with your organization and conflicts, please.

Bill Stead: Bill Stead, Vanderbilt University Medical Center. I am Chair of the full committee. I have no conflicts.

Rebecca Hines: Alix.

Alix Goss: Alix Goss with Imprado, the consulting division of DynaVet Solutions. I am a member of the full committee, a member of the Executive Committee, Co-chair of the Standards and Review Subcommittees. I have no conflicts.

Rebecca Hines: Thanks. Debra.

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

Rebecca Hines: Denise Chrysler.

Rebecca Chrysler: Hi, I am Denise Chrysler. I am with the University of Michigan School of Public Health and the Network for Public Health Law. I am member of the Full Committee and a member of the Privacy, Confidentiality and Security Subcommittee. I have no conflicts.

Rebecca Hines: Denise Love.

Denise Love: Denise Love, health data consultant. I am a member of the Full Committee, member of the Standards Subcommittee and recently trying to become a member of the Privacy and Confidentiality Subcommittee. No conflicts.

Rebecca Hines: Frank.

Frank Pasquale: Frank Pasquale and I am Chair of the Privacy, Confidentiality and Security Subcommittee, member of the Full Committee and no conflicts.

Rebecca Hines: Jim.

Jim Cimino: Hi, Jim Cimino, Professor of Medicine at the Informatics Institute at the University of Alabama, Birmingham. Member of the Full Committee and the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Jacki.

Jacki Monson: Good morning. Jacki Monson, Sutter Health. I am a member of the Full Committee and a member of the Subcommittee on Privacy, Security and Confidentiality. I have no conflicts.

Rebecca Hines: Lee.

Lee Cornelius: Llewellyn Cornelius, University of Georgia. I am a member of the Full Committee and the Population Health Subcommittee and I have no conflicts.

Rebecca Hines: Margaret.

Margret Skurka: I am Margaret Skurka. I am the owner of MAS Consulting. I am on the Full Committee and the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Melissa.

Melissa Goldstein: Good morning. I am Melissa Goldstein with George Washington University. I am a member of the Full Committee, a member of the Privacy, Confidentiality and Security Subcommittee. I have no conflicts.

Rebecca Hines: Nick.

Nick Coussoule: Good morning. I am Nick Coussoule. I am the Senior Vice President and Chief Information Officer with BlueCross BlueShield of Tennessee, member of the Full Commit, member of the Standards Subcommittee and the Privacy, Confidentiality and Security Subcommittee. I have no conflicts.

Rebecca Hines: Rich.

Rich Landen: Good morning, Rich Landen. No organizational affiliation. I am a member of the Full Committee, Co-chair of the Standards Subcommittee, member of the Executive Subcommittee, member of the Review Committee. No conflicts.

Rebecca Hines: It doesn't appear that Vickie is on yet. So moving to staff, Sharon Arnold, good morning.

Sharon Arnold: Hi, how are you?

Rebecca Hines: Sharon is the Executive Staff Director of the Committee.

Maya, are you on?

Maya Bernstein: Yes. Good morning, and I thought that Sharon was on too. It looks like she is connected.

I work in the Office of the Assistant Secretary for Planning and Evaluation at HHS, and I am staff to the Executive Director of the committee and to the Privacy, Confidentiality and Security Subcommittee.

Rebecca Hines: Thank you, Maya. Rachel would you like to say good morning and introduce yourself?

Rachel Seeger: Good morning. I am Rachel Seeger. I am Senior Advisor at the HHS Office for Civil Rights and I am lead staff to the NCVHS Privacy, Confidentiality and Security Subcommittee.

Rebecca Hines: Thank you, Rachel. Lorraine.

Lorraine Doo: Good morning. This is Lorraine Doo with Centers for Medicare and Medicaid Services and lead staff to the Standards Subcommittee.

Rebecca Hines: Okay, I think that is everyone. I will turn it over to you, Bill.

**Welcome Remarks/Agenda Review**

Bill Stead: Thank you, Rebecca. Again, welcome, everybody. One note, this is the first meeting where Jim Cimino has been able to join us for the full committee, so, welcome, Jim.

Just briefly to review the Agenda, we are going to begin this morning with an update from Sharon Arnold on ASPE from its perch, and then Brian Moyer is going to join us to do an update from the National Center for Health Statistics. Then we are going to have a block where Frank is going to lead a discussion of the project scoping for the Privacy, Confidentiality and Security Subcommittee, followed by a block led by Nick on the approach to the 14th Report to Congress.

Then after lunch, Paul Sutton will give us an update on the National Vital Statistics System, and Chesley Richards will join us to share about the CDC Public Health Data Modernization Initiative. The last part of the day will be a panel discussion of the privacy, confidentiality and security perspectives on data collection and use during the pandemic public health emergency.

Tomorrow morning we will regroup and focus on standards with a follow-up on the updated NCPDP HIPAA standards that we submitted, our letter of recommendation after the last meeting, and then an update on the HITAC Task Force on the Intersection of Clinical and Administrative Data, and then plans for the August hearing on the CAQH CORE operating rules for federal adoption.

Just before lunch we will have an update on the Division of National Standards, CMS, and then after lunch we will come back to discuss what might be a near-term or short-term rapid response project around privacy, confidentiality and security considerations for data collection and use during the public health emergency. Then we will reflect on what we have learned and review the workplan.

That is the current draft of the Agenda. Are there any questions or suggestions for modification?

Rebecca Hines: Bill, Vickie Mays is in on the attendee side. Vickie, good morning. Would you like to introduce yourself?

Vickie Mays: Sure. Vickie Mays, University of California, Los Angeles. I am a member of the full committee, member of the Privacy, Confidentiality and Security, the Review Committee and Standards. And I have no conflicts.

Bill Stead: I don't believe Lorraine introduced herself, did she?

Rebecca Hines: She did.

Bill Stead: Okay. I just missed it. I think we are ready to turn it over to Sharon. Sharon, welcome.

**ASPE Updates**

Sharon Arnold: Thank you very much. When I was looking back at our last meeting and what has gone on since then, it was hard to believe it has only been three months because it has been jam-packed.

When we last met in March we had just been on 100 percent telework at HHS for about a week and things were happening very fast. They have continued to happen very fast, although I think we have been falling into a rhythm now. We continue to be open and running even though many of us are not in the office.

The Humphrey Building where we work is still open because it houses the Office of the Secretary and the Secretary's operation center, which we call the SOC, which is the nerve center of information during an emergency and is run by the uniformed public health service officers of the commissioned corps. So there's a lot going on in the building even though many of us are working from home.

There are currently two public health emergencies in effect right now, and each of the public health emergencies has a 90-day cycle, so the Secretary can renew after 90 days. Secretary Azar renewed the public health emergency related to the opioid crisis on April 13 and it will expire July 11th. He also renewed the one related to COVID-19 on April 20, and that will expire July 21st. We expect that both public health emergency declarations will be renewed by the Secretary for another 90 days.

The Department continues to push out data and information through its Public Affairs Office, and since our last meeting the Department has issued a number of types of guidance. OCR has issued guidance on HIPAA flexibilities related to civil rights laws, media access to protected health information in covered facilities, and how health providers can contact former COVID patients about blood and plasma donations.

And in light of the death of George Floyd and the protests across the country, OCR also issued guidance to remind people of the requirements of Title 6 of the Civil Rights Act and Section 1557 of the Affordable Care Act which both prohibit discrimination in federally-funded programs on the basis of race, color, national origin or ethnicity.

FDA has issued a number of guidances for the US drug supply and other areas including clinical laboratories and commercial manufacturers of diagnostic tests for COVID-19 during the public health emergency, the development of drugs and biologic products for treatment and prevention, IRB review of individual patient expanded access to investigational new drugs and biologic products, as well as guidance for industry, investigators and IRBs on medical product clinical trials during the PHE to ensure safety of trial participants and minimal risk to trial integrity.

CDC has also issued a number of guidances including those for transportation workers, for communities of faith, for direct service professionals and group homes for people with disabilities, for people with developmental and behavioral disorders and their families and caregivers, and for people living with dementia.

CDC issues continual updates to data and to recommendations for keeping oneself safe regarding masks, social distancing and handwashing. CDC also issues guidance to doctors on protocols and access to

testing and to labs for conducting tests. Finally, CDC issues guidance to private sector organizations about the three-phased approach to reopening.

We are going to hear about the particular activities of NCHS from its new Director, Dr. Brian Moyer, in just a second, and we will hear more from CDC from Chesley Richards later on.

Finally, our Administration for Community Living has published a survival guide for navigating ACL, guidance for administering Older Americans Act programs during the COVID-19 pandemic.

Of course, the major development is the Coronavirus Aid Relief and Economic Security Act, or CARES Act, was signed into law on March 27th. This was an over $2 trillion economic relief package and included many types of funding for HHS programs including some of the following highlights.

There was a provider relief fund that HHS is using to support American families and workers and the healthcare providers, and HHS is distributing $175 billion to hospitals and healthcare providers on the front lines. It requires private insurers to waive an insurance plan member's cost-sharing payment for COVID-19 testing. It covers funding for COVID-19 testing for uninsured Americans. And, due to the Department's efforts, at least four of the major health groups have waived cost-sharing payments for treatment related to COVID-19 for plan members.

In particular, I want to highlight that the CARES Act authorized more than $1 billion for COVID-19 response activities to the Indian Health Service, including increases for hospitals, clinics, alcohol and substance abuse and mental health funding, and for other HIS programs for medical equipment, maintenance and improvement for purchased and referred care.

There are a number of research activities going on in the Department including Operation Warp Speed, which aims to deliver 300 million doses of a safe and effective vaccine for COVID-19 by January 2021. This is part of a broader strategy to accelerate the development, manufacturing and distribution of COVID-19 vaccines, therapeutics and diagnostics.

NIH has launched a centralized secure enclave to store and study vast amounts of medical record data for people diagnosed with coronavirus disease across the country. It is part of an effort called the National COVID Cohort Collaboration, or N3C, to help scientists analyze these data to understand the disease and develop treatments. This effort aims to transform clinical information into knowledge urgently needed to study COVID-19 including health risk factors that indicate better or worse outcomes of the disease and to identify potential effective treatments.

HHS is making use of supercomputing facilities and personnel of other federal agencies with appropriate expertise to help analyze data about COVID-19 to understand the progress of the disease, affected populations, effectiveness of treatments and to improve outcomes. More about these efforts will be announced in the coming days.

ASPE is responsible for managing the Emergency Paperwork Reduction Act waiver process for data collection activities related to the COVID-19 public health emergency. This allows data collection for the specific preparation for and response to public health emergencies to avoid the lengthy public comment and review process associated with obtaining information.

A couple of other things that are going on that you may not be aware of. The Census deployed a household Pulse Survey by emails and texts to study how the COVID-19 pandemic is impacting

households across the country from social and economic perspectives. The survey asks about how jobs, finances, access to food, health, housing and schooling of individuals and those they live with have been affected by the ongoing crisis.

We are also in the midst of preparing the Department's FY2022 budget, and ongoing other work that we tend to do.

Finally, hurricane season has just started and it is expected to be a particularly rough year, so we are getting prepared for that as well.

That is a little bit of what we have been doing in the last three months. Before I end, I want to say a few words about the three members for which this will be the last full committee meeting, Lee Cornelius, Alix Goss and Bill Stead.

Dr. Lee Cornelius is wrapping up his second term, bringing expertise and research to improve the health and wellbeing of under-resourced communities to the committee since 2012. Lee has brought a steady presence to the committee's work on challenges in the availability of population health data through his gift of careful listening. He has raised important questions at critical junctures to the committee's deliberations and he has been a reliable voice at the table during decision-making moments.

Last year, he received an award from the Council on Social Work Education for his lifetime achievements in social and economic justice. Lee, we are very grateful to you for sharing your expertise with the committee and we will miss you.

Alix Goss is also nearing the end of her second four-year term. With her lifelong experience in standards in both the public and private sectors, she was nominated to the committee in 2012. In 2015 she stepped up to serve as Co-chair of the Subcommittee on Standards leading NCVHS's work to define a Predictability Roadmap for Standards Development.

Among Alix's significant contributions has been defining the opportunity for burden reduction through conversions of administrative and clinical data standards, providing leadership both with the committee and through the committee's collaboration with the Office of the National Coordinator Task Force on this issue.

Alix has a unique ability to take in volumes of information and generate concise, objective analyses to share with others for a collegial discussion. This is a perfect talent for an advisory committee member and leader. We will greatly miss your steadfast leadership.

Finally, Dr. Bill Stead, the committee's outgoing Chair, has been providing visionary leadership to the committee, serving as Chair since 2016 and Co-chair of the Population Health Subcommittee for three years prior. With your leadership, Bill, the committee has collaborated effectively with the health industry, 100 Million Healthier Lives, National Library of Medicine, the Office for Civil Rights, CMS and the Office of the National Coordinator. These partnerships have enriched the committee's deliberations and amplified uptake of its products.

Members and staff have valued your approach to identifying and crafting tangible recommendations to HHS that address near-term challenges while also bringing the long view to the committee's work. And I can tell you we are really going to miss your wisdom and guidance.

I would like to extend sincere gratitude to you, Bill, to Lee and to Alix for your collective 24 years of dedication to the work of this advisory committee. You should all be very proud of the accomplishments that the committee achieved during your tenures, and the Department has truly benefited from your service. Thank you so much.

Lee Cornelius: Thank you.

Bill Stead: Thank you.

Let's see if we can use our "raise hand" button to ask Sharon questions. If any member of the committee would hit their raise hand button, they should go to the top of the list and we should be able to recognize you.

Sharon, I think the thing that would probably help subsequent discussion is to hear in your words what you think from ASPE's perspective what would be most helpful or actionable to you now in the privacy, confidentiality and security aspect of the pandemic. You have discussed that with the Executive Committee but I think it would be helpful for the full committee to hear your own words.

Sharon Arnold: As we discussed at the Executive Committee meeting, I think that there are two things that would be particularly helpful from my perspective. One is that, at this time, there is a lot of public health data that folks are interested in sharing for the public's benefit on COVID-19 status, and as far as I can tell there is very little guidance out there generally about how to share that information for maximum transparency while also protecting privacy and confidentiality.

And so I think the committee in its wisdom might think about what kind of guidance to give state and local health departments and other entities about how to provide transparency while also protecting privacy. I think this would be a huge gift to the community. There aren't good standards out there.

The second thing that I think would be particularly helpful is that during the pandemic people are exploring the use of lots of new data types, including from social media, cell phones and things like that. These are new data types that we don't have a lot of experience with, and people are thinking of it in terms of the current pandemic. But in my experience, once you collect data and you have it, people are not likely to give it up even when it is not an emergency.

And so, while the rules for use during a public health emergency may be different, I think that having the committee start thinking about these new types of data for the future, for after the emergency is done, again, how do we protect the safety and confidentiality of that data after the public health emergency. What do we do with that data, how do we store it, how do we protect it, how do we move forward and think about other uses for that data?

Again, this is another area where I think we would all benefit from the committee's wisdom and deliberation here.

Bill Stead: Thank you, Sharon. I see that Vickie's hand is up.

Vickie Mays: Thank you, Bill. Sharon, I have two questions. One is this idea about if you look at what the Census is doing in terms of the Pulse Survey, it has been incredible what they have been releasing each week that's helpful to people because you can do it by state, you can do it by MSAs and things like that.

And it really raised for me whether or not anyone in HHS is thinking about how to use its data-gathering mechanisms during pandemics, emergencies, et cetera, to really focus in.

That data is not clinical, and so there's clinical stuff that we need, there's public health-like stuff that we need. And so I am wondering if there's a committee, whether we should be doing it or somebody does this gap analysis about what your data-collecting mechanisms might do.

My second question really has to do with still this continuing concern about not having either accountability or standards that require that race and ethnicity be collected -- not be collected, but be filled out. But you can't keep sending these forms in and then it takes us weeks later to go back and get that. And that seems to be like a requirement issue or something in the reporting of data.

Can you talk to those two things?

Sharon Arnold: I think with respect to kind of new ways to collect data and thinking about new data resources, I expect that Brian Moyers will talk about that a little bit because I know that NCHS has been thinking about new ways of data collecting and how our data collections are changing in the current environment.

But I think that around the Department we are not only looking at how we can collect data but what data are available already that we could utilize. There is no reason we should start doing data collection when data are available on a private basis or through other mechanisms. So we are doing a lot of that work kind of on the fly and are trying to coordinate and collaborate around the Department on that. Certainly, this is a moving target now.

Whether or not the committee would be helpful in that, I think the committee tends to be more helpful, at least in my perspective, in doing work that would be helpful to the Department as we move forward, so, not trying to catch up to work that we are doing right now. And I think this is a case where, if the committee were to deliberate, we would be working in parallel with people in the Department, and that is not a great use of anybody's resources.

So that is why I kind of held back on recommending that topic for the committee's deliberations. It is a really important topic and it's something that we are thinking about and something that we certainly would want the committee to weigh in on. But I think we need to come up with some recommendations of our own and then maybe ask for the committee's viewpoint on that or additional things, so the timing just seems to work together.

With respect to standards for race and ethnicity, my belief is that we just put out standards for testing saying that the testing data needed to include race and ethnicity. I know that we have been working and struggling with consistent race and ethnicity data across our data platforms, but I think that is a requirement that just came out recently.

Maya or Susan, if you are on the line and could correct me I would appreciate any update, but my belief is that that just happened.

Vickie Mays: Yes, it is the issue of accepting forms that don't have it. So it's now how to collect it or what to say, which I think that is what that does, but it's that we accept incomplete forms and then it takes weeks to go back and investigate.

So some standard about either you don't get paid or reimbursed for this if you don't have this on it -- something that says to the person sending it in, I have to do this just like I have to have the accuracy of a clinical data point, I have to have certain things about the person be present. So that is what I'm thinking about.

I know what you are talking about in terms of the other, and I thought that was quite good and I was very appreciative of that being done.

Sharon Arnold: Any other questions?

Bill Stead: We have Denise Love and then Rich Landen in the queue with questions, but, Maya, are you good?

Maya Bernstein: Yes. I just wanted to know if Susan was on the line, but it seems like you got an answer to the question.

Bill Stead: Denise Love, do you want to add?

Susan Queen: This is Susan. I was just going to mention that one issue to keep in mind is that when the government is collecting the data using the standards, the entities from whom we're collecting may not necessarily themselves be collecting it via those standards. So community health centers may not necessarily be using the federal standards although they have to report their information using the standard format. But they may not themselves be doing it. Just like any doctor's office that most of us go to, it is highly unusual to actually see the OMB standards when they may be collecting race/ethnicity, so that is another significant issue.

Vickie Mays: Thank, Susan. Again, I just think it's one of those things where we need to start moving on some policy recommendations for people who are doing this to get better at it.

Maya Bernstein: I would just add that the only thing I have seen is, in the community-based testing sites that are being run by the Office of the Assistant Secretary for Health jointly with FEMA, we are now getting in the Version 2.0 case-level data, although not identifiable, but case-level data that has sort of testing site, age, gender, and it does have race/ethnicity information, also pregnancy status, test results and so forth. Although, at an individual level, it doesn't have enough information to identify the individuals.

If your question is about how fast that is getting in, I can't really address it, but I know that we are collecting that kind of data. Thank you.

Bill Stead: Lets move on if we can to Denise Love's question.

Denise Love: Sharon, thank you for the update. My questions were answered but I have another small one that you may or may not be able to answer.

As we think about Dr. Richards' modernization presentation later today, are there things in that CDC modernization initiative which could be quite significant that some of these issues could be embedded into, the way the CDC collects and requires data from states, rolled into this modernization to fix some of these problems?

Sharon Arnold: I am going to defer to Dr. Richards' presentation and let him address those questions. I think it is possible that that could be considered.

Denise Love: I just see an opportunity converging with that. So thank you.

Bill Stead: Rich, would you like to ask your question?

Rich Landen: Sure. Sharon, thanks for the presentation, very informative. My question is, a couple of years ago in May 2018, NCVHS submitted a letter of recommendation and a meeting summary that talked about the US vital registration and vital statistics system, and the question is did the Department find that useful in how it formulated its response to the pandemic? And your thoughts about if it wasn't as useful as it might have been? Not immediately of course, but over time, if you could perhaps give us some feedback on how to better structure any advice we may in the future render to the Department on the topic of the vital registration and statistics system in the territories.

Sharon Arnold: I do believe the Department found that very useful. I'm sure you understand that the recommendations of the committee are one piece of input that the Department considers as it makes changes. I am not equipped to speak to kind of the other considerations that were taken into account but would defer to presentations later tomorrow that might speak more specifically to NCHS and CDC's responses to the pandemic.

Bill Stead: Thanks for that, Sharon. I think that Paul Sutton will be perfect to answer that question. He will be on later today.

I don't see other hands up, so thank you, Sharon, we really do appreciate the information and perspective.

I think I saw Dr. Moyer. Would you like to introduce him, Rebecca?

Rebecca Hines: Thanks, Bill. Brian Moyer is our new Director of the National Center for Health Statistics and he comes to us from the Bureau of Economic Analysis, the BEA, one of the government's other principal statistical agencies, where most recently he served as Director. Brian has overseen innovation efforts to modernize statistical concepts, methods and operations, including expanded use of big data.

Brian, welcome to the committee. We are so delighted you can meet everyone today even if it is by Zoom.

**NCHS Update**

Brian Moyer: Good morning, everyone. It is a real pleasure to be here. I hope everyone is doing well and staying safe. As you know, this is my first meeting with all of you as the new Director of NCHS, and I have been on the job now for all of about two months. What a time to join CDC.

As Rebecca just said, as a bit of my background, I come to the new job from the Department of Commerce. I was at the Bureau of Economic Analysis for about 27 years, so for a long time. I was the Director of the agency for the past 10 years or so. For those of you that don't know, the Bureau of Economic Analysis is the principal federal statistical agency that produces the GDP, gross domestic product, measures for the US.

Before I left the Commerce Department I was also serving as the acting Undersecretary for Economic Affairs, so I had both BEA and the Census Bureau in the office there of the Under-secretary. The reason I mention that is because also in that office was the entire operation around the evidence-based policy-making work and the Federal Data Strategy, so we had the official role I was serving in but we also had the evaluation officer and the chief data officer all there in the Undersecretary's office, so all that work for Commerce was concentrated there in that office.

I mention that because, as I come into this new role I am transitioning to the statistical official for HHS, so I do have some experience with that and I am looking forward to bringing that to this new position.

Let me start by just sharing with you some of my initial observations around some vision for NCHS, or an updated vision for NCHS, and I will be frank. It is too early for me to say I have completed a fully fleshed-out vision, but what I have at this point are some initial observations, some initial reactions, some, call them areas of opportunity. Let me put it like that.

Let me start with data modernization. There are three primary areas that I feel we can make progress on the data modernization front. The first is better harnessing new data sources and techniques. As I said a moment ago, I did a bit of this work at Commerce and I really do think that the idea of harnessing big data like electronic health records and using those new data in collaboration or in conjunction with new data techniques like ML and AI and so on can really bring a new perspective to NCHS. It can really improve the timeliness and hopefully the policy relevance of some of our products, so I am looking forward to doing that.

Frankly, given the way response rates and so forth are going on traditional surveys, it is almost a must at this point to sort of blend traditional data with these alternative data sources.

The second area within data modernization that I would like to point out is an expanded capacity for statistical analysis. Can we better marry what's happening in the health world with what's happening in the economics world, for example. Can we make some statement about how COVID is impacting economic wellbeing? Just not economics, but other disciplines also sort of blended more with the health statistics, so again, that idea of extended scope around statistical analysis and just general expansion of that analysis.

The third area that I mentioned is better connecting what we are doing at NCHS with the broader CDC enterprise as well as the broader statistical system. I mentioned a moment ago that I spent a considerable amount of time working on the Evidence-Based Policymaking ACT and the Federal Data Strategy. Well, these are two initiatives that have at their center this idea of greater connectivity and greater interoperability across the entire system, and we want to see NCHS being a key player in that, and I think it's something that we are well positioned to move on.

The second part of the vision that I will mention is that of the NCHS workforce. I have been so impressed when I look across the Center at the great talent that we have, so my objective is going to be to promote more coordination, more collaboration, more empowerment to engage the workforce and to encourage more innovation across all staff within NCHS.

That is just quick overview of where I am coming from. I'm going to continue to flesh out this vision. I just wanted to get some of my initial thoughts out there with you. Certainly, I would welcome your input, I would welcome your feedback. I value having conversations with anyone who would like to have those conversations as I am fleshing out this vision going forward.

COVID is obviously impacting the entire US statistical system. At NCHS you probably know a bit of this already, but our household surveys, which are in-person interviews, have been moved to telephone interviews. But interestingly, the response rates remain relatively high.

Our National Health and Nutrition Examination Survey, NHANES, which as you know is the physical examination survey using the mobile examination centers, is completely out of the field until further notice, but I will point out that we are repurposing those trailers. The DC government is using them to do COVID-19 testing at senior care facilities, so we are making good progress in sharing those resources and I am very proud that we are able to do that.

As you know, our staff is close to 100 percent telework at this point, and I would say that the staff has been most resilient through this time. We haven't missed a release. We have been able to keep things on track, and I am very proud of all that we have been able to do. Not only have we not missed releases but, as you will see in a minute, we have actually been able to step up some of our work, some of our releases across the Center. Kudos to a very talented NCHS staff for all their efforts.

Then I would say, along the staff line, that many of our folks are assisting in the CDC formal response. There are those that are directly participating on the response team and then there are many, many folks at NCHS that are preparing the statistical material that are needed for those response teams.

In terms of what we are doing in response to COVID-19 on the statistical front, NCHS has been able to respond very rapidly to the statistical needs of the pandemic. Many people have been actually surprised at how quickly we have been able to respond. That is all a great thing. In some ways it's a bit of a new world, especially on the vitals side. We have been able to get out there very quickly, and I think it's a testament to the investments that have been made in past infrastructures that has allowed us to do this.

I would just identify three areas, ways that we have been responding to the pandemic. Accelerating the availability of our current statistics -- As I mentioned, the vital statistics is probably the greatest example of this. We have been able to provide COVID death counts in a very timely manner, and we continue to provide new cuts on these data almost on a weekly basis. We have been able to accelerate the data and we have been getting a lot of good coverage, a lot of use of the data. It is really good to see NCHS being on the front page of the Washington Post and getting some credit for this really important work. And, as I said a moment ago, also is payoffs from past investments in our vitals program.

We are also expanding our existing surveys. We are putting new COVID-related questions on our Health Interview Survey. We are looking also to add questions to our provider survey, so across the board we are trying to add questions where we can to make our surveys more relevant to the current pandemic to get at issues like telemedicine and retail clinics and access to care and so on. So there is lots of activity going on in that front.

And finally, I will mention we are also partnering with the federal statistical community. Here the one thing that comes to mind is the Pulse Survey. I heard it mentioned earlier. This is the seven-agency effort across the statistical system, and it is a great example of how we can work together -- even though we have a decentralized statistical system -- how we can work together to accomplish great things.

On the NCHS side of this thing, we are focused on collecting real-time information on mental health and access to medical care and health insurance coverage. And let me say, I have been part of the statistical system for a very, very long time, and I can't ever recall a time when we were able to come together so quickly to put a survey in place, to get responses, and to get that information out to the public. I say

kudos to all seven agencies and to the Census Bureau who have been participating in this effort. It is monumental and I think it is a first for the US statistical system.

I just wanted to give you a quick example from the Pulse Survey. This map and the associated ranking on the right-hand side of the slide give a heat map of the category of delayed medical care associated with COVID-19. As you can imagine, this map and this information has been widely disseminated and has gotten a lot of attention for NCHS. This is just an example. Lots of other data has also been available in the Pulse Survey, and I should say not just health-related data but economic-related data and so forth.

Let me turn now to the budget for NCHS. The total NCHS budget for FY2020 is $228 million. This is up a few million from the FY2019 level. The one thing I would note as you are looking at this chart is that the 2020 budget also includes an additional $3.4 million from the $50 million CDC Public Health Modernization Initiative that was put in place in FY2020, so we benefited $3.4 million from that $50 million increase.

I know, as we look forward, there is talk of that data modernization money falling from about $50 million down to I believe about $30 million, but we are hoping that we can continue to be part of those data modernization funds. So that is a look at FY2020. Let's go to the next slide and see what's happening in FY2021.

The President's budget for FY2021 has our total budget authority down about $5.4 million, so we're down from $174 million to $169 million. But again, that is the budget authority, that is not the reimbursements and so forth. But the decrease is consistent with the overall reduction in the CDC budget for FY2021. In fact, the impact on NCHS's budget, if you look across all the centers, is actually smaller than many of the other centers. So, in some ways we are fortunate that while there is an overall decrease, what's hitting us is considerably smaller than what's hitting some of the other centers.

I would also show that throughout there if we're talking about FY 2021 there is a tremendous amount of uncertainty around all of this at the moment. Obviously, this budget was formulated before the COVID impact and also we are in the middle of an election year, so there are all sorts of other things going on.

Of course, when we're talking about all the budget possibilities for FY2021, we have to also talk about all the COVID-19 supplemental funding that has come along. Most importantly, I would just take a second to talk about the Coronavirus Aid Relief and Economic Security Act, the CARES Act, that provides CDC with $500 million in funds for COVID-19-related modernization.

I will conclude here by talking a little bit more about this modernization funding. Chesley Richards is going to be joining in this afternoon, as I think was mentioned a few minutes ago. He is going to be joining the call this afternoon and he will give us a more complete update on this work.

But I will just say that at the moment, CDC is still in the process of allocating that $500 million to the various centers to figure out how CDC best responds to this modernization demand. NCHS, I will say, has certainly made a set of proposals on how to move forward. Obviously, we are hopeful that our proposals will be accepted or partly accepted as we think about the broader strategy for CDC, but what I wanted to do here is to share with you a couple examples of some things that we put forward and Chesley will go into more detail this afternoon.

Some of the proposals that we made include upgrading our vital statistics system. I know some of you mentioned some recommendations that this group has made over the years, the memos and reports

that have been put out, and some of those ideas are embedded in what we are proposing on the vital statistics front.

We are also proposing forecasting the COVID spread and impact through improved modeling for analysis and as you can see from this slide, integration of data from multiple sources, so this kind of goes back to what I was talking about at the beginning when I was talking about a vision. There are some low-hanging fruit around data analytics and modeling and alternative data sources that I really think NCHS can benefit from in the immediate run, and we are proposing some of those here under the modernization funding proposal.

And finally, I will mention that we are expanding or we would like to expand data visualization and data approachability. One of the things -- and I am sure you all have seen this -- that has come out of this pandemic is that it is not only producing the data in a very timely way but is getting those data out there in a way that users can understand them. Sometimes the very technical explanations of things end up confusing folks, and so we are trying to think about how we can meet the needs of our technical audience but, at the same time, meet the needs of our more casual users or those folks that are just trying to get the top-line understanding of what it is we are proposing.

I know that was rushed, but what I wanted to do is just sort of give you a broad sweep of what's happening at NCHS and, beyond that, even probably more importantly, introduce myself to all of you and open up a line of communication hopefully going forward where we can have back-and-forth. I certainly would welcome your comments on any of this material that I just presented. As I said at the beginning, as I think about vision for NCHS I would really value any thoughts or any conversations that we could have that would inform that vision.

Again, very nice meeting and very nice meeting all of you, if only virtually, and I really appreciate your time and you inviting me to part of this discussion. Thank you so much.

Bill Stead: Thank you very much. We are at the end of our time, so I think what we will do is hope that we can continue this dialogue at our subsequent meetings. The committee is an extraordinarily inter-disciplinary and diverse resource so it will work well with the kind of cross-sector thinking and mixture of new and old approaches that you are talking about. What you say resonates very well with many things we have discussed in the past.

We are really glad you are in this role and we would like to help in any way we can.

Brian Moyer: I really appreciate it. I have an open-door policy with staff and I would really encourage an open-door policy with all of you as well, so please don't hesitate to shoot me an email or give me a call. I am happy to chat.

Bill Stead: Thank you very much.

Frank, I think we are ready for you to take the baton.

**Subcommittee on Privacy, Confidentiality and Security (PSC)**

Frank Pasquale: Thanks, Bill. Those were two very informative presentations. It's just fantastic to get those sorts of insights and to be dynamically integrating them and updating our plans during this meeting. This is going to be a real priority of mine.

Today what we are going to be talking about -- and thank you for putting up the first slide -- is the project scoping for the Privacy, Confidentiality and Security Subcommittee 2020-2021 workplan, and just to give a preview of the three PCS segments of today's meeting.

First, we have the project scoping that I am going to lay out today. This is just today's agenda for today's meeting, but I will go through all three segments of PCS right now.

First, we are going to go through today some possible areas of focus, particularly getting ourselves acclimated with the ask from ASPE for something that was much more directed and contemporary, up to date, with respect to a lot of the requests they are getting with respect to COVID death. That is going to be a focus.

But before getting into that, in today's hour session from 10:55 to noon today I want to talk about the bigger 2020-2021 plan for PCS, because I want to contextualize that ask in these larger projects that we have been talking about since at least mid-2019.

Later today we are going to hear from two really fantastic experts on privacy, confidentiality and security, Professors Mark Rothstein and Helen Nissenbaum. Mark served and had a very distinguished service role on this committee I believe over 10 years ago and is still doing fantastic work and has a piece coming out in the American Journal of Public Health covering a lot of the issues that we have already discussed and I think is a source of great expertise.

Professor Helen Nissenbaum from Cornell's Digital Life Initiative has written one of the globally leading books on privacy, Privacy as Contextual Integrity, and she will also be providing some very important insights I think on some of the issues that we are facing and considerations that we will be discussing.

Tomorrow we are going to try to get down to brass tacks in the third PCS-led session of this general meeting in terms of thinking about our next steps. I will be giving some more specific case studies with respect to some of the things that were brought up earlier today by ASPE and NCHS and some particular questions and approaches we can take. Also, we will propose that we have either or both of the scoping documents that will be led by PCS members to inform everyone about the issues on a much greater level of depth and detail than I can get into today.

And then also to recognize, just as we looked at some of the gray literature in our scoping with respect to non-HIPAA covered entities, that there is a lot of knowledge and expertise out there that is not yet published research, and that we want to have a chance to get testimony from individuals. And so we are going to propose a hearing in September to get some of the really cutting edge, leading expertise on the very critical issues that are coming up with respect to ethical, legal and social implications of new forms of data collection and older forms that we need to catch up on.

One of the themes that I think we will definitely hear in Helen's presentation is that the concept of both the need for and the danger of a great deal more data collection during disasters is something this committee has grappled with over the years, and certainly many policymakers have grappled with over the years, but what always seems to happen is that the emergency passes and then there aren't sort of in place durable and helpful guideposts for future emergencies.

I think part of our broader vision here over the next few years is how do we contribute to something that is sort of a trusted public health surveillance infrastructure. How do we contribute to having guidances that would be more robust over time and so that we are not reinventing the wheel during

emergencies? Because sadly, if we look at some of the literature on pandemics, there were many, many warnings that something like COVID could happen to the US. We had lots of planning built in, and yet we didn't I think have quite the type of response that we would have liked, and so I think that is something we really need to have some ongoing discussions about.

To get to this hour, from 11:04 to noon, some of the possible areas of focus that I will go over are sort of the things that PCS has been discussing since last summer and what are our possible areas for focus in terms of our expertise in contributing to our advisory role. Then, we are a little bit behind, but the scope of the particular problem of the ask from ASPE with respect to guidance on COVID data collection, some discussion of themes that would particularly related to HIPAA-covered entities.

In tomorrow's session I want to do more focus on the non-HIPAA covered entities because that was already brought up and I think it is something that is going to be increasingly important. As was mentioned, the lack of survey response means that we may need to go to alternative data sources. And then finally, some next steps.

I will try to go through these slides relatively quickly so we can have ample time for some discussion today.

The short-term ask with respect to what we have heard from ASPE and what we discussed as a subcommittee last month was a toolkit for state and local health agencies on how to collect, use, protect and share data responsibly during a pandemic. Fortunately, NCVHS has already generated a toolkit for communities in the context of data-sharing, and I will get into some of its prescriptions and recommendations in a bit.

Perhaps one way to frame this is to say how would we update this toolkit. What worked that was published in 2015, what changes, what are sort of the updates that we would want to do to that, and I will propose some of the areas of potential focus and project-scoping and expert advice with respect to that.

Longer term, we had discussed at the March meeting plans for a trusted public health surveillance infrastructure in the face of new pandemic threats. Part of the framing of that long-term issue area was that I think too often privacy, confidentiality and security concerns are thought of as something that we add in at the back end of already existing research projects. But I think it is better thought of as practices of data collection and practices of data security being built in at the very front end of public health surveillance infrastructure and other forms of surveillance infrastructure.

Another thing that we discussed that has been sort of back-burner'd a bit is under 2(B), unexpected or unintended consequences of interoperability rules requiring HIPAA-covered entity providers to transfer data to non-HIPAA covered entities. That is certainly something that we can be talking further about, but I don't think it is going to be at this meeting. I am happy to discuss further how we might lay some groundwork for going into that after the emergency has passed.

Then there were the secondary topics, AI, opioid and substance use disorder, standards for terms of service for health apps, conflicts between transparency and data protection and research agenda on de-identification methods. Again, I think these are all things that are certainly very valuable PCS topics but that are perhaps very difficult to fit in given our current budgetary situation, workflow, et cetera.

So let's think about, just to start with respect to this ask and the updating of a toolkit for communities, through these topics, one of the things that I think an advisory committee has the luxury of is we can bring in more of an ethical planning, long-term perspective. We are not being charged with solving concrete problems day-to-day that are coming up that policymakers and regulators must solve.

So, as we think about a toolkit for data-sharing, one of the things that I think -- and we heard earlier from Sharon about the lack of guidance in some of these areas -- is sort of thinking through from the perspectives of the expertise that we have on public health from the industry, from a legal perspective, from other perspectives, what should happen with data in an emergency.

One of these questions on the broadest level of extraction is what are fair information principles for a pandemic? How would we update the FIPPs -- this goes back to HHS's role in thinking about privacy policy back in the 1970s with respect to the FIPPs, 1960s and 1970s -- and what data should we be collecting, and how does that data get shared and how do we use data that would be, say, from what might be called fringe, alternative data sources, and both promote and guard against potential misuses of integration of that data into extant forms of public health surveillance?

One other question is what rules are all right to override to advance public health and what should remain in force and perhaps be inalienable. And this is a very difficult question that a lot of policymakers are facing now both at the state and the federal levels. We really want to encourage as much data collection as possible that can lead to knowledge that can in turn lead to action. That is a very important thing. But we also need to be aware that perhaps there are some rights that need to really remain in force and that some are perhaps inalienable that should not be overridden.

Furthermore, what level of identification of data is appropriate for which purposes? When do we need identifiable data, when is aggregate data more appropriate? And is case-level data without identifiers an adequate compromise? If so, when?

I think for many people that follow this material closely and for many members of the committee, these questions or this framing may be relatively familiar. You may be tired of hearing about these different levels of identification. But what we have been hearing is that there are some situations in which people are being asked for this data and they may not be aware of these concepts, and so how do we make some of the critical concepts of data protection and use available and accessible to a larger community? I think that is really critical.

And then how do standards differ at local, state and federal levels? That is another issue that we can go into and talk about. Are there best practices to be learned from? Are there some places that are doing a really remarkably good job at data collection, and are there ones that are lagging behind? I think that sort of analysis, looking for best practices, is what Brandeis called the US laboratories of democracy. We have the great advantage of having many different approaches and then we can learn from that.

So that I think is another topic that I would love to hear from experts, experts on federalism. There is lots of interesting scholarship on federalism in our medical system, so you have a lot of perspectives you can get from there.

One graphical perspective, and I apologize for the size of this, but the broader lesson from this graph is that, at a glance -- this is guidance that was put out by HHS on may I disclose protected health information for public health emergency preparedness purposes. One thing that is often desired by

those who are in this decision-making role is a simple algorithm, and I think that this graph, this sort of flow chart, is extremely helpful and clarifying on one level.

But I also think that there are opportunities for us to think about are there things that the flow chart is saying are stopping or saying should be stopped that we want to think about as a committee as being things that might be quite necessary, particularly with respect to a pandemic. And are there things that it's promoting without adequate knowledge of the dangers involved?

That I think is another theme that we are going to explore, that we can talk about in the time we have for discussion, is that sort of reconsideration and thought about these processes.

More topics -- This is actually a picture of the cover of our toolkit for communities using health data, this report. Once collected, where may the data get disclosed? For what other purposes if any should it be used or could it be used, and how long can we keep it, and what guardrails do we put around it so it is not misused for other purposes? We have a lot of concerns about misuse of this data, and that could sort of erode trust.

And one of the things that is a very big theme of some of the health literature on data and disparities is with respect to marginalized communities. If you have marginalized communities that are fearful of misuse of the data or use of the data in a punitive as opposed to helpful role, that is going to undermine our understanding of the reality of the problem. And so, in terms of thinking about trusted public health surveillance infrastructure, trusted forms of data collection, sharing and use, how do we avoid that?

I recall also that in the news there was a very unfortunate use of the term "contact tracing" with respect to protesters, and I think it is worrisome. I have not looked deeply into exactly what that process was, but when you have that sort of promotion of an idea of a mixture of data, I think it doesn't conduce to building trust. I think in terms of thinking about what are durable and enforceable ways to preserve accountability with respect to novel forms of data collection, that is something that would be critical to updating a toolkit like this one.

One case study, just to make this a little more concrete, is imagine you have researchers, state agencies and others requesting home addresses or neighborhoods, code-level data of persons who tested positive for COVID. What issues could be raised about that? One of the things I would love to hear during our discussion is other things you have heard about.

If we are to move forward on this type of project, one of the things that really will ground our analysis and guide us is what are the projects being proposed right now. What are the things that are being proposed right now, what is going on right now? What are the analyses that are being done? How well are these apps leading from data to knowledge to action?

There was a recent decision by the Norwegian data protection authority that not only stopped the use of the COVID app that was being used in Norway but also ordered destruction of the data. And one of the things we might want to think about with respect to that is how did they come to that decision. How did they come to the decision that essentially was so non-proportional -- the degree of privacy invasion was so non-proportional to any conceivable benefit from that data that they were willing to order the destruction of data? It is quite a remarkable turn of events there.

I think going further in terms of thinking about case studies, on the flip side, what are the case studies where we have some really vital need for the data and we are not getting it, and what can we learn from that?

Some of our guiding principles here are, of course, promoting public health. That is critical, and I think it is the foundation of the Vital and Health Statistics System. But we also need to make sure that we have some means of accountability, thinking about notice and consents, and if we don't have a notice and consent regime or de-identification or other risk mitigation, which could include security measures.

One of the questions is to what extent are waivers policy. We do have notice of enforcement discretion with respect to waiving penalties with respect to covered entity healthcare providers or business associates, and so these are some of the things we have to think further about. How are these operating as policy, and how might they evolve as policy and how long do they last?

Another potential toolkit update is government and non-governmental data collectors and users. When we think about non-governmental data stewards, the current toolkit mentions them and says they do not have an affirmative duty to share this data, a lot of the data that we are discussing. Might that be something to update? The numbers on some of these slides are to pages in the existing toolkit. And how might that be updated?

One of the things we need to also think about are data use agreements, DUAs, and accountability. And in terms of advancing openness, transparency and choice, how do we keep communities and individuals informed about their data uses and benefits? How do we keep them consulted about that use? How do we ensure that there are, when appropriate, consents to proposed data uses and, when not appropriate, alternative means of protecting community interests?

And so, again, I think that goes to the idea of data that is being used in order to really ensure that we are addressing this crisis and perhaps also larger public health issues, but that can be counted upon not to be going into secondary uses that would be inappropriate.

Some of the things that would, in terms of ensuring appropriate transparency, would include updates to, say, business associate agreements, BAAs. We have an existing HIPAA and HITAC regime which depends on contractual arrangements between covered entities and business associates, so we want to address in these business associate agreements things like the legal consequences of sharing data in violation of the BAA with respect to this type of novel data.

Secondly, a potential update would be that we would have potential requirements of sharing, but again, that would be a very controversial topic and it's something we need to discuss and really suss out among members of the committee in a report, and certainly after hearing from experts in the field. Also, if direct individual notice is impossible in an emergency, blanket community notices or other forms of ensuring -- via the internet -- that there is knowledge available about what data strategies are being put into place.

Community involvement is brought up on page 25 of the existing toolkit, and one of the things that is brought up also with respect to these ideas is having advisory boards. And here, I am inspired by Sasha Constanza-Chock's work in Design Justice, her recent book, to say there really should be nothing about us without us, right? And enabling these types of community involvement with respect to data collection practices and data use practices is something that I think the privacy community does need to

do more and that the larger research community has certainly been involved in with respect to community involvement in IRBs but that it is something we can always improve upon.

Especially when we think about the problems of health disparities that are really emerging with respect to COVID, and the disparities literature already documents a great deal of effectively either certain structural discrimination or structural racism within the healthcare system. And I think addressing these types of problems is something that is going to be critical in terms of having a data strategy that we can get buy-in for from all members of the community, because I think it's something that is really addressing those who have concerns and will be both important to response and to data collection.

Accountability is also something that's really critical. One thing that is a potential topic for consideration is a point person who's accountable for the data collection, transfer and disclosure who can identify and respond to lapses in protocol so it doesn't just dissolve into, well, there are all these different entities that may be responsible or may not be. Also, with respect to data use agreements with organizations requesting data, clarifying responsibilities and legal force of the documents.

Security, one of the most important ones. I forgot whether I put security onto tomorrow or today, but I will add that, with respect to today's conversation with respect to security, complying with -- to what extent do we want compliance with HIPAA-mandated administrative, physical and technical safeguards to go beyond HIPAA-covered entities. This is something that the committee already addressed in the Beyond HIPAA report, some elements of this.

In thinking about COVID, it is particularly a challenging area because we have to balance on the one hand the emergency status of this data, how important it is to have more data from a public health perspective, but also the exceptional sensitivity of the data. We have already seen states that are using data about people either having COVID or not having COVID with respect to, say, unemployment determinations. Do you need to go back to work or not? Are you on benefits or not?

When we think about this broad range of ways in which data could be of use, either to the advantage or disadvantage of the data subjects, that really highlights the importance I think of security and of continually evaluating security risks with respect to this type of data. I will have more details on some of the potential security recommendations in the slides for tomorrow.

With that, thank you. I will open it up to discussion. I don't know, Rebecca, if you want to call on people or do you want me to? I can do it either way.

Rebecca Hines: Whatever would be most helpful.

Frank Pasquale: If you could call on people that would be terrific.

Rebecca Hines: Happy to, sure. Just a reminder, at the bottom of the participant box there is a raised hand button. Alix.

Alix Goss: Good morning. That was an amazing update. My brain is just trying to grasp all of those opportunities and the considerations. Privacy and security is a very important topic, and the aspect of trust and information-sharing is something that is pretty critical to our evidence-based learning objectives.

I feel like you have a tough challenge ahead, Frank, in trying to really find the right slice of the pie for how we move forward, and what I am very excited about is the aspect of the public health infrastructure conversation and the privacy conversation being front and center right now, as I think that is philosophically something we should take a deep dive on. We have long had concerns with the fragility of the public health infrastructure.

With Sharon's update we are really getting the full picture of opportunity that will be refined in subsequent afternoon discussions, but I am curious if there is sort of a first-pass preference from PCS on where they would like to go. I have seen you lay this out and I know we have talked about it a bit in the Executive Committee, but is there sort of a sweet spot that seems to be emerging from the subcommittee's discussion at this point?

Frank Pasquale: I definitely – I don't want to monopolize because I am only one member of the PCS Subcommittee, so I don't want to monopolize that conversation. But I would love to hear. Please, members, it would be great to hear from you about what you are thinking now, because this is just evolving so dynamically.

Rich Landen: Like Alix, my head is spinning. There's a lot of content here, Frank, and it is just wonderfully presented. Practically every bullet we could spend a lengthy time discussing and talking about how it fits into the landscape.

A couple of observations. One is I really think this is substance-packed, and whatever support I can lend to it I certainly would be willing to give.

Second, I think it is incredibly good thought, that much of this is building on and modifying and updating work we have already done, so we have a good infrastructure and we are not just kind of abandoning that stuff we have on the shelf but, rather, trying to update that and adjust for and saying here's the normal world; now here in the pandemic how do we talk about exceptions. I think that approach is good.

I guess the other comment that keeps floating to the top of my mind is the community advisory board. You gave a couple of examples, churches and meat packing plant, but the list is actually fairly infinite -- funeral homes, conference and concert venues, convention centers. How do you deem who needs -- the board can't exceed a size where it becomes unworkable, so how do we direct people -- how can the hotspots be included when those hotspots will vary tremendously from month-to-month and week-to-week and community-to-community?

I guess those are my three major observations, and again, this is a tremendous undertaking, and boy, like Alix said, how do we find the right slice.

Frank Pasquale: I will just respond very quickly to say the question of the community advisory board is a real interesting one and a difficult one. And I think what is also just difficult about this moving target thing is that we are now getting very interesting data about where are the clusters happening, and also getting data about how important are clusters to overall spread. That is a really critical issue.

One of the things I am trying to do here is to figure out what resonates with members of the committee as a whole, and what seems impossibly difficult to do in like six months to a year. And I think what I'm hearing from you, Rich, is like the community advisory board issue may be something impossibly difficult to try to address responsibly within six months to a year because it is not simply operational; it goes

deeper. And it is not even just about integrating values and existing legal authorities into an existing toolkit. It really goes to some very fundamental and philosophical questions about the nature of representation when we talk about community involvement in these spheres.

I definitely have been taking notes with both you and Alix and I will continue to do so as I hear more about what resonates with members, what doesn't resonate or seems shouldn't be part of this project or just seems too hard.

Rebecca Hines: Nick?

Nick Coussoule: I just wanted to respond a little bit to Alix's question earlier. I think as part of the subcommittee we have been talking a good bit about the things that we may undertake that are interesting and prescient and difficult at present, and pair that a little bit with what Rich was just talking about -- what can we actually done in a time period that is meaningful.

It is an interesting challenge. One, how can we leverage the existing work? I think Frank did a great job of presenting some examples of work that we have done in the past that is really helpful to inform work that we can continue and build off of going forward.

I also want to highlight that I think we can build off of a comment Bill made earlier in regards to NCVHS, that we are a very interdisciplinary and diverse resource and we also have some capabilities, specifically, in my mind, a kind of convening authority, how we can bring people together from various backgrounds and parts of our industry that can make a difference.

One of the challenges in most of the work that we have done at least historically -- and I will just reference the time I have been here, and the things that I have seen are generally very long term in nature. Part of the challenge we have is we also recognize some very immediate needs that line up with a lot of work that the committee has done over the time period. But fundamentally, we are not really structured to act quickly from the standpoint of actions that may be currently undertaken -- or not actions, but initiatives that may be currently active in other parts of the ecosystem whether it's in the federal government or other committees.

So I think it is a challenge to recognize. Can we provide some value in the short term, but, also, are we undertaking something that frankly is big enough -- and this is going to sound terrible but -- big enough to matter over the long term and that we can leverage the skills and capabilities of both the members of the committee and our convening.

So I think Frank laid out a whole slew of different ways to look at it and I think they are all very relevant, but part of what we are looking for also is feedback on whether these resonate with other members. Like I said, I can speak for myself, but there is lots of other input to this as well.

Frank Pasquale: That is great. Thanks so much, Nick. That really is very helpful.

One very quick response is, if I were to think about one thing that comes up as a theme in this presentation and that also comes up tomorrow it is data use agreements. The principle could be -- I think the toolkit, it doesn't have a model one and I am not saying we should draft one, but I think there are ways that would be a relatively pragmatic thing, something that I actually have worked on before with respect to the learning healthcare system and data acquisition consent. And it's something I did

some research on with the Seton Hall Center(?) in 2014 on cloud computing and business associate agreements, and thinking about to what extent can we learn from that model and also update it.

So that could be one specific thing. It is still a big thing. And I really like your language here about small enough that we can provide value in the short term but big enough to matter in the long term, and that is one reason I tried to frame much of this presentation as fitting into the long-term scoping and workplan for the PCS Subcommittee.

Rebecca Hines: Melissa, you are up next.

Melissa Goldstein: Thank you, Frank, for that amazing presentation that has made me wonder what to talk about first. I have two main points.

The first is that we are in this period of emergency and we have been in periods of emergency before. This one, of course, has its own characteristics and maybe its own scale. Having lived through a few others that are smaller scale but the country has certainly faced large emergencies before.

In all cases of emergency, there is this urge among both government and non-governmental actors to change the rules, and then the fundamental problem that we face in the area of privacy and security is that, once information is released, you can't grab it back. It is out forever, and it doesn't have the same protections in the future. So it raises the severity of the consequences that might have.

To finish the first point, we have models including the toolkit of what happens during an emergency and then what happens when the emergency slows down. We have already seen an increase in lawsuits and an increase of blow-back, including at the local level, against public health authorities for what has happened with release of data, which is very interesting to me when we get to the idea of community advisory boards, or community advisory questions. The issue here is who would we ask.

There are tensions right now that I have been reading about between elected officials or appointed officials at the local governmental level and the local public health authorities. So the public health authorities may be advising, for instance, wearing masks, but then the elected or appointed officials disagree with that and then ultimately use their power to undo what the public health officials have said. So it's a microcosm of what we have seen at the state and federal levels as well but now it is playing out at the local levels, which I find fascinating.

My second main point is the idea of discrimination, and in this regard I am very excited to hear from our expert panelists today. There is the idea of over-discrimination and sort of concrete results of discrimination in employment and insurance, in other areas where we can see and find economic damage and perhaps personal damage, maybe even legal damage.

But, coming from a very small town myself, I am very interested in the idea of stigma. When we get into applications or the ability to trace people's movements, we get into the idea that even aggregated data may eventually become identifiable, and who is moving where after what large event and where they go to smaller events and where spreadable activities are occurring, and how those individuals -- say, when you have a community or county that has two or three instances a day, that now is becoming maybe nine or ten infections a day. It is not so hard to figure out who those people are because everybody seems to know everybody. And this is where I grew up. And so they become identifiable.

And what does that stigma look like? It is not pretty. And it becomes discrimination, and it becomes distrust of authorities. And we are now facing in this country such a large blow-back against law enforcement for racial and ethnicity reasons, and this is all part of a very complex balance that we need to dissect and figure out how to approach in a justifiable way.

Frank Pasquale: Thank you so much, Melissa. I do think that is a really important perspective. To give a very concrete example of the tensions here, you may be following the South Korean example where they have been profiled both in the formal academic medical literature and in a very interesting article in the New Yorker recently as being the model of contact tracing.

But part of being that model is that they release things like footpath data, or at least they have released things like footpath data of people identified with COVID based on cell phone location data, and that has raised some concerns. There are others who say that is a really deep privacy concern and it is worrisome, but others say, well, it's part of something that has avoided literally thousands or tens of thousands of deaths, and so it seems proportionate. There was also recently the cluster from nightclubs that provoked some anti-LGBTQ discrimination.

And so I think there are some real concerns about the proper level of granularity and proper tradeoffs between identifiability and the risk of stigma there. I have also read things in papers about small towns. Already, there are some concerns in the US about the small towns and release of information.

So, yes, absolutely. That is something that I think could be part of the de-identification prong of this if we go in that direction and limitation of datasets, is being more cautious to the degree that you are in a rural area with easier identification of individuals.

Rebecca Hines: Vickie, you are up next.

Vickie Mays: Thanks. I want to go back to Nick's comments because, to me, that is what I was also going to talk a bit about. It really is this issue of there are lots of things here and there are great things, but at the same time, I think it's where can we have the greatest impact.

When I look at this, what was in the toolkit from several years ago, it's like the newness is really different. It's like we are in a different era in the way in which technology works. We have a different set of norms about certain things. Like the community involvement, I would say we shouldn't even get in the middle of that in the sense that, you know, NIH has us do this in terms of our centers and large grants. It is very complicated, it costs money, it really needs thoughtfulness. And so I think us getting in the middle of that would be something that I am not sure that is where the big impact of where our expertise is would work.

That is not to say that the issues are not important but starting to talk about the churches and the religious leaders, I don't think we are there.

But I think some of the bigger technology issues and contact tracing -- We know right now that contact tracing is going to open a hole can of worms. We know that how that data gets used is critical. I can see there are useful things from before, but I think just given them now, it is such a different landscape.

So I would prefer that we kind of say what are the areas that are likely to really go off the rails here, and that has to do with the data usage agreements, it has to do with contact tracing, it has to do with

identification and reuse. Those are really the today kind of issues that I think we bring the best expertise to, to stop the very things that Melissa is talking about.

It's like we should think about what can we put out quickly to prevent, stop or bring awareness to what's going on, as opposed to just taking the laundry list from before.

Frank Pasquale: Great. Thank you so much, Vickie. Thank you for your intellectual leadership on so many aspects of this. What I have learned from the literature that you have recommended and other things, has been really influential in drafting this. I think focusing in on the contact-tracing can of worms, I like that as sort of a very accessible way of thinking about that bucket of issues, combatted by data use agreements or cutting edge technological methods of addressing some of those concerns is really helpful.

I think North Dakota already has had a contact-tracing app released, to some criticism, and so that --

Vickie Mays: It has.

Frank Pasquale: Yes. Thank you.

Bill Stead: This is a very rich discussion. Again, Frank, thank you for the really thoughtful overview that you and the subcommittee have pulled together.

One thought I will just put on the table that may parse the complexity you are dealing with. I think it would be helpful if we could do something quickly, and I think of quickly measured in weeks to single-digit months, not months to a year, and to do that in a way that contributes to a longer-term project so that you are in essence trying to work at those two scales in parallel and help that get you traction.

I think you have done a very nice job at a first pass of how to do something that could be extraordinarily short and could in essence point people to the right sections of the previous toolkit. In essence, it would be a short, here are the pieces of this that communities, developers and others -- mainly communities; I think that is where we are really trying to help quickly -- can use as a reference as they are trying to grapple with these problems.

And then you could pick one or two of them, and I personally sort of love the intersection of contact-tracing and data use agreements, the technology. I love the way that you all were framing that. You could pick that as the thing you were doing the deeper dive for your longer-term project.

That is just one way of trying to think about how to parse this, because I do think people are grasping now and they don't have many authoritative sources that have been written at a level that is designed to be understood by communities that aren't experts in this space.

I just put that out there as a possible way to tease your way through it.

Frank Pasquale: Well, thank you. That makes a lot of sense to me as well. I think both science communication and legal communication are critical here to try to stop the worst outcomes and try to promote really good sharing.

Rebecca Hines: And Denise.

Denise Love: This is a daunting task, and, Frank, I really appreciate how you framed it. I agree with all of the comments that preceded and I will defer on the short term. I like where we are going.

But I was thinking as you were talking that the committee is uniquely challenged to look at things after the dust settles, so, in the rearview mirror, to follow Nick's and Vickie's comments. So maybe as the dust settles on all of this, the committee may be in a unique position to sort of look backwards and say what worked, what didn't work, where were the problems.

I also am interested in how the public and private roles in data use, policy and release might be recalibrated in this crisis, because COVID is exposing all the weaknesses not only in society but in our data systems that have been broken for a long time in many ways and they are becoming more evident. And so, in the long view, what can we look back and convene and reflect on and integrate into the short-term work we do.

Frank Pasquale: Yes, I like that a lot. Thank you.

Rebecca Hines: Denise Chrysler, your hand is up.

Rebecca Chrysler: I think my hand belonged up shortly after Melissa spoke. The priority I have been seeing is where we are getting blow-back. I have been in the public health law field for many, many years representing public health agencies, and I have never seen the kind of lawsuits, the kind of political activities that I have seen with the tension between what is seen as government intrusion and individuals', they would say, civil liberties. I will just give you an example.

About a week and a half ago, Kansas passed the first -- and I think it is the only so far -- contact-tracing privacy act. Under that act contact tracing is voluntary, and my understanding of the whole history of that act and the impetus was opening up society so you had businesses collecting information on individuals in case there is an outbreak. And so it's the tension of wanting to expand what people can do, yet having ways to deal with exposures.

This is the first time I have ever seen lawsuits against public health agencies to require them to actually disclose information to first responders about positive cases, or governors' orders to do so.

It would be really great if we had a way of tracking, and we may be tracking the blow-back, because that gives us some idea of how public health measures that are probably unprecedented and just so widespread because of a widespread novel pandemic, you know, the kind of issues that are coming up where we may contribute with regard to the toolkit and in other ways.

Frank Pasquale: Thank you so much, Denise. This idea of the blow-back is so interesting to me as well, because when I teach public health we go back to the case of Jacobson versus Massachusetts in 1905, which laid out a pretty sophisticated and balanced perspective between the balance between individual rights and the state's police power. And then coming up to the present day, we have a recent Wisconsin Supreme Court decision, 4-3, sort of throwing out some critical public health measures there.

It is just a fascinating area where I think that blow-back is really critical to examine, and for us to be able to say here are things that just internationally everybody is doing it, you know. Or not. Or say maybe this a uniquely unprecedented and very troubling form of data collection. But I think that sort of thing is something in terms of providing helpful information.

I also think at Temple University, Scott Burris has this really interesting database of public health and the law really trying to keep track of different public health measures and also some analysis of the outcomes that may or may not be attributable to them. I think that is a really critical area because one of the things I have also studied in my work as a legal academic on privacy is opportunistic privacy clients, and that is something we need to always watch out for as well. You know, when people say I can't give you that data because of HIPAA and it turns out it was actually just because it is inconvenient to the business process. That is something that is very worrisome.

And I worry about a similar politicization or opportunistic misuse of different principles, et cetera, in this area as well. So I appreciate you putting that on the agenda.

Rebecca Hines: Any other questions or comments to add to the mix?

Bill Stead: Let me just ask whether Frank feels that he has what he needs from this discussion, Frank and the subcommittee. You have been doing two things. You have been spinning us up so that we can be there to help you, and you have also been getting input as you figure out how to set your compass. Do you have what you need or do you have other questions you want to ask the committee now in advance of the time you are going to have later?

Frank Pasquale: I am good now. I am definitely, on the basis of the notes that I have just taken and the comments raised, going to revise the slides a bit for tomorrow in terms of thinking about potential focus areas. I think this discussion has really set up a more focused and hopefully productive and forward-thinking discussion for tomorrow.

I feel in very good shape and I really appreciate all of the very thoughtful comments today because they have clarified a lot I think both for me and for PCS going forward. Thank you.

Rebecca Hines: Because we have some time, I would like to ask the staff, Maya, Rachel and others, to the subcommittee if you would like to add anything that might help our thinking around what would be most useful and timely.

Maya Bernstein: I just wanted to call the members' attention, at least on the PCS Subcommittee, to an article Rachel just circulated to us via email that is very timely on contact tracing. Rachel, do you want to say something about that? I thought it was very timely.

Rachel Seeger: This is Rachel. Hopefully folks can hear me. I just sent around an article from Politico Pro, which is subscription only, but a really important piece of this is letter signed by 38 state attorneys general asking Google and Apple to make sure that all COVID-19 contact-tracing applications adequately protect consumers' personal information.

The letter is really interesting, so hopefully people can take some time at lunch to take a quick look at it, as I think it is important for our discussion moving forward.

Frank Pasquale: Thanks so much, Rachel. Yes, I do think that is a really critical area for attention, sort of thinking about the public-private cooperation here and the terms of the cooperation. And Helen Nissenbaum I know has made some comments on that very issue and I really look forward to hearing from her perspective as well.

Rebecca Hines: I went ahead and sent it to the full committee, so if others want to take a look at it and in future discussions this afternoon and tomorrow you will have seen that. I see Vickie, your hand is up.

Vickie Mays: One of the things that we might be in a good place to comment about in terms of contact tracing is what is adequate training around the protection of the data. I brought this up with the Congressional Black Caucus, that the states differ tremendously in what qualifies you to go on to do contact tracing. Johns Hopkins is using six hours, State of California has 20 hours.

One of the things that would be useful is, if we have something to say about that, to try and push it out as part of the training or part of the requirement in the collection of that information.

Frank Pasquale: I really like that idea. It reminds me of the National Academy of Sciences report on Childhood Education from years two to eight where they recommended a college degree for anyone who was in those sort of caregiving roles. We can't go that far, clearly, but I think we can say things about the proper level of training because, first, there is a pretty vibrant, thriving market for HIPAA training out there or for other forms of health privacy training.

And secondly, it is really critically important data, and so communicating to people that are potentially a massive new workforce, potentially thousands of new people, about how they need to think about this. They are not intuitive concepts I think for most people.

Vickie Mays: Exactly, exactly. So I think whatever we can do to raise that awareness, to put that into that workforce is critical. Some of the workforces are just government employees that are being sent out to do it. But there are other states where it's new jobs for people who actually are part of the community, is who they are reaching out to. So that I think will be an interesting way to pick up on what Bill was saying. People are looking for direction.

Frank Pasquale: Yes. I also think the role of public health nurses and public health experts is something that is so critical. I think we are learning more and more that very successful countries have a big corps of these professionals. I think Japan had at least 25,000, maybe even more, public health nurses that were cluster-busting and were really going after particular hotspots in a very effective way.

I know that Amy Kapczynski at Yale has written a very effective piece recently with Gregg Gonsalves on the public health corps, and I think part of that emerging literature has to include, and part of our recommendations has to include, how does this emerging corps of professionals view the protection of data, the really sensitive data that they will be collecting.

Rebecca Hines: Okay. Any last thoughts before we shift gears to the 14th Report to Congress?

Frank Pasquale: I am good. Thanks so much to everyone for the discussion.

Bill Stead: Thank you, Frank.

Rebecca Hines: I will turn the floor back over to the Chair.

Bill Stead: And the Chair will turn the floor over to Nick to begin to help us think about the 14th Report to Congress.

**NCVHS 14th Report to Congress**

Nick Coussoule: Thanks, Bill. I am going to walk you through a little bit of a history here as well as hopefully open it up at the end for discussion about some of the things we need to think about in regards to the 14th Report. The basic agenda for what we are going to go through is I'm going to talk a little bit about the purpose of the Report to Congress. We have a number of new committee members and I know several of us have been through a couple of iterations of this, but it is a bit new.

Then I am going to go through an overview of the last two reports that we have done, obviously, the 12th report and the 13th report issued in 2017 and 2019, trying to get a theme. We have done these every two years.

And then I am going to talk about the framing and approach to the 14th Report that we expect to issue sometime in early 2021 in the spring, reviewing the guidance that we got from our CMS partners and ASPE as well obviously leveraging a lot of work that has been done by the committee since the last report.

Then I will tee up some thoughts on the major themes and focus areas and takeaways, which is really what I was engaged to discuss. And then I will review the proposed timeline of the work effort that pretty much mimics what we have done over the last couple of years.

The purpose of the report in layman's terms -- and you will see some of the statutory language in a minute -- is really to report to Congress regularly on the implementation status of the HIPAA simplification provision. So, how well is this being implemented, how well is it working, what kind of issues might be there, et cetera.

But we have also tended to use it as also a way not only to, what I will call, document the history of what has happened but also talk about opportunities that may present themselves. For instance, ways in which HIPAA might need to be modernized to enable a very different digital health system that didn't exist 23, 24 years ago when HIPAA was first passed.

Then ideally it is directed towards Congress, so, what kinds of ways Congress could potentially enforce productive change. Not only get informed but to potentially enforce change, realizing that this is one data point, obviously.

If we go to the 12th Report, there were a number of themes and trends. This was issued in early 2017 but it really encompassed 2015 and 2016 from a calendar perspective of work effort. There were, again, a number of themes. We were talking a lot about the balance of the benefits and challenges in regards to the administrative simplification provisions. We talked a lot about the convergence of clinical and administrative needs and challenges.

And you will recognize this as a theme going forward, but this was really -- again, if you look at the report, it's about a 40-page report with lots of details and also lots of references and links to documents that are part of the work product of the committee over that time period. So I really would encourage, and hopefully the members have had a chance to read these two in particular. We did include them in the agenda book.

But also, one of the other themes that was recognized during that time period was what I will call the juxtaposed data liquidity needs along with securing data challenges. So you will hear some of these

themes are very relevant going forward. Again, this was four-plus years ago but very relevant going forward, including some things we just discussed.

Also, I think another theme was the need for data at a granular level for local action but also aggregated for population health.

So that is a lot of the work effort and things that have happened coming into the themes that were part of the report to Congress. You see here again the standardization, innovation to improve efficiency, and that is really one of the drivers of the administrative simplification provisions in the first place.

Privacy and security components do that. To practice data stewardship. Taking advantage of technology. As we have noted, it has changed significantly in the last five or six years. And then partnerships, and partnerships will become important because it is not simply a partnership maybe between those of us talking on the phone but how the Legislative Branch, Executive Branch and industry might come together to make differences and changes.

When we issued the report, we covered a number of different deliverables from the NCVHS, and these details are all available on the website and the supporting materials. We had five different themes and findings that were issued in the report in regards to administrative simplification; four for privacy, confidentiality and security; three for population and community health data; and two for data access and use.

One thing you may note is that the statutory request is specifically with regards to the administrative provisions. At the same time, the committee does work in a number of different areas. We have multiple subcommittees -- Standards, Privacy, Confidentiality and Security. We have had data group standards and public health data. Even though those aren't explicitly called out as a requirement to report to Congress there is a lot of overlap in the work that happens to inform the success of the administrative provisions.

And so the 12th Report and the 13th Report got a little broader than what the statutory language might allow to provide more context, and some of the challenges in regard to what I will call the interoperability requirements or the interconnectedness requirements of that.

We also outlined some key steps. In each of the last few reports to Congress we outlined not only what I will call what has happened and the status of what has happened over the last time period from the last report, but also a few key next steps. And this is a bit of a foreshadowing warning. One was the need for a predictability roadmap for adoption of standards and operating rules, and the second was challenges with health data -- and I use that term in quotes -- no longer being restricted to the HIPAA world; i.e., the Beyond HIPAA questions. And then third would be next-generation vital statistics. So, a clear need along with existing challenges.

These became part of the significant work efforts over 2017 and 2018, which then led us into the 13th Report to Congress, so both covered what happened as well as laid out a little bit of an agenda as best we knew at the time for what we were going to be covering going forward.

The 13th Report, which was issued in May of 2019 which covered the work time period, the calendar years between 2017 and 2018, was pretty comprehensive in scope. Again, a bit of a long document, but there were some very clear messages that came out of that and reflected significant work on a number of different fronts in the standards world, in the PCS world, as well as in the data access and use world.

Some of the messages were that the world has changed very significantly and it highlighted differences or the challenges in the integration needs between the administrative and clinical worlds.

I would probably argue -- and I don't have the same length of history in the healthcare ecosystem as many of my compatriots here do, but I think there was historically a pretty big divergence between administrative activities and clinical activities, and I think we all recognize that the further we go along in time the more blurry that distinction becomes. That was clearly recognized in the 13th Report.

There was also a call to action, what might we need to do, and we framed that up as well. And resetting the trajectory, and new strategies and new opportunities. We tried to get a little more aggressive in regards to the comprehensiveness or thinking process with regard to the actions. And then I indicated that the revisions to the HIPAA rules would, in fact, facilitate the industry agility.

I think one of the themes that came up was that HIPAA was originally set up and did a really good job of outlining a lot of very good activities in regards to trying to drive simplification and reduction of burden from the process, as well as protection for individuals of their data. Unfortunately, as the world has changed pretty significantly, we have had a bit of a call to action to say that the structure that is in place is sometimes not necessarily helping but in some ways may be hindering the pace of change that is necessary for that progress.

In that report we also recognized the necessity of all players to be involved. As I indicated earlier, the legislative, executive and industry players reflect the sheer complexity of the ecosystem and the pace of change, but by no means trying to diminish the significant benefits 20 years in to the legislation along with the limits. Again, that is a little bit of foreshadowing to what's coming.

I think I covered this, but this is the summary of the way we organized the report. There was a call for action which laid out what we were trying to suggest or recommend, the status of the administrative simplification and implementation, so that was more of the specific statutory requirements to what has happened. Also talked a good bit about the data that was necessary for the management of population and community health. It gets into a little bit on the periphery of specifically the administrative provisions, but also relevant.

And then the conclusion and next steps, which led us into some of the work that has happened over the last year and a half which we will then talk about.

If I then look at the 14th Report to Congress and the framing approach, we had some guidance from Sharon specifically to make sure we were adhering closely to fulfill our reporting mandate to address really what I was talking about earlier, which is the extent to which the entities and people are compliant with the administrative standards and the extent that they are meeting the security standards adopted under that. Let's move forward to the next page and then I will try to summarize a lot of it.

Also, whether the federal and state governments are in fact receiving information of sufficient quality to meet the responsibilities and problems that exist with respect to the implementation and the extent to which the timetables are met. That is kind of the statutory language by which we are supposed to report.

With that in context, we may take a slightly less holistic approach to all of the committee's work, at the same time try to take some of our work which may have been in some ways a little bit conceptual in the 13th Report and try to set the table for a little more administrative and clinical coordination work. There

has been a significant amount of effort that has occurred over the last couple of years in particular with regards to partnerships with the HITAC committee, the new work that's happening in regards to ICAD, so, the partnership exercise between HITAC as well as some of the NCVHS committee members working on that -- Alix and Rich and Becky.

If we give credit to the standards that are widely adopted -- which I believe we should -- they have had significant value, and that is evidenced by work that is being done by others to gather industry feedback, to look at total cost and burden of processing those administrative transactions historically on paper or through websites or through phone calls, and trying to do them electronically in a standard fashion. Clearly, it demonstrated significant benefits to the industry.

One of the challenges that we have is that the work or the success that has happened in the last number of years in regard to that fits pretty well in what I will call the simpler kinds of transactions, and simpler really meaning more administrative generally and not so much clinical. Where those lines have become blurred I think is where we have seen a little more of a stall or less take-up and more complexity in trying to implement transactions that have a much more clinical-focused component to them and not just administrative, and we haven't seen the same level of take-up. Frankly, part of it is it's just harder.

If we look at the scope, clearly the activities, reports and letters that we have done in 2019 and 2020 would be part of the scope. Obviously, we are in the middle of 2020 so we haven't yet written the story of this one, even if we wanted to, because there is lots of good work to happen throughout the rest of this year as well. We do anticipate that we will have a workplan, but we anticipate that a good bolus of the work that happened in 2019 will be included.

One of the things we publish every year as a committee is our accomplishments. If you look on the website for the fiscal year accomplishments for 2019, they were pretty significant, in little ways, conceptual as well as recommendations. I will cover them a little bit in the next slide.

Some of the areas that the committee focused on in the last 16, 17 months and reports that came out -- and most of these are 2019 either derived reports or early 2020 -- there was the Beyond HIPAA framework and letter to the Secretary that were issued. Again, this was lots of work that happened over a significant period of time to come out with some very good work in regards to the Beyond HIPAA framework.

Some really good work in regards to the Predictability Roadmap collaborations with ONC in regards to the conversion of clinical administrative data. And then the relatively recently started formal ICAD Task Force to try to address some of those challenges and activities.

I call this a culmination of the health terminology or vocabulary work. Again, significant work done in partnership with NCHS and others over adoption and implementation of health terminology and vocabulary standards and guidelines for the curation and dissemination of those standards over time. Really good work presented that way as well.

And then significant discussions and recommendations in regards to a strategy for approach to ICD-11 and related developmental work that happened through an ICD-11. These works and reports have been issued and they are on the website if you have not had a chance to see them.

I have been involved with the committee now going on five-plus years so I was involved in both the 12th Report and 13th Report, and most of the work effort that has happened here I have had a chance to see.

And it is really informative, and I think indicative of the long-term nature of the committee's work in that very few things we do have a very simple start and stop point. A lot of them build on themselves and they adjust as the industry and the dynamics on the ground change. But there is very little that we have done that you can't go back and create good learning and knowledge and leverage that going forward to also recognize the challenges and changes.

Now I am going to get a little bit into how do we frame up the 14th Report. These are my thoughts in regard to how we might do that, a couple of just thinking processes first, before I get into the slide.

One is we obviously want to focus our work on the data and the facts, so we don't ever want to minimize the fact that part of our obligation is to report on the adoption of the standards, on the value that has been derived from them, the opportunity that may be in front of us for that for simplification as well as burden reduction. And we greatly appreciate the information we get from others in the industry and I think some even on this call that help us with that information-gathering and reporting. We also recognize the pace of change in our industry has only accelerated.

Those were both discussed at length in the last two reports to Congress, I think to some degree hinted at. They were talked about a little bit in the 12th report and significantly focused on in the 13th report and even more relevant as we have done the work over the last year and a half with the committee and in partnership with others to recognize that challenge that the pace of change has continued to accelerate.

We will cover the transactions that worked well, and again, as I indicated before, what I call relatively simple transactions, and I am not trying to diminish the difficult of that at all. But if I look at it in a relative scale, some of the transactions from a simplicity standpoint are very different when you don't have to have the same level of clinical information in order to make judgments and decisions.

Some other thoughts. One is obviously we update on the status of the recommendations, the implementation of the HIPAA administrative provisions and the impact upon action or inaction on the furtherance of automation. We have done a number of reports and some of them are informational in nature. We have also done a number of recommendations which we made to the Secretary hopefully to drive or help inform part of the information that leads to hopefully action that would improve the ecosystem.

Part of the challenge that we have is also trying to reflect on where inaction may be not helpful or not allowing the industry to move forward as fast as it might, so I think we need to cover both of those things and talk about the impact of action or inaction on the furtherance of the automation challenges that we are reporting to Congress on.

My belief is that the HIPAA Administrative Simplification regulations have been an accelerant for driving automation and reducing burden across the ecosystem, so, on payers and providers. We could argue who benefits more. That is not really relevant to my thinking here, but there clearly was a direction in regards to standardization and automation and security that has helped remove a good bit of administrative work that no longer requires the same resource amount but also, frankly, speeds up the process. I think both of those are very relevant from the standpoint of reducing the number of people or uncertainties and really increasing the quality and increasing the speed by which things happen.

The third thought or major theme from my perspective is that the world has, in fact, changed in multiple ways that make the existing regulatory process and structure potentially a barrier to implementing

instead of an accelerant. I list a few of them here. Improved might not be quite the right choice of words, but expanded care integration, risk management and payment models. They have all changed pretty significantly across the industry and have made in my mind essential a more cohesive and aggressive integration between clinical and administrative functions.

I may challenge that even more so than that to say that it is almost impossible to look at advancing this without really getting aggressive in regards to looking at the clinical and administrative integration. I am not sure it's really feasible or desirable to separate those two things from a practical standpoint going forward, at least from a thinking process and a design process and a strategy process, and then, depending on how you execute, you get into more details. The burden reduction driven by automation and simplification must be looked at and can only be materially advanced by looking across that.

I am just kind of repeating myself in the bullet point, but again, the driver for trying to automate and simplify is -- again, if I look at ONC's advisory committee, HITAC, part of their driver is trying to reduce burden, reduce physician burden and provider burden. Part of what we try to do in regard to the administrative simplification provisions and what we are charged with is doing the exact same thing across the ecosystem.

As the clinical needs -- I indicated earlier whether it's care integration, care management, risk management, payment models, whether it be bundles or value-based models or transition from a fee-for-service to a pay-for-value kind of model, they are requiring a very different look at how that information has to flow together in order to create improved levels of automation activity. I think that requires a rethinking of the framework and the partnership between those two processes. The clinical standards typically have gone down one path and model, the administrative standards have gone down a second path and model.

The administration has clearly indicated a desire for data liquidity, for data access and ownership by individuals, data-sharing across the ecosystem. These are even relatively new, a guidance that has come up and been issued. As we look at our obligations in this realm, trying to understand how those come together in the best way without creating duplication, without creating conflict, at the same time making sure it works for all the parties involved, is a challenge that I think requires us to try to push that framework a little more aggressively.

The timeline that we would like to pursue this in is that during the summer months this year we would like to develop a detailed outline of the report. Again, some of it we recognize will need to take into account things that will happen through the rest of the year, so we will have to make some amount of guesses during this time period about what is going to get included and why.

We want to get all the subcommittees' input into this and then we will get the Executive Committee's discussion and guidance in the summer so that by the fall we will have I think a good framework for it and we can start drafting, iterating versions of this. The process has worked pretty well over the last couple of iterations of this that I can speak to, having been involved in it, to iterate pretty significantly on this.

Again, we have lots of members of the committee, as Bill indicated earlier, very interdisciplinary and diverse resources, also different viewpoints and ways of thinking about it. So, as we iterate through this and get feedback from the committee it is very helpful to inform and make sure we are creating a picture that talks to everybody and not just to certain of us that are involved in certain aspects of this work kind of in our day jobs.

And the Full Committee would review, discuss and refine it in the fall. Then hopefully in the fall and winter of this calendar year and going into next year we would continue to refine it and iterate. Again, we have Executive Committee meetings pretty regularly, and we will obviously go through this during the full committee meetings that we schedule at other relevant times. And ideally in the late winter, so, early in the next year, we would review, provide some input and finalize that, and then the full committee would approve it early next year.

That is the general timeline that we would like to pursue. Really what I would like to do now is open it up to other committee members in regards to thoughts, in regards to how we frame this up, the themes that we might want to include and any takeaways that you think we should be considering as part of this, and also anything in regards to either schedule or approach.

Rebecca Hines: Alix?

Alix Goss: Excellent job, Nick. That was a lot of content to lay out and you did it masterfully.

I have been along for the same period of time as you have been in developing the 12th and 13th Reports to Congress, and I think the approach we took in the 13th Report helped to sew the pieces together at the congressional level and the administration level and the industry level. And I think that under our responsibilities to Congress we provide a good service and a value add in recapping not only the work we have done but also that reflection point.

It is great to see so many of our efforts woven together especially over the last year and a half that really reflects some of the direction that we got from Congress and the 21st Century Cures, most notably our collaboration with the Office of the National Coordinator's Federal Advisory Committee, HITAC, Health Information Technology Advisory Committee, and the resulting work that we have done that led to our public-facing collaboration and solicitation of efficient industry feedback through the intersection of clinical and administrative data, ICAD. We will talk more tomorrow about what that group is doing.

As much as stuff has changed, we have also been making progress on the things that we have identified, and I think that is a nice balance act that you laid out.

In particular, I think the inaction aspect I want to call out or build upon your thoughtful remarks about the progress we have made but also the lack of responsiveness that has happened in regards to our recommendations and understand some sensitivity around that. But I really feel like it is important to bring forth sort of a takeaway I had from the Predictability Roadmap deep dives that we did and the work of the committee even before Predictability Roadmap that engaged the industry, and would like to just underscore the sentiments that I have heard from numerous testimonies that the effort we put forward to thoughtfully vet, consider, analyze and produce recommendations and the fact that they do not get traction, and that it creates further barriers to our progress in our standards and vocabularies is something notable.

There is a lot of work that goes into not the committee's -- I am not talking about what we do as NCVHS; I am talking about all the industry -- that they do to pre-vet, analyze and consider thoughtfully what remarks to make to us, and then we take that body of work and advance it in formal recommendations, and we think we have got kumbaya and industry momentum around something and we lose it, and then we recycle topics and never make progress.

I think that the Predictability Roadmap discussions around having the black box becoming more transparent is a theme that I would hope we can appropriately address in the next report to Congress because it is a part of the strength of the public-private partnership, which is a winning strategy. And how to just continue to advance the transparency. Because there are a lot of very valid reasons why we don't get the progress that we expect.

And the community, the industry as a whole, needs to have a better window into the real barriers that our federal partners encounter and the challenges they have. I know that we have been trying to take some steps within the Standards Subcommittee to further understand those barriers and how to continue to have an olive branch out and work with our federal partners to bring that information back to help the public part of our process better understand that.

And so, if we can create more of a dialogue around that within this next report, I think that would be positive.

Rebecca Hines: Rich.

Rich Landen: Amen to everything that Alix said. I like the structure, I like the approach, I like the emphasis on this is going to be an iterative process, so I think it's a really good path and process that you are laying out, Nick.

I am also thinking of the context of the pandemic and this is an election year so there are going to be a lot of new faces in Congress, so it is probably appropriate, given the environment, to narrow the focus relative to what we had last year and again, to pick up on Alix's point, really hammer some of the things that really need to be addressed.

Also, by reducing the scope a little bit relative to the previous report, it allows us, the subcommittees, to focus on the current development and whatnot since the timing of the past toward this report is contemporaneous with the projects we have going on now. You know standards has the core hearings, and the operating rule hearings and we have ICD in the background and we have the ICAD work going on, and privacy and security has its plate full as we heard earlier this morning from Frank and others.

So I think it is a good scope, it's a good process, it's a good focus, so it has my full support.

Rebecca Hines: There are no other hands. I just want to remind us -- of course, Rich and Alix, you know this well -- but Frank as a new chair of a subcommittee, we will be relying on you to do some initial drafting of chunks of the text, as we did last time, and obviously it gets iterated eight, nine, ten times when you put it all together because we need it to cohere. But just to remind folks that that is how we started to a large degree last time, was with input from the subcommittees. So just a reminder that we are going to need to do that again.

Maya Bernstein: You will have ample help.

Rebecca Hines: Thank you. Bill.

Bill Stead: One other sort of context piece, as we go through the day and tomorrow and we're working on our active projects and we are thinking about the workplan, it is early June. This Report to Congress will cover anything the committee actually completes before the end of December.

So, to the degree this lens helps you make choices about what to do, particularly when you're thinking about rapid turnaround or not or what we have to do to actually bring our part of the discussion on the convergence of administrative and clinical to a useful point, to the degree whether or not ICAD, with all due respect to our members that are trying to move that ball, whether it in fact comes to closure in the timeframe we need it to, to inform our work, we probably want to still go on and have the discussions about the conclusions we can make so that we have that information from the perch of this committee to roll into the report as you begin to frame it.

We are beginning the discussion early partly to be able to use the last half of the calendar year to inform the report.

Rebecca Hines: So let's put the timeline slide back up because I want to make sure everybody knows what we are about to do. That means that over the next number of weeks, we, meaning Bill, Nick and myself, will be putting together an outline and asking for your input, and this will be led by the chairs and co-chairs of the subcommittees through the Executive Subcommittee.

Bill Stead: Just a fine point on what Rebecca is saying. That means that when we have the July and August Executive Subcommittee calls, the then-current outline will be in front of the Exec Subcommittee and it will be iterated in each of those calls. In that process, since all the co-chairs are engaged in that iteration, you are then positioned to engage the subcommittee to do the liftings.

Rebecca Hines: The reason I bring that up, because it is summer, is that you will need to be having regular meetings with your subcommittees about this to get their input so that when we start drafting you all are in a position to write, to edit, to craft anything, recraft, so that when we get to the November full committee meeting we have something we can all look at. And I want to remind you that Alix, Bill and Lee will not be with us, and if we do have new members they won't know how to approach this.

There is a small group of members, really, who have been around for the last two years, and four if you count the development of the previous report, which is a really helpful experience to draw from, just to say that there is going to be a relatively small group of us who really need to get our hands and arms around this as we iterate back and forth to have something in decent shape by January-February of 2021.

Nick Coussoule: I was just going to say the really important part in the short term for the other committee members and certainly the chairs is to think about what you strongly believe should be included in the report so that we can lay out the framework and structure. The details are obviously going to have to come. Some of them aren't going to exist yet, because as Bill indicated, this is going to cover likely some things, products, that come out for the balance of the year.

I think the first order of business would be to really try to frame it out about the things that we believe strongly we should cover or that would be included in the last two years window, and from there we can obviously work through the details. But I want to make sure we don't get too caught up in the details of any given item, but that we first focus over the next handful of weeks on making sure the framework is right.

Alix Goss: Wonderful, because actually that is sort of where I was going to start, so, building on what Nick just said, having a good outline. I am really grateful for that summer 2020 work of Rebecca, Bill and Nick building that out, because I know from the Standards Subcommittee's perspective, we are going to be very heads-down focused on the CAQH CORE hearing that we will be having in late August. And so we

have about a month to get all of our educational prep work and resources prepared so that when we receive the written comments at the end of July or first week of August we will then be able to synthesize all of that going into the August hearing. Because it will be a major component, I would imagine, or artifact under Rich's leadership, they will be bringing home some recommendation letter I would imagine back to the full committee in November for vetting, review and approval, hopefully.

Meanwhile, there are going to be some very interesting co-activities going on with the robust effort of the ICAD, which does not expect to have a formal, finalized report to the Health Information Technology Advisory Committee, HITAC, until the end of October.

So, if we can kind of get our arms around the stuff that we have already done, captured, the philosophical things that we want to really capture and have a few placeholders, that may help us manage workloads, because the summer is going to be with Rich and Deb and Jacki and I all off playing in ICAD at the same time, writing the Intersection of Clinical and Administrative Data report with the prior authorization exemplar set of ideal state-related recommendations as well. There are going to be a lot of competing resources over the summer.

So, if we can maybe start to orchestrate us under Rebecca's skillful hands of time-boxing us and trying to figure out how the pieces will fit together, I think that would be most helpful, because I'm feeling like we are going to get stretched, at least in the Standards Subcommittee perspective, really thin. We are also working on bringing several new members into the fold who have tremendous expertise but may not be operating geeks on steroids like some of us.

So I think it's just an interesting balancing act. I think we have a lot of the pieces of the puzzle of how we operate already in place, but I am a little bit concerned about how we chunk out the work to make the timeline and, more specially, trying to forecast where we think about what we want to say about the convergence project, which I didn't think would actually get kicked off until we got the report from HITAC, ICAD, because we were going to be off doing CAQH CORE operating rule vetting.

Nick Coussoule: Let me weigh back in. I think Bill was hinting at this. I will be a little more explicit.

I think it is incumbent on the different subcommittees to think about, as we proceed with the different work efforts and initiatives, are there deliverables we can complete this year even though they may not be the end game of where we want to go but that can help us inform and share which then become part of the report.

So I think it is important. Obviously, we don't want to deliver some half-baked thing just so we can include it in the report. But if we can make enough progress to have meaningful deliverables even if it is not, quote, "done at the end", I think it is really important to think about that so that we can inform Congress about those activities.

Alix Goss: And considering the amount of work that we have already done with ICAD and the amount of work that we, as NCVHS, have leveraged as a starting point for that work, I think we do have at least a good story to tell.

What piqued my interest was sort of coming to some conclusions. That is my struggle, like getting to the recommendations. That I am feeling in the moment may be a bridge too far, but I defer to my esteemed co-chair, Rich, on that.

Rebecca Hines: It may be, Nick, that over the next three to four weeks we ask especially those of you who are a little more engaged around the projects that will get included in the report to think about the framing, to help us think about the framing, and how we can mix and match different ideas so we land on the right one.

I will send these slides out, but also the project scoping document is in your materials, so pretty much everything we see here is in that two-page document that is in the agenda book.

Nick Coussoule: Alix?

Alix Goss: I am good, thank you.

Rebecca Hines: Well, you did it. You gave yourselves a full hour for lunch. Bravo!

Bill Stead: I really want to thank Nick for taking the lead and getting us to this point. I think this gives us a firm foundation to build forward on. We are adjourned for lunch.

(Break for Lunch)

**NCHS Update: National Vital Statistics System's Response to COVID-19**

Rebecca Hines: So Paul is the Deputy Director of the National Center for Health Statistics Division of Vital Statistics, and he has very kindly offered to spend some quality time with us around what that office is doing around the response to COVID-19, and he gave a presentation to NCHS staff so long ago now, probably six weeks, that the world may have even changed since then. So Paul, thank you for taking time out of your day to brief the committee so we know where things are.

Paul Sutton: Great, thank you, Rebecca. Again, my name is Paul Sutton, Deputy Director of the Division of Vital Statistics. And thank you very much for the opportunity to talk to you a little bit about how we've been responding to the COVID-19.

As most, if not all, of you know, NCHS Division of Vital Statistics has been working for some years now on modernizing the system to improve timeliness and efficiencies. Those efforts initially were focused largely on making sure that all jurisdictions had electronic death registration systems, and we're very close to that now. The last states are in the final stages of rolling those systems out. And more recently we've had a big focus on system interoperability.

Those efforts have yielded some pretty significant improvements that are very relevant to the current situation. For example, we've seen a big timeliness over the past five, ten years in reporting of death information to NCHS, from less than 10 percent ten years ago, to over 60 percent today. We've also seen improvements in the release of our final data, where that information is being routinely released in less than a year.

More recently, we've become much more involved in releasing provisional data, quarterly estimates, monthly drug overdose estimates, weekly flu and pneumonia estimates. All of these things have helped us to develop a system and test and prove a system that is much more flexible, much more timely, and much more responsive to major events like the COVID-19 pandemic. It's also created a much more resilient and proactive system, and I'd like to talk about that a bit more today.

First, I'd like to take a couple of slides to just talk about a timeline. As far as a response within our division, it really goes back to around mid-February, when internally we began having conversations about what-if scenarios if COVID became a significant impact in the United States. And by February 26, we decided that there was enough evidence to suggest that this could become a major significant issue that we began developing certification guidance that we thought would be important if the number of deaths began to increase, to help ensure that the quality and consistency of that data was as high as possible.

The first preliminary guidance related to how to certify a COVID-19 death was released just about a week later, on March 4. And at that time, there were still just very, very few deaths in the United States, and as that guidance began to be disseminated out through the state vital records offices to certifiers in those states, that initial preliminary guidance, we did start to see the number of COVID-related deaths begin to increase, and while there is a lag in getting information into the National Vital Statistics System, because of improvements in timeliness I mentioned earlier, we were beginning to see significant numbers of data in our system, as well.

Some of you may not realize it, but the certification guidance, or the certification on the death certificate, the certifier just writes in text format their best assessment of the cause of death. The actual coding to ICD-10 codes for all deaths in the United States occurs at NCHS, so as you can imagine, our

systems weren't initially set up to code COVID-19. It was a new cause of death. A new ICD-10 code was created for it, so we had some system updates, and during the mid-part of March, March 17 through 20, our systems were updated to accept that new code and coding rules were updated, et cetera, and I'll be talking about that a bit more later.

A few days later we launched the very first NCHS-specific COVID-19 page, which housed our preliminary guidance as well as some other information we'd been providing to the states, and also links to some of the frequently asked questions that states were asking us, that had responses on the main CDC page, et cetera. By the end of March, the number of deaths had begun to increase to the point that we began to prioritize manual coding of deaths from some certain jurisdictions where the numbers were higher, to make sure that data was available as soon as possible.

In April 2, the final certification guidance was released. It was entirely consistent with the initial preliminary guidance but added some additional detail and examples. I'll talk more about that later. And just a day later, we released our very first counts of provisional deaths, on April 3.

A little later that month we had -- an opportunity was given to us to present on the clinical outreach and community action webinar which was a major opportunity to reach a very large number of clinicians that would potentially be certifying deaths. Estimates vary exactly, as people could log in directly and also watch it via other social media applications, but we believe there was probably on the order of 15,000 watched that webinar, where our staff talked about some of the surveillance activity we're doing, and most importantly, went over the certification guidance in some detail and answered questions.

At the end of April we released a new visualization focusing on excess death, not just COVID-specific, but all deaths and excess mortality, and throughout April as the number of deaths really increased and the number of different types of tables and data that we were releasing expanded, we did a pretty significant redesign of our COVID-19 related data pages to better organize and package that, as data had been added very rapidly.

Through the rest of the presentation I'm going to back and talk about some of the things I've already mentioned, but in a lot more detail. What you see here is the final certification guidance. If you haven't taken a look at it, I certainly encourage you to. As I mentioned previously, this was a document that early on, when we first decided to do it, there was no certainty that the number of deaths was going to get anywhere near where it has today, and certainly, in hindsight, though, this has become one of the more important documents that we did. I think it was evidence in a great opportunity for us to be very proactive and get ahead of the curve as far as having guidance about how these would be certified. This was for a variety of reasons.

The guidance addressed a number of issues that have come up and had to be addressed, particularly earlier on in the response, about how deaths should be certified and counted, et cetera. There are several main points. One is that if COVID played any role in the death, it is supposed to be mentioned on the death certificate. If it contributed to the cause of death, not necessarily just the underlying cause, but if it contributed to the cause of death, it should be mentioned, and if it's mentioned on the death certificate it will be coded.

The guidance also addressed the use of abbreviations which can be problematic in coding. Usually we discourage abbreviations. However, we did initially say that COVID-19 would be accepted and continues to be accepted as probably the most common thing reported on the certificates. The guidance also

specifically addressed the issues about other preexisting conditions that might have complicated the death, and those would be reported in part 2 of the death certificate. And very importantly, this guidance, even before it became an issue, it talked about the idea of certifiers reporting deaths as probable.

This was not new guidance. This was entirely 100 percent consistent with death certification guidance that NCHS had been providing for decades. But we did specifically spell it out, in that we don't ask certifiers to know with 100 percent certainty what cause of death. What we ask the certifier to do is make their very best medical judgment of what caused that death, using all the evidence available to them. We understand that, certainly early in the response, testing wasn't as widely available, and requiring it to be lab confirmed made no sense and would be inconsistent with normal reporting processes.

So we, consistent with normal reporting of all deaths, said that certifiers could write probable or presumed if they saw fit, but all they're really asked to do is report their best medical assessment of what caused the death.

Here's a few examples that were included in that. Examples are always good to help convey your point quickly. In this example, it shows in part I the causal chain with COVID-19 being on the lowest line, indicating that it would be the underlying cause in this case, and then in part II some of the other conditions that might be mentioned as well that are also captured on the death certificate.

Here's one more example, specifically showing that it's acceptable to write a probable. It's not required to write a probable, but it is acceptable if a certifier feels it's appropriate that they think it's likely and they want to put in something like probable, that can be done. However, I'll tell you that whether they write probable or not it's going to be coded exactly the same way.

Once a death has been certified, and the record gets to NCHS, that's when the coding occurs. I mentioned early on that WHO did introduce new codes for COVID-19 initially. They just released a single code, U07.1. Shortly after that, they followed with a second code, U07.2. For a number of reasons, some of which I've already touched on, NCHS made a decision early on to use a single code, primarily because it's more consistent with the way death certification encoding has been done in the United States for other causes. In no other situation do we make a distinction between confirmed and not lab-confirmed cases. That just isn't a normal practice, which is what the U07.1 and U07.2 were intended to do. Since that wasn't normal practice and it would have been a significant change from the way physicians are normally instructed to report a certificate, we did stick with using the single code U07.1, so that is the code we use in the United States exclusively for COVID-19.

Underlying cause, of course, does depend on the conditions reported and, importantly, how they're listed on the certificate, and what I should say, though, is that we from the very beginning expected and it has proven to be true that the vast majority of the COVID-19 deaths would in fact also be reported as underlying cause. In fact, nationally, pretty consistently about 94 percent of the COVID-19 deaths have an underlying cause of COVID-19, as well.

Again, as I mentioned early in the timeline portion of the presentation, cause of death coding practices at NCHS had to be modified and updated. Coding systems were not set up to code COVID-19 or accept the U07.1 code, so coding manuals had to be updated, coding logic had to be modified within our system, and initially, all COVID-19 records had to be coded manually. That has changed a bit as time has

passed and we've been able to add some auto-coding as well. But initially, all COVID-19 deaths were coded by one of our nosologists.

Managing manual coding also was very early on recognized as a potential problem, since we knew that at least initially all of the COVID-19 deaths would have to be coded manually, and in the case that if the numbers did increase, we knew this would be a pretty significant increase in the volume of records that would have to be coded by our nosologists. In fact, at the peak, the daily volume of records requiring being coded by our nosologists nearly doubled, so a pretty significant increase in those deaths.

To manage that from early on, we did a number of things that helped us to maintain a timely reporting of deaths. Under normal conditions, non-COVID-19 conditions, our goal is to keep manual coding backlog under 10 days, and back in January we were about at eight or nine days' backlog on coding the manual deaths generally. In anticipation of the possibility of a large number of records to code, we did begin shifting resources around, and tried to get that backlog as low as possible in the very early stages, and in fact, very early on the backlog, we were able to get that down to just three days. As the volume began to increase, that backlog did begin to also increase, and got up to about seven days, but never got beyond seven days required for backlog. I think working early on was an important part of that.

To achieve that, we did a few things. Again, not necessarily high tech, but things that were taken ahead, and having mechanisms in place that gave us flexibility. One obvious one is we began to prioritize certain records. In this case we shifted our focus and prioritized the 2020 record, even though some 2019 records were still coming into the system, those did wait longer, so that we could make sure these COVID-19 deaths were being coded rapidly. We had a contracting mechanism that was designed from the beginning to give us some flexibility to add some contract coding capacity quickly, and we executed that, and then we also added some overtime for our federal coding staff to increase capacity and maintain timely reporting.

Again, over time, we did also were able to begin doing some auto-coding as well, and currently it's about a third of the COVID-19 deaths are coded automatically, still leaving a large number that have to be manually coded, but it has been a significant contribution to the overall effort. We have been flexible in our coding a little bit. One of the things you might remember that I mentioned a few slides back in our certification guidance is abbreviations. Initially, from the very beginning, we did accept the COVID-19 abbreviation, but initially had decided that other abbreviations, such as COVID, without the specification of the year, would not be accepted as a valid COVID-19 code, and that in those cases the state would be queried, asking them was this a COVID-19, and then if they responded back we would update the coding.

A number of states approached us, most notably New York City, that they were seeing a lot of just COVIDs on their things, and as usage of the term, and it became standard practice to just shorted to COVID, we did adjust our rules and began coding the COVIDs automatically to U07.1. Other more general terms like just coronavirus, continue to be coded to the generic COVID code, coronavirus code, B34.2. But they are queried back to the states, and the state, if they indicate that they are the 2019 variant, will be updated to U07.1.

Now turning to the data we began releasing, as I said, we began releasing provisional data in early April, and the initial release included weekly updates similar to what you see here, although this is the most recent data as of Monday -- not the most recent, it's updated daily. And this week at the bottom 3-28-20, at the time, was the most recent week we were reporting, so in the first week of April we were

reporting deaths through 3-28-20, although there were many fewer deaths being reported that time because it was still largely incomplete.

Today, the slide continues and has many more weeks to it. This is, again, the data through Monday. You can see that in the most recent week, which is 6-13, week ending last Saturday, as of Monday, we had only reporting 166 deaths, however one feature that we've included in these tables from the very beginning is this third data column of expected deaths, which does a couple of things for us.

It's a comparison of the number of deaths reported to the number of deaths we would see in an average year -- so, looking at the last couple of years, and looking at the average year for that same week. The two things it does for us is one, is like here it says only 15 percent, so that gives us a clear indication that the data is still largely incomplete and it obviously should be looked at with a lot of caution. However, as we go up a few weeks, up to the April and May, we can see that the percentage being shown there is actually well above 100 percent, and while we don't know what complete data is until much later in the year, as all data has been received, anything over 100 percent would begin to give an indication that there's some excess mortality going on. It's not an accurate measure, but it does point in that direction. And that's been included since the very beginning.

We've also included not just COVID deaths from the beginning, but also the all-cause mortality, as well as some, the last four columns, looking at various combinations of COVID-19 with influenza and pneumonia. These were things that again I think we did fairly proactively back even about the same time we made the decision to start working on certification guidance. We also started a conversation with our colleagues in the National Center for Immunization and Respiratory Diseases, NCIRD, down in Atlanta, to get some ideas of if the numbers began to increase, what would be useful information to have, since these influenza and COVID-19 could potentially be cocirculating in some numbers. And these are some of the things we've come up with, and these numbers are being used quite a bit, and I'll give an example of that in just a minute.

The other thing is even though we've been using and reporting provisional data now for a few years, quarterly estimates and weekly flu and pneumonia estimates, and monthly drug overdose provisional estimates, the audience for those has still been fairly focused and an important audience but not the types of numbers that are looking at the data now, so we've made a real effort to try to explain provisional data and what it is to folks. Some important things to remember about the provisional data is the provisional counts are not final and are subject to change. In fact, every update adds data not just to the most recent time period, but all previous time periods.

Provisional data are not yet complete, death counts should not be compared across jurisdictions, and the reason for that is that timeliness among jurisdictions vary so much. So, in the most recent weeks, one jurisdiction may be substantially complete, and another may be at 10, 15 percent of what you expect, and so you have to interpret that with a great deal of caution, particularly in the most recent weeks.

Why the numbers are different. Death certificates take time to complete. States report at different rates. It takes extra time to code the COVID-19 deaths. As I mentioned, initially all of them were manually coded, and the majority of them continue to be manually coded, which does currently add about six or seven days to the timeline when they'll be available to report on. And other reporting systems use different definitions or methods of counting deaths. So that's important.

To help explain all that we did put together a couple of one-pagers, sort of plain language things. These links at the bottom take you to those, and I'd encourage you to take a look at those documents. One, just sort of general numbers, similar to some of the pertinent numbers, definitions of understanding the numbers, and the other one is looking at data quality.

Since we first reported COVID-19 deaths, we have continued to expand the amount of detail and information that we are updating on a regular basis. I already talked a little bit about the first tabulations in the pneumonia and influenza. Now we also have some tables available looking at other causes of death, both as comorbidities but also just other causes of death with or without COVID-19. Again, trying to address that excess mortality question.

We've added tables related to sex, age, race and Hispanic origin. And also expanded the amount of geographic detail that's available. So in addition to the national tables and the state-specific tables, we even have a couple of information at the county level, although obviously when we get down to that level, there's a lot of suppression, and anything below the national level, consistent with our normal reporting of provisional data, counts of between one and nine are suppressed.

Here's one example. This isn't the way the data actually looks on the website, but it's all available on the website, is the race data, where we have counts by race groups. We have the distribution of those deaths across groups, and then we've provided both an unweighted and a weighted distribution of the population for comparison. The rationale behind providing both is that the unweighted is just the population as it exists. However, we know that COVID-19 deaths are concentrated in certain areas, and we also know that race and Hispanic groups, the numbers differ a lot geographically. So the idea of the weighted distributions was to align the geography where populations live a little more closely with where numbers of deaths were actually occurring.

The thing that's important to note, though, however, and we're adding some additional language to our website to better address it, is that there are other confounding factors, importantly age, that these adjustments aren't controlling for, and we're looking at ways to better present and control for some of those other factors, as well. And hopefully over the next week or two, we'll be adding some additional information that'll help address not just the geographic issues but also age as a confounding factor in looking at risk.

It's not just us releasing data, our data about COVID-19. The response down in Atlanta has been updating this graphic based on the publicly available data, so they get it the same time as everybody else, but we've been working with NCIRD for quite a few years now, and the green portion of this graph is basically identical to the flu and pneumonia surveillance activities, where they have a seasonal baseline and the upper white line is an epidemic threshold, and any time the percentage of death is above that epidemic threshold, that begins to raise some alarms. And we can see the green humpback around 2018, that was a pretty bad flu year. That was what they were tracking.

More recently, what they've been doing with COVID-19 is they've added another dimension to it, and beginning with the yellow portion of the graph, is it's not just pneumonia and influenza, but also COVID-19. That started back when there were just a handful of COVID-19 deaths, but then we can see the impact of that combined group, and that at its peak in mid-April, 24.8 percent of deaths were related to one of those causes of death. This is a figure that's been updated a few times and is available on the CDC website.

In terms of releasing data, these are the main webpages. The first one an NCHS webpage that brings together not just the data from the National Vital Statistics System, NVSS, but also some of the data coming from the surveys is a more recent addition. The very first page that was released is the second link, and that was even before there was any data. And then the third bullet are the two pages that were added that began to include data. The first link on the third bullet is really the most-visited NCHS webpage perhaps of all time. In May alone, it had 7 million hits, which is significantly more than any other NCHS page, and speaks to the interest that folks have in this provisional data.

But in addition to the actual HTML tables that are presented on the webpages, that are more for consumption directly in your browser, all the data is also simultaneously made available on data.cdc.gov, including some additional detail that isn't available in those static tables on the page, and what -- making it simultaneously available there is it provides additional tools for exporting the data in a whole variety of formats, and it also provides APIs for automatic access, and we know that there's quite a number of groups and organizations, both inside CDC and external, that are using these APIs regularly to pull that into their systems. I was talking to a group from NIH just recently, and they developed a tool for their researchers to use that automatically updates using that API, so it's a great tool to have available.

The final thing I wanted to mention is that in addition to just the counts that we've been showing, there is this whole issue of excess mortality. There's an effort done to put together some visualizations based on some modeling that helps to account for the underreporting or the lag in reporting in the most recent weeks, and looks at both the number of COVID deaths, but also all-cause mortality above a threshold. So this figure is for the entire United States. You can see back in 2018 that bad flu year, it barely got above that threshold, but more recently we can see that there's a large number of deaths, many of them in the blue, which are the actual COVID deaths, but also in green, that aren't necessarily coded as COVID, that are in excess of that threshold of excess deaths.

This data is also available by jurisdiction. This one is for New York City, being perhaps the most extreme example, where you can see the excess mortality is quite remarkable, not just the COVID-coded deaths, but also the green, and I think that's going to become increasingly important as people look back on this pandemic retrospectively and make an assessment of the overall impact, et cetera.

That is my last slide. I'm happy to answer any questions if there are any.

Bill Stead: Thank you, Paul. As people begin to raise their hands, I will just start. I am Bill Stead, I'm chair of the committee.

We really appreciate your service and your leadership, particularly around rapid release and provisional reporting. One of the things that we grappled with when we did a fairly deep dive into the vital records statistics systems a couple years ago was whether it would be possible to decouple reporting the fact of death, just the fact a death occurred, ideally with a GPS code, from all of the other work that takes place to put information around that fact, in a way that really could provide a more instantaneous weather map for both local and broader purposes. Has that concept been discussed at all? Are there equally radical, if you will, things that you're thinking about now that you've had to deal with this?

Sutton: I don't think it has come in as much to this specific COVID-19 discussion, but we have had some conversations about the idea of reporting based on all-cause, without waiting for coding to occur. That's possible. One of the challenges is many states already report data quite quickly, and if they don't have a -- if the cause of death is still pending, they'll go ahead and submit the record as pending, and we would

still have information about the fact of death, and later the state would provide the information about the cause, which would allow us to do that. Not all states do that, however. Certainly, that's what we want states to do, but many states do hold the record until the pendings are resolved, which limits that ability.

But to the extent that states are providing that information, that is something we could do. We have not done it yet. The idea of totally decoupling the two, I think, is potentially problematic, depending on how radically you're talking about decoupling, in that you could potentially damage the entire system, because the value of the national vital statistics system is that it is essentially a census -- it's 100 percent. And if you decouple it and the fact of death became the only piece that was a census and the rest of it was essentially a survey or a voluntarily cause of death, I think there's a serious risk of the system. But if they stay the same system, and the states are able to go ahead and report the fact of death immediately followed up by the pendings, something along the lines that would still improve timeliness, it would certainly be possible.

Bill Stead: Thank you. I see first Nick's and then Vickie's hands are raised.

Nick Coussoule: Paul, thanks for the great information. I have one question. I clearly get the timeline issues of not all the data gets there as soon as you might like to have it. Do you have or do you publish any kind of confidence interval? I.e., if we go back four weeks, we're 95 percent confident in the data, or if we go back eight weeks or three weeks. Do you do anything like that, that even at a macro level or even at a more granular state level, where a confidence level is higher that the data is more complete?

I think about it from a health plan perspective, it's similar to our actuarial exercise where we go through looking at claims lag from when we get claims in. I just didn't know if you provided any kind of guidance like that.

Paul Sutton: It is not particularly sophisticated, but in our drug overdose reporting we present the estimated percent completeness with those data by state as an indicator of quality. But the challenge truly is, it works reasonably well in a normal year. But in an instance like COVID-19 where the numbers of deaths are much, much higher than normal, and there's no way to know exactly where the top end is, it becomes quite challenging. It is something that we're looking at and we're trying to do a better job of, because it has become incredibly relevant in provisional data to be able to make adjustments.

There's also, in the excess mortality model, there's some of that going into the model, but it's not necessarily -- some of that information is available in the dataset associated with that visualization, but I'm not sure it would go into the level of detail you're thinking about. But it is available in sorts in a few different places, but it is something that we need to continue to work at and find better ways to address.

Certainly, if we continue to release as much provisional data as we are now, I think that leads to an important topic, is that the -- while we had been making sort of incremental progress in in how we release provisional data through some of these other efforts, it was brand-new rules starting a few months ago, and the world has really changed radically, and being able to go back now is going to be a challenge, and probably is impossible. Part of the next steps for us is thinking, well, now that we have taken this step and we're providing so much information on a very frequent regular update, how can we turn this into something that is not just a special event for COVID-19 but is part of our normal reporting processes? I think that's going to be our next big challenge.

Nick Coussoule: Yes, just to follow up briefly, that's kind of where I was going; I think as more and more you realize that timeliness matters for being able to provide that information, I'm guessing you're going to get more and more challenged to provide that information much more rapidly, so that will be an interesting conundrum that you all face.

Paul Sutton: Absolutely agree.

Bill Stead: Vickie, then Frank.

Vickie Mays: Thank you for being here with us today. As you know we're definitely very interested in vital statistics, and so it's nice to have you and I appreciate the depth of the presentation that you did, because it really helped to kind of see what you struggled with. Because as you know, there's been a lot of criticisms about the slowness in getting the race and ethnicity data, the mixture of the antibody and viral test data. I agree with what Rick was just saying, I think there's been some challenging times in terms of trying to really get things out rapidly.

One of the things I'd like to ask about is in modernization. Part of what some of the funding from Congress to CDC was to put up a public health surveillance system that could be improved, to modernize your data collection. Can you really talk about, in the modernization, how, for example, you'd be able to respond in terms of the issue of mortality data collection? We saw the problem in Puerto Rico with getting the data there. We're seeing the problems in terms of this. That would be one question.

The second would be, is any of the modernization that you're going to do also going to be for the NVDRS? Because that's our only place where we can look at police shootings -- I'm sorry, it's called legal interventions. That, in terms of the quality of the narratives, my team is working, we're funding by NIH, we're working to develop algorithms, for example, to make that data more usable. So I'd just like to hear about this modernization theme and specifically what you are doing in those areas.

Paul Sutton: Sure. Let me start with the second question first, because I think it's actually shorter. NVDRS is not an NCHS system; it's a CDC system, so I can't comment in great detail on that, although we do work with the NVDRS folks, and I think there are a lot of opportunities to better integrate vital statistics directly into NVDRS. Right now they sort of are parallel activities. Both are dependent upon the death certificate, us completely, and the NVDRS the death certificate initiates the cases in most states. And I think there is a real opportunity to integrate those systems better. But currently they are basically separate, parallel systems. That's about all I can say about that now, but there are opportunities and there are conversations going on to help to have more --

Vickie Mays: That is one of the modernization issues, is the systems being parallel, to be more overlapped, because that's what's presenting the problem, I think, to some extent.

Paul Sutton: That is something that I think we need to do -- that's actually something that we've been talking to the Injury Center about, where that NVDRS is housed, for a while, is about how we can better do that.

In terms of the modernization specifically within the National Vital Statistics System, I think the work that we have already done, the value of it is evident when you look closely at what's happening now. When you talk about the resilience of the system and its ability to continue to operate, I think what we have seen in COVID-19 is really quite remarkable. The states that have electronic death registration systems have almost completely maintained or even improved their timeliness throughout the

pandemic. At the same time, those that don't, as staff got diverted to other activities related to the response, they have struggled.

It's a challenge. If they have a very manual, paper-based process, and the staff are doing other things, things stop. If you have an electronic system where it's largely an automated process, things continue to work. The modernization effort, in the sense that having electronic death registration systems and to some extent increased interoperability between systems, has allowed the system to be fairly resilient and to continue to operate as well as it was prior to the pandemic, honestly.

I think there's still a lot of progress to be made as far as allowing and automating and standardizing the way data flows through that system, particularly with the medical examiner/coroner systems right now, to make sure that that data is getting into not just the National Vital Statistics System, but also NVDRS and other surveillance systems that rely on the medical examiner/coroners. There's a lot of opportunities there. Many of those medical examiner/coroner offices are still heavily paper-based and not well integrated with other systems, so there's a lot of opportunity there for modernization.

I think the National Vital Statistics System is really an example of what can be done with modernization, but we're not all the way there yet. We've made huge progress, and I think it's shown in our response, but ten years from now we'd be able to do a whole lot more the we can now.

Vickie Mays: I guess what I am specifically interested in is that in epidemics, where we start having sketchy reports about mortality, is there anything that can be done to do the post-investigations to get the records quicker? Like in Puerto Rico, there's still a lot of missing data about deaths. We saw in Katrina, it took a long time to get that. So I'm trying to get a sense of is there something in the system that can make that happen faster? People are clamoring for it, we need it in terms of planning, but it just seems that after these big disasters what happens is we kind of respond to what we need to do for the disaster, but afterwards, it's still kind of the regular number of days that it takes to go and finish the records. So is there anything that's being looked at, like using the electronic health record, or something, that's going to give us the data faster to give us that record?

Paul Sutton: Sure. I will say a couple of things. The Puerto Rico example is an excellent example, and it's also an example where they don't have a good electronic death registration system in place, and had they had one, I think it would have been different. But on top of that, and the next step that you talked about, is system interoperability, and looking not just at intraoperative between case management systems that I mentioned, but also how you can plug into the electronic health records. And there are current activities, really just at their infancy at the moment, but certainly places to invest on both the birth and the death side, where information could potentially be pulled directly from the health record to help populate information that's going into those records and help speed up, potentially improve quality, although that's an area of concern, and if not directly populate the certificates, at least serve as sort of a decision support system for those that are completing it, to give them -- here's the most relevant information you need to be considering as you complete the record. So there's a lot of opportunities there that work has begun on them, but there's more to be done.

Bill Stead: Denise Love, you have your hand up?

Denise Love: Yes. Thank you, Paul, for this, and to follow a little bit on Vickie's question. I've been on some calls in the last couple of weeks, and we have potentially 50 state hospital discharge data reporting systems. Many of them are capturing not only the ICD-10 for COVID, but as of -- retrospective

to January 27, 2020, there is a National Uniform Billing Committee has assigned a DR code, a condition code, that many of the hospitals are using, and this is tied to reimbursement.

So my theme today is the rear-view mirror, after the dust settles -- we're in the thick of it right now -- but that is potentially I think these are rich sources for validating some of the death coding or what the gaps might be when we have more time, because we have these systems out there that might be easier to sort through than the electronic health records, and they're fairly uniform and are capturing this data in many states. So I just wanted to not let that go.

Paul Sutton: Sure. Absolutely. I think it's an important and valid point. There is a little bit of difference in the purpose, and when you're talking about CM codes as opposed to mortality codes, but the idea of using and linking those two data systems as a way to help validate and confirm I think is important.

One of the things that we are beginning to look at is looking at having more options to be able to link the vitals to other data sources. We're a little bit limited right at the moment on what we're permitted to link to, outside of the National Death Index anyway, and looking to have more flexibility in our agreements with the states to allow us to do more linkages like what you're describing that would allow after-the-fact analysis to evaluate quality of the data.

Denise Love: Right, and one thing that COVID can maybe bring is that sense of urgency to make these changes that we talked about for years, but now may be the time to start pushing some of these things through. Thank you for your work.

Bill Stead: Vickie, is your hand a holdover?

Vickie Mays: Yes, it is. So sorry.

Bill Stead: Paul, I think you have whetted our appetite and then answered our questions. So thank you very much for both what you're doing and taking time out to bring us up to speed. We're really grateful.

Paul Sutton: My pleasure, thank you all.

Bill Stead: I think I saw Chesley Richards on. Chesley is going to speak to us next. He is the Deputy Director for Public Health Science and Surveillance at CDC, and he's a fairly kindred spirit of the committee because of his expertise at the intersection of public health healthcare and health IT, and so we're really pleased that you're able to take some time to speak with us about the modernization work that is underway with CDC.

**CDC Public Health Data Modernization Initiative**

Chesley Richards: Thank you, Bill. Thank you, Rebecca, and thank you to the committee for giving me the opportunity to update you today. I don't have any slides, I'm going to have some oral comments that's take about 25 minutes, and then the rest of the time I would love to engage in a discussion.

As Bill said, I'm the Deputy Director at CDC for Public Health Science and Surveillance, and under my direct responsibility are the National Center for Health Statistics, the Center for Surveillance, Epidemiology and Lab Support, the Office of Science for CDC, and the Office for Laboratory Science and Safety. But the more interesting role I have, I think, is to really be an advisor to the director and to the senior leadership about data modernization and improving our data systems, which is something since I

took this job in 2013 that I've been incredibly interested in trying to move forward, and I think some of the questions that you directed to Paul, at the end here, I will try to address in my comments.

My comments are going to be broken out into four general areas. First, I want to talk a little bit about the vision of what we're trying to do and the background to it. Then I'm going to talk specifically about the data modernization initiative that was launched last year with a broad set of partners. I'm going to spend some time on how -- picking up on some of the things Paul talked about -- on how COVID-19 has really dramatically changed and accelerated, I think some of the things we have been trying to do. Then I'm going to finish up and highlight what I think are some common themes that we're wrestling with both within CDC and at public health agencies that I would love to engage the committee to think about and talk about.

First, with the vision. Really, for me and for the people who have been working on this, the vision is real-time data for real-time action. The rationale for this is something that we have recognized for well before I took the current job as deputy, but certainly since I've been here, and that is that data that we need to make decisions and to take action in public health is too slow, it's too incomplete, it's too often faxed or paper-based, it's a burden to the states and the requirements that CDC puts on state health agencies, with our myriad of reporting schemes.

We have a workforce today that is not, in numbers and in skills and in retention, where we need it if we're going to really take advantage of the advances in data science, and we have a very tremendous difficulty at both the national and state and local level, in many jurisdictions, to incorporating emerging technologies, tools, and software, that would help us do our job better, more completely, and faster.

In 2014, I started with folks at CDC and with partners outside, with something called the surveillance strategy, and that effort really had a lot of pieces, but the main part of that effort was to improve the crosscutting data streams that we depend on across the agency. The agency and in public health has a myriad, a hundred or more, individual data silos that aren't interoperable, and while they provide value for the individual diseases in which they are based, that lack of interoperability and the ability to come from common platforms really holds us back.

So what we tried to do in 2014 without a budget initiative, but just with the best efforts, using whatever funds we could scrape together, were to identify four areas where we wanted to make progress on improving a crosscutting data stream, and electronic death reporting and electronic death registration was one. I want to commend Paul and previously Delton Atkinson and Charlie Rothwell for their vision and efforts in this area. But really to get to more complete and timely death records.

Syndromic surveillance, which is reporting from emergency departments and giving situational awareness; electronic lab reporting, which is the reports that are coming from clinical labs to the public health department; and then finally, notifiable disease reporting, and reportable disease reporting. Reportable disease reporting are those case reports of over 100 different disease that go from providers, clinicians, hospitals, labs, to the health department, and then a subset of that information is sent to CDC, and that's called notifiable disease reporting. To improve those systems.

We set out some initiatives in those areas to make progress. We had metrics. And by 2018, we had realized progress in -- now, looking back on it, very modest aspirations in terms of the overall system. For death reporting, it's hard to realize that just a few years ago, less than 10 percent of death records got to NCHS for a national database within 10 days. By 2018, that was up over 60 to almost 70 percent.

With syndromic surveillance, electronic emergency department reporting, we had less than 50 percent of the country in terms of coverage. By 2018, we were up over 70 percent with a new analytic platform that local jurisdictions could make much more use of the data that they were getting. For electronic lab reporting, if you can believe this, again back then, less than 50 percent of lab reports came to health departments in electronic format, and it was still mostly paper, and by 2018, it was up over 80 percent.

Then finally, on notifiable disease reporting, the problem of too many different reporting formats was reduced when we have over 100 diseases that are reported through that system, in the CDC, and we were able to create electronic messages that would capture 60 of the diseases with a single type of format, and then some better formats, more consolidated formats for the remaining conditions.

We also introduced around this time an initiative to speed up the electronic reporting of cases at the local level called the Digital Bridge initiative to do really electronic case reporting, and I'll talk a little bit more about that when we get to the COVID section.

In 2018, when Dr. Redfield came, we crystallized having achieved these modest outcomes on the surveillance strategy an initiative called the Data Modernization Initiative, and Dr. Redfield, when he assumed the directorship really made it a priority to focus on improving our core capabilities, and the top one that he was focused on and has been focused on has been data. He engaged Congress in a meaningful way in a bipartisan way and with both houses. We also had a very strong partner coalition that included CSTE, APHL, NAPHSIS, HIMSS, and other partners, and they initiated the Data is Elemental campaign to really do, to expand the work we had already started and really bring it to completion.

If you think about, as a vision, as a metaphor, the superhighway, we want a data superhighway in which information data flows from the clinical providers in the settings in which that data is collected, to health departments and to CDC in a seamless digital superhighway, that also implies not only a directionality from clinicians to the health departments and CDC, but importantly a directionality back from CDC and health departments to clinicians providing them feedback, guidelines, advice, and information to better manage their patients.

So this partner coalition along with the congressional support and the CDC leadership led to a series of discussions and a proposal for a $1 billion investment over a 10-year period in public health data. We were excited about the potential for that, the reality was that we got a $50 million appropriation in 2020 to get things started, and I think an understanding from congressional appropriators about the need to invest in this area, and this was pre-COVID.

The three areas in the Consolidated Appropriation Act of 2020 that have been focused on in getting money out to the states have been external investments in states, over half the money is invested in state health departments and organizations that represent local and state health departments, and then a portion for CDC's modernization, and then a portion of the money, a small portion of the money, for innovations so that public health would have at least some area, some innovation fund that we could use to explore the new things that were coming along.

One of the new things, as I mentioned, was electronic case reporting, and that was an initiative again that we started without CDC funding, but we had champions in John Lumpkin in particular, and Dave Ross and Andy Wiesenthal, who were able to -- and John and his role at the Robert Wood Johnson Foundation was able to fund the initial efforts in electronic case reporting, and really was instrumental in bringing together the coalition of partners that would be necessary for that initiative to move forward.

So we had a lot of activities that had borne some fruit. We had the formation of a leadership focus at the CDC and partners outside and congressional interest in an initial appropriation, and then as all of us have experienced, coronavirus and COVID-19 arrived. As was alluded to earlier, I think COVID-19 has better than ever highlighted the problems with the data we have in public health, and yet, I think has opened the door to possibilities to achieve what we have been dreaming about, that are now closer and more real and have real funding behind them to accomplish in a shorter period of time.

With the COVID-19 response, there has been a lot of funding that has gone out to the government agencies; CDC certainly received a substantial amount of funding. We have had funding go directly to the states to improve what they're doing around laboratory reporting and other data elements, and we have received $500 million through the CARES legislation that really, although it's coming at a time and labeled with COVID-19, our congressional appropriators have made it very clear that their expectation is that we're not building a $500 million COVID-19 system, but we're making this investment with an idea toward improving all of the data infrastructure, both at CDC and in public health.

Now, I want to come back to the metaphor I used earlier, the data superhighway, and where I think we are now is we've got a mix of -- depending on what state you're talking about or you're talking to CDC, we have a mix of multilane concrete superhighways, and we have a lot of dirt roads and gravel driveways. That has, again, in this data sort of environment around COVID-19, that has been exposed in a very raw way about how we can get data quickly from one point to another point, and then it sits and has to be manually transcribed or some other archaic way of getting that data moved to the next part of the data stream.

It's been so challenging, in fact, that we have had to have help from HHS and direction from the taskforce, the President's White House taskforce, on some of the activities that CDC has traditionally led. This has, you know, been a challenge, but I think all working together we have made some real advances.

One advance has been to be able to create a data analytic data lake that allows us to bring these streams of data in, plus over 200 other data sets that can be leveraged for a more complete analyses, and to Denise's point earlier about bringing in datasets like administrative data or other types of data that may be relevant, we have now got a computing environment managed at HHS called HHS Protect where many of those more integrated analyses can be performed. That we had been working on at CDC in a project called Decipher. So we had the start of it, but the ability to scale it with HHS's help has been dramatic.

I think the other thing that we are concerned about -- but it's a good concern to have -- is that even with all the investment during COVID-19, this massive infusion of $500 million for data issues, there will be a tail. There will be a continuing cost that will be necessary if we're not going to get back into the place we have been in the past. I'm happy that in the President's budget for 2021, there's a $30 million request for the data modernization initiative.

Now, that's smaller than the $50 that was appropriated in 2020, but in that budget, in the President's budget, there was no proposal at all. So with the $30 million in the coming budget of 2021, I'm very optimistic that we'll begin to establish that continuing money that will help support and maintain the investments that are going to be made with this much larger appropriation related to coronavirus.

I think the areas, the key activities that we see in both of these efforts, both the Consolidated Appropriations Act 2020 $50 million and the CARES Act of $500 million, are really supporting the states,

and we realize that state and local public health agencies are in many different places. Some are more advanced than what CDC does, and some are doing the basics and really need strong support, both financial and technical to advance.

So not only supporting the states, but supporting the nongovernmental organizations that help support the states in providing technical support, engaging academic institutions and the private sector as partners in the solutions for both the states and CDC.

At CDC we have to accelerate our data ecosystem from one that is primarily an on-premises server-driven data system to one that's primarily a cloud-based data system. We have to upgrade our data science workforce and tools. We have to be able to support innovation in areas across the agency involved in data collection, from surveys to the ways we use electronic health record data.

And then finally, we need to be able to really -- and Dr. Redfield has been very clear about this, and I think the senior leadership and when we talk to partners outside -- our ability to do artificial -- use artificial intelligence decision support, forecasting, those types of tools, to not only have an understanding of what is occurring now, but to increasingly be able to better predict what is coming and to plan for that.

So I want to finish up with some comments about the common themes that I see that we've had to wrestle with and continue to wrestle with. The first is in public health, since I'm from CDC, the tension we have between doing things at national scale versus the local control and relevance that state and local health departments need. We have policies; you know, the technologies that we have in terms of their deployment at both a local and a national level are a minor issue compared, for me, a minor issue compared to the policy issues about who owns data, what types of data can be shared publicly and when, how can a common operating picture for the nation incorporated from 50 different states and several large cities and territories, how do we balance that? These are issues that I think we have to deal with, and I'm happy that we have had good discussions, I think the vast number of them, with other state partners to begin to explore how to do that in an effective way.

A second issue that we all deal with is workforce, and there's the issue about funding for workforce, and you know, one of the things I often hear is that we need data scientists and really sophisticated IT professionals and that they'll go work for private industry and they'll get paid much more, they won't work for public health because the salaries are so low comparatively. But when you talk to young people coming out of some of the best universities with these talents, they're less concerned about the salary, not all of them, but a good portion of them, because they love the mission we have in public health.

But they are concerned about coming into an environment where they'll be asked to use tools and approaches that are 20 years old. They want to be able to use the tools and the skills they have that are now. So as we upgrade our technical environments in the states and at CDC, I think there's an opportunity to engage a workforce that we haven't had access to at scale previously.

Finally, a next one is a systems issue that we think about our various systems whether it be the National Vital Statistics Program or the influenza surveillance efforts, or healthcare quality improvements or healthcare infections data systems, or HIV data systems, we think about those systems and those systems are really people and methods, insights, reports, that culture, versus the IT infrastructure.

I don't think we can take all of our various systems that support inquiry into the various diseases and turn them all into one mega-system. On the other hand, if we continue to operate in a siloed way in terms of people, in terms of the methods, but also in terms of the IT systems, we're not going to be able to take advantage of where the industry is going in IT and the ability to have common platforms, operating platforms, and shared services. So we have to be able to merge the two. We have to be able to, from a technical standpoint, technological standpoint, have systems and platforms that support multiple different areas of surveillance, but to also maintain that specialized understanding that's necessary to really understand individual diseases.

Another area is cost and how we resource the things we need to do. For example, the concept of IT data shared service and how the costs for that are borne when we get our funding in categorical programs, and you know, that is an issue that we've wrestled with at CDC and I'm sure in many states it's a challenge. So having language in our various funding legislation and in our technical documents and guidance to states that allows flexibility in how those funds are used, as long as the funds do support what they are intended to support in terms of the diseases, I think we're going to have to find a way to make progress on that balance.

Standards development and adoption. There's a real difference that I've become much more sensitized to over the years between saying I'm using a standard, whether it be FHIR or an HL7 2.51 message using -- I'm using a standard approach to data collection or data transfer versus I'm using the standard that we've all agreed on, and getting to the standard would help us a lot in getting interoperability, semantic interoperability, but the process by getting to the standard is not an easy one, and really requires good governance broadly.

Another point is the collecting of data a priori versus harvesting what is already existing in electronic health records and other sources. Most of us in public health have been trained and raised in an environment where we're most comfortable making our own survey and putting it in the field or doing our own chart abstraction, and yet we're in an environment where much of the data we want exists somewhere in electronic health record or other digital data source, and we need methods to pull that data. We need to be able to move to that kind of more automated way of collecting data and less of the labor-intensive ways we've done in the past, and this is particularly important, as was mentioned before, for areas where the data that we're getting now is often very incomplete around race, ethnicity, and social determinants, and yet there are other data sources that may have value in getting some of that data more systematically.

Then I am going to last end up on -- my last comments will be around policy, and I already alluded to this earlier, that some of the hardest discussions we've had, both in COVID-19 and in previous discussions, have been about who owns the data, who controls the data, who grants access to data. We have anecdotes that I can share about data sources coming to CDC and us commenting on a particular local jurisdiction's place in the epidemic and being chastised for getting out ahead of the local jurisdiction. That's not a new problem. That's been a problem that has existed for a long time.

The opposite of that is when I first came into the job that I'm in as the deputy director for science and surveillance, I asked to see syndromic data, the top syndromic data that was coming into our national syndromic surveillance system by HHS region, not even by state, and I was told it took three days to get the data, and I was told that it took a negotiation with the states to allow me to do that. Well, we can't have a national system if that's the operating environment.

So this is a tough one, the policy issues, but I'm looking forward to honest and open discussions with our state and local and territorial and tribal health agencies to really make progress on those areas.

So with that, I'll finish up my prepared comments. I want to thank again the committee on your interest in this area, and I'm happy to take, if we have time, any questions. Thank you.

Bill Stead: Chesley, thank you very much. That was a very thoughtful overview, and your comments align well with the thinking that the committee went through a couple of years ago when we did a pretty deep dive into the vital records and statistics systems, and so I think one question I guess would be at that time we based our recommendation to the Secretary was that the federal government -- and we really said the Secretary should take a lead role in advocating for a more resilient coordinated system, recognizing that the activities are federated, but with today's, the kind of the cloud technologies you're referring to, ending up with a common platform would solve a lot of both the workforce and other kind of issues around the capture, and let the states put their energies into how they want to use it and work in their various programs.

Is there anything in the policy realm where NCVHS could be helpful at this juncture?

Chesley Richards: Thank you for the question, Bill, and I think, first of all, I want to thank the committee for that recommendation and I will say that part of our efforts that have borne fruit in discussions with appropriators about the need for investment and making progress on some of the things I've laid out have been possible because we have had departmental support, and certainly when Dr. Redfield came, I met with Dr. Redfield and the Secretary, and the Secretary was point blank with me. He said we have got to get you guys -- you have to move to a system that can allow the kind of predictive analytics that I got exposed to in the private sector, and I think he in that discussion understood that we can't get to that if we have the balkanized type of data collection and data systems we have got now. So I think that the recommendations you have had, I would just continue. I think the thing that the committee can do is continue to make that an important part of what you tell the Secretary.

I think part of the progress as well is also in trust, and I gave the anecdote about the local jurisdiction being upset with a national person saying something about their local situation that they didn't even know about, and that's an important thing. If I'm a local health official or state health official and I've got somebody from CDC or HHS or the White House talking about my state and I don't know that and it's my data, that's pretty bad.

So I think it's not just having -- let me put it this way. I don't think we can get to a viable working environment that benefits everyone if we at the federal level impose these things on our states through the funding mechanisms. That's not the heavy-handed approach that I think is going to get us there. I think it's going to have to be a partnership.

But I do think we are bearing fruit. We are having more success with many states in terms of the way we use our syndromic surveillance data, which is really real-time coming from EDs, millions of records, every day, being able -- that's already been useful at the state level and the local level, but I think we're beginning to use it both in the EVALI issues with electronic cigarettes we used it much more, we've certainly been using it in COVID-19, and so I think that trust is building and I would like to keep us on a track that will continue to build that trust.

I think having common operating environments as well that one of the things that has been beneficial with syndromic surveillance is we listen to the states and we upgraded the platform with tools that were

much better suited for what they needed to be able to use the data locally, so giving value back to the states in addition to them giving us more access, I think, is part of the equation.

Bill Stead: Thank you. I see Nick's hand is up.

Nick Coussoule: Thanks, Chesley. Actually that last point is exactly where I was going, and how do you work with the states by saying, by the way, we'd like you to do this differently in order for us to be able to get better information more quickly, but, oh, by the way, when we do that, we can then provide you with hopefully some skills and capabilities that you can do at your level that local jurisdiction or regional jurisdiction may not have the opportunity to do. So I didn't know what kind of feedback you're getting from the states or other entities in regards to if you can provide that, it may help them invest in a better way for you to get the data faster.

Chesley Richards: I definitely think that is a key area where we're trying to do more, and I think we can do more. I think one of the nice things about the current environment is money has suddenly melted away as a problem for most of these things. We have more money than the agency has received in a long time for these issues, and the states are flooded with money. But I think it's incumbent upon us to spend those resources wisely and to ensure that we're building in the value that will be necessary to sustain things when we don't have this sudden huge pot of money.

I am also concerned about clinicians and hospitals and all the people who are in the reporting chain from the very front line to public health, whether it be at the state and local level or at the national level, and you know, we've had a history with, for example, with case reporting. It's no surprise to me that when you look at some of our COVID data that it's very incomplete when you think about the process in some of these jurisdictions or paper processes that would require a clinician to stop what they're doing and fill out a form. That's not the way we're going to be able to make progress is having those kinds of things.

So we're gratified that electronic case reporting has really taken off. We've gotten 400,000 case reports now in a set. We started with just three pilot sites in Houston, New York City, and Utah, a little over a year ago. And in this environment we have been able to scale it to having reporting occurring in 33 states, thousands and thousands of clinicians participating, the EHR vendors participating, and most of the health departments, once they start receiving these feeds of electronic case reporting data, are just astonished.

I heard from New York City, they said they were astonished with how much data they were getting, how complete it was, how good it was. It was beyond anything that ever got in their case reporting in the way it existed before. But the good thing about it is it also sets up an environment where we should be able to structure reports that can go back to clinicians to say, you know, you've had this reported. Here's the context. Here are things that will be useful for your patient care. Here are things to look at. That bidirectional flow is something we really need to take advantage of.

The other thing I would say about electronic case reporting -- and again, I'll just shout out about John Lumpkin, his instrumental role, I know he's been on the committee before. But he has been instrumental in keeping this effort moving forward, but the nice thing about this effort in electronic case reporting that I think is something we should be modeling in other systems like electronic death registration and other things is it's automated. It doesn't require a clinician to do anything, and it takes out the 40 agreed-upon, 40 or so agreed-upon variables that we have all agreed on with public health and health departments and our partners that basically are the bulk of what we would want on any

disease that's reported. It's not everything, but it's enough to get a health department the important data, get them started, and if there's additional data, they now can reach back to the clinician, but it's a more focused reach back.

So I think the themes of use the data that's available in the EHR, automate the process, make it really speed through with as little human touch as is necessary, and yet, also do it in an environment that can protect privacy and confidentiality and is cybersecure. I think those are the key elements for success, and a commitment to bidirectionality. I think those are the key points for the future.

Bill Stead: Vickie, I see you and then Denise Love.

Vickie Mays: Chesley, thank you very much for this presentation. Nick, I think today we're just in lockstep, because something that Nick raised was kind of the same thing I wanted to raise, but now I'm going to ask it in a different way.

The states differ so greatly in capacity to respond quickly to things, and so I guess the question for me is is there -- I remember working with Delton -- was there some kind of flow chart or something that could help us to really wrap ourselves around where the gaps are for what kind of states, like for these states that are still doing paper, here's the problem. These states, because I think that the variety is the problem, but we need to be able to make some comments, because Congress is very interested in actually helping to fix the problem, and those of us who are trying to help them, we need to give them that information. So I don't know if you have schemas or if you have a way you could do that.

And then, Bill, a couple of questions that are online as well that I just want to point you to.

Chesley Richards: Thanks, Vickie. That is a great question, and you know, it's not one that I have a pat answer for. I will take it more as a suggestion.

The pieces that you're talking about exist in different places, but I don't think we've put the effort with the states together to bring it into a single picture that can show both -- not only the heterogeneity, because we have talked about that with Congress, that we have one state that's basically all paper and very backward and really has a minimum of resources. We have another city often that is already got integrated data flows not only in public health and with clinicians, but with their electricity department, their housing department, a lot of other non-health sources to get at social determinants. But I don't think we have put together that sort of common operating picture that shows the heterogeneity and then shows where the biggest blockages are.

We do have a logic model that we've drafted for the $500 million to really help understand where those investments, but I think the next step would be to take it to the kind of resource you're talking about. So that's a great thing that I'll take as a suggestion.

Vickie Mays: I guarantee you that the Congressional Black Caucus is interested, and now is the time that they're trying to help fix it.

Chesley Richards: I do want to make a comment, and I hope Paul doesn't get upset with me, but when I think about death records and not only death but birth records, and we think about the role of the EHR, the kinds of things when I was talking about innovation that I think we need to be able to fund in a small way until we have solutions that could actually be scaled, but the things we should be exploring are, you

know, in the context of an electronic health record, can we build in decision support that gets you to the completion of a death certificate much more accurately and much faster?

Can we use natural language processing to identify things that would otherwise be a laborious chart review? Can we do linkages, not only at a national level for analytic research databases, but build in linkages in the electronic health record that clinicians and people at that local level can use to understand the context of a death, and you brought up the National Violent Death Reporting System; that's an example of many different types of systems that we have at the agency, but what's been unique about the injury program and the way they have worked with that system is they have been our partners from the start, both from syndromic surveillance and for death reporting to incorporate that data into what they do, and part of what we think we're going to use the resources available in the $500 million will be for systems like NVDRS to get them to a higher state of technology and shared services than they are able to do with just their appropriated funds for opioids and other things.

Now, if we do that for all the major systems at the agency and we do it again in a siloed way, we're not going to have near enough money to upgrade every system, but if we do it with shared services, built on a common operating platform that can support these systems, I think we'll make a lot of progress. I hope that makes sense, but I wanted to address that that you had brought up earlier.

Vickie Mays: That is absolutely wonderful.

Bill Stead: Thank you, and now Denise, then Rich, then Alix.

Denise Love: Thank you very much, Dr. Richards. I am going to go back to my comments earlier about the 50 state data systems. You know, the CDC in this modernization may have an opportunity to build a broader warehouse of healthcare data. Right now, the most of the data outside of vital records, going in to my knowledge, are measures or pieces of healthcare data such as in the environmental public health tracking, very discrete measures from participating states, and I think there's been some talk and broader support to build an intramural research database of some of these healthcare datasets.

One of the ones that I know CDC does not have but I have been advocating for them to think about is all payer claims, because combined with hospital data, they bring in the pharmacy, ancillary outpatient datasets of the insured populations. But I see a day where CDC, with some of this restructuring and modernization, could develop an honest kind of brokered research warehouse that provides these state datasets on healthcare, but enriches them, provides enriched data back to the states, but also can share across programs to enhance the reportable diseases in others.

I think CDC is in a unique position to provide such decision support algorithms and tools that states need. Individual states can't really look at inter- cross-jurisdictional data, cross-border data. They really cannot do those strategic linkages alone, and it's too expensive, and so somehow figuring out a governance structure where states are at the table with CDC to redesign how you take in the data and compile it, aggregate it, and give it back.

So that's my plug.

Chesley Richards: That is a great plug, a great suggestion. We have as part of this effort around data modernization, we have over the last few years created inside the agency a data hub that has Medicare data, HCUP, AHA, we have some private sector databases like IQVIA, and that's for the intramural inside the agency people to have one place to go to be able to look at all that data. The two characteristics

that you mentioned that are missing from that is it's warehousing those datasets and making it easier to have access, but we haven't built tools in to be able to bring the data and have that as an analytic environment. It's more of a warehousing environment.

So that's one thing, and then making that available outside to people, I think, is another thing we could do, and I think your point about the all-claims databases seems to me right on target, that that would be a great resource, and if it could be in an environment like that working with you and others, we might be able to provide resources, not only for inside the agency, but for their public health departments.

Denise Love: Right, I think the states could benefit from your expertise on forecasting, but also synthetic data. I think if we were smarter about synthetic data, we could look at our small numbers more effectively, because that's really holding us back in public health.

Chesley Richards: Yes, I think that is right. We have a number of projects with Georgia Tech Research Institute to try to make progress on the synthetic data, also to make progress on natural language processing and artificial intelligence process. So scaling that and really making it available to the states, I think that you're right. I think that would be a great resource. So thank you for that.

Denise Love: Great, thank you.

Bill Stead: Rich?

Rich Landen: You mentioned EHRs and the desirability of harnessing the power of EHRs to do some clinical decision support in terms of generating, autogenerating reports and forms and eliminating a lot of manual processing and getting rid of the paperwork. As you mentioned that there's hundreds of data siloes within the federal agencies, within provider organizations there's also data siloes. So like the EHR is not the only system in a provider organization. There's practice management systems. There's communication systems. There's billing systems. All of which are integrated or not integrated to lesser and greater degrees depending on the sophistication of the organization.

While I'm absolutely behind you in your vision of harnessing the power of technology, my question is really are you in active communication and collaboration with the Office of the National Coordinator in building approaches to harnessing what you're describing as an EHR linkage, but is really a linkage to multiple provider-based systems.

Chesley Richards: I think that is a great question and let me attack it in a few ways. One, yes, we are. Don Rucker and I are in dialogue weekly. We have been on a number of calls with a variety of people he's wanted us to talk to. We have a seat on the HITAC that was initiated by Karen DeSalvo when she was there. So we're engaged at a policy level. They are aware of the things that we're interested in. We're commenting from a public health standpoint on TEFCA and other things that they're doing.

So there is, I think, a good and strengthening relationship with ONC, and I think ONC has been helping us understand. One of the things that we have been talking about recently is what's the role of the HIEs in this in states where HIEs are strong, and do you work with an HIE or do you work through EHR vendors or do you work with clinical systems or a combination of those?

The other thing I would say is we've also initiated -- well, in a couple ways. First of all, the Digital Bridge initiative, collaborative, that I talked to you about with electronic case reporting that John Lumpkin has been so instrumental in. That includes representatives from ONC and from EHR vendors, particularly

Cerner and Epic, but others as well, from the AMA, from other -- from large clinical systems across the country and the public health organizations. So it's a broad diverse set of partners where we have a lot of these discussions.

Then beyond that, I've been to Wisconsin at the invitation of Judy Faulkner to spend some time at Epic, along with a group from CDC. We spent time at Cerner. We're trying to understand, you know, there's a balance between how much can we do with, for example, a national EHR vendor as both Cerner and Epic are doing who can pool together the data that they have on 100 million people. What kinds of public health inquiry can be done with that kind of resource? Versus a more integrated healthcare system database that has much of the data that you're talking about that may go beyond the EHR itself, versus dealing with an HIE that's getting data from not just single healthcare systems but all kinds of providers in a well-run well-functioning HIE, and it would be great if there was one answer for all of this, but there's not, and I think where the committee can help is from your expertise if there are particular approaches that you think might bear fruit and be relevant to public health, with this multitude of different ways of getting at the data, I think any advice you have there would be welcome.

Rich Landen: Just a quick comment, NCVHS and specifically its standards subcommittee is working closely with ONC and with its advisory group, HITAC, we have a taskforce looking at how we integrate the administrative data flows that have grown up under HIPAA and ACA with the clinical data flows and data standards, and I think the nexus of that activity also impacts a lot on where and how data will be available across clinical and administrative platforms as a potential data source to feed some of the processes that you're describing.

So we will keep that in mind. I'm glad to hear you are in active conversations with ONC, because we can now incorporate that into some of the discussions in this task force on integrating clinical and administrative data standards. So thanks a lot.

Bill Stead: Alix, and then Melissa Goldstein.

Alix Goss: Rich, thank you for introducing the topic that I was interested in discussing, and I agree with many of your remarks, and the need for us to further consider some of these public health purposes, and as we, building on your thoughtful remarks, the subcommittee on standards has its own convergence project, and I'm wondering from this discussion if our discussion, our plans for the convergence project, which has also been based around prior authorization, needs to take another prong of example or consideration as we look to the broader ecosystem and pull in some of the work that we've done on the vital records and health statistics aspect with our population health hat on and think about whether or not we want to maybe revisit within the standards subcommittee as a result of today's presentation an immense amount of considerations that Chesley brought us to expand our project scoping statement maybe a little bit to not only take on the prior authorization example but maybe to add another example, which is those secondary uses of public health. We're going to have clinicians and the care teams capturing data in an EHR that then flows through to payer systems and to support patient interaction and engagement in their healthcare.

The other piece of this is this public health aspect in the learning healthcare system, and so we may want to think about how does our convergence of administrative and clinical data really have a much broader arm set around those capabilities that all start between that patient and provider interaction, and then all that data, you know, the record once reuse kind of thought process of the ICAD Intersection of Clinical and Administrative Data taskforce, is something maybe we can leverage and really bolster any

-- evaluate how and should we bolster our project scoping to take more squarely on the public health aspect, because I think it's been there as a thread, but I don't know that it's prominent enough, and after today's set of presentations, I'm thinking we might be short-sighted if we don't revisit the scoping document, and that might be a nice punch towards tomorrow's brief discussion if we don't have time today to continue that.

Bill Stead: Do you want to respond or do you want me to go to Melissa?

Alix Goss: Go to Melissa, because I think we've got to have a natural placeholder for it.

Bill Stead: I thought that was you thinking more than asking a question.

Melissa Goldstein: Hi, thank you for coming today and giving us such an important presentation. I'd like to revisit the idea of trust that we were speaking about earlier, but instead of from a federalism perspective, state, local, federal authority, and exercise of that authority and, let's say, navigation of that authority, I want to talk about individual, individual patient trust.

From the perspective of where we stand now, which of course is a very different place than we stood in March and a very different place than we stood in January, but we have seen over the past several months a hit, frankly, among the public about trust in public health and in CDC, in particular. The federal government's public health infrastructure and the federal government's response to COVID-19.

What I am wondering, and I know that you're probably all too intimately familiar with the revision of the regulations and quarantine and isolation that happened, I'm wondering if you think that the privacy regulations that govern CDC are adequate in preserving patient trust, the public's trust, in what we might call the new era of data modernization, and I'm thinking specifically about the difference between intramural data and this release that we were talking about a little bit earlier possibly to the outside, because we all know -- you know, I've spoken about this already today. Once data is out, it's out, and if it's not carefully protected all along the pathway from patient to provider to local to state to federal, right, if it's not protected, then it's out. So I am wondering if you think that the statutes and regulations that govern, I would say, CDC-held data right now are adequate, or if they need to be updated to keep recent enough with where we are going with data.

Chesley Richards: I think that is a very interesting and complicated question, and I don't have a good straightforward yes/no answer for it, but I can share that it has been a different environment, let me put it that way. It has been a different environment in this particular pandemic in terms of data that we historically would receive for us to use, where we might be criticized as being too insular in holding it too much, not sharing it, but the flip side of that is sort of what you talk about, that I think to a person the responsibility that we all feel that we have to protect the data, and we have to ensure that data that we have been entrusted with isn't cavalierly shared, put out in ways that would have a negative effect on a jurisdiction, on a hospital, on a person.

Much of the data we get is deidentified. So it's not identified explicitly at the individual level, but as we all know, as tools become better and better at reidentification, you have to put out less and less of the variables and run the risk of reidentification occurring. So that's a technology challenge that we have to stay ahead of and whether the policies are there, it's not clear to me, but I will say that I do think that the scientists at CDC do take seriously almost to a fault that they need to protect -- that they need to keep this data within the agency.

Now, in this environment with COVID, that has really been stressed, and it has been a stress for us. It's been a stress for the relationship we have with the states in that other entities want to see the data that we have, because it affects their particular mission, the health data is playing havoc with the stock market and name your industry that has a federal relationship, and that has created challenges. I think HHS Protect as an operating platform was a response to that, that we had to elevate it out of CDC and put the data in an environment that more people in the federal government would have access to for inside government analyses, and this created a great deal of stress for many of us.

It was in the end, has been handled in a way where the data use, the intent of the data use agreements that are in place has been continued, but in terms of the legal framework there, I'm not sure. I'm not sure that we have necessarily what we need. Now the other thing I will tell you is that our relationship with OMB and the privacy, the Paperwork Reduction Act has been a challenge in that we have been scrutinized with every data collection we do at a level that most other agencies aren't, because we're not exempt from that requirement.

So that's not a privacy issue, but it is wrapped up in this whole set of administrative requirements that we have that if we're not careful in our effort to protect privacy, so bog us down that our data is irrelevant and people turn to other data to answer the questions they need to. So again, it's a complicated set of interrelated issues, but I think you're right to ask the question, and it's one that we need to explore further, I think.

Melissa Goldstein: Thank you. That was very helpful.

Bill Stead: We are down to about 5 minutes, and we have a question, a couple of questions that have come into the chat that I think are probably actually more targeted to Paul, but I'll let the two of you figure that out. They're from Nancy Kreiger at Harvard School of Public Health, and basically, is asking, the first question is they've just published a paper that shows significant increased racial and ethnic inequities in COVID-19 mortality in working age adults, and wondering why age-specific rates are reported in aggregate instead of being more granularly reported, and because they just -- the aggregate obscures very significant findings. I don't know if there's --

Chesley Richards: I will take the supervisory prerogative to defer to Paul.

(Laughter.)

Paul Sutton: Thank you. I appreciate that. The issue that's raised is one that we are aware of, and depending on how you disaggregate, we do begin to run into problems with small numbers and confidentiality and some of the things just discussed. As I mentioned in our presentation, we are looking at some ways to modify and expand what we're doing and showing with race to break out the age in particular to show that, because certainly there are some big differences in age distribution of the population for the different racial groups. I believe, I was just looking at this recently, the median age for non-Hispanic white is something in the neighborhood of 45 years old, years of age, and for Hispanics it's more like 28 is the median age. So there's a radical difference in the age distribution.

We recognize that as an additional need and as we figure out the best way to approach displaying that data while maintaining the appropriate levels of protecting the data and can justify what we're doing, we'll be expanding that information.

Bill Stead: She also asks why the CDC weights the estimates for racial/ethnic composition based on where the cases arise, because that can fundamentally miss the realities of various forms of racial, ethnic, and economic segregation. Comment on that?

Paul Sutton: Sort of the same response. We are not weighting the deaths. We're weighting the population distributions for comparison, and we present both and give users the opportunity to look at both distributions. Currently they are presented in separate tables, and one thing that we're looking at is in the near term is moving those into the same table so that it's more easy to compare the two. But we do feel that they both provide important information. The unweighted populations do address the questions of burden. The weighted populations begin to address the issues that there is geographic differences between where COVID-19 is actually occurring, both infections and deaths, and where various racial groups exist. So it's particularly in the early part of the epidemic, the infections and deaths were concentrated in several large cities, New York City being most notably, the racial composition of New York City is quite a bit different than even the rest of New York state and certainly the entire country. So the weighted distribution was intended to align the underlying population with where the deaths were actually occurring, but the unweighted is certainly presented as well, and the user has the opportunity to look at that information, as well.

Bill Stead: Thank you very much for those clarifications. Thank you both for spending so much time with us. This has truly been helpful and you're doing the kind of things we wanted to be done. So thank you very much for your service and leadership.

Chesley Richards: And thank you for the committee's interest. We're gratified that you're interested in pursuing these issues, and they're critically important and we need your insights and recommendations. So thank you.

Bill Stead: Very good. I think we have made it to a break, if I'm remembering right. Yes, she's got it right up in front of us, if I just would look at the screen. So we'll break for 15 minutes and restart at 4 Eastern.

Break

Bill Stead: I got a thumbs up from Rebecca. Great. Take it away.

**Privacy, Confidentiality, and Security Perspective on Data Collection and Use during the COVID-19 Public Health Emergency**

Frank Pasquale: Thank you so much and thanks Rebecca and thanks to everyone for a really enlightening discussion this afternoon.

For this session, it is my honor to have the chance to introduce two very important thinkers and doers within the realm of data policy, data privacy. I will be introducing Helen Nissenbaum and then Mark Rothstein. And then if they could present in that order, that would be great. And then we will have an opportunity to ask them questions and to further discuss some of the topics relating to perspectives on data collection and use during the COVID-19 public health emergency.

Just to do the introduction first to introduce Professor Nissenbaum, Helen Nissenbaum is professor of Information Science at Cornell Tech. Her work spans societal, ethical, and political dimensions of information technology and digital media. Her books include Obfuscation: A User's Guide for Privacy and

Protest, with Finn Brunton and the landmark work, Privacy in Context: Technology, Policy, and the Integrity of Social Life published with Stanford University Press in 2010.

She has grants from the National Science Foundation, the Air Force Office of Scientific Research, the Ford Foundation, HHS, the Office of the National Coordinator at HHS, and DARPA. She is the recipient of the 2014 Barwise Prize of the APA and she has contributed to privacy-enhancing software, including TrackMetNot and AdNauseam. Both are free and freely available. She holds a PhD in philosophy from Stanford University and an honorary doctorate from Leuphana University.

I will also just introduce Mark now and then we will be able to begin our presentations. Professor Mark Rothstein has a joint appointment at the Brandeis School of Law and School of Medicine. He holds the Herbert F. Boehl Chair of Law and Medicine and is the founding director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine. He joined the University of Louisville in 2001 and he has concentrated his research on bioethics, genetics, health privacy, public health law and employment law. And from 1999 to 2008, he served as chair of the subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics so sort of the successor or the predecessor to our current PCS Committee.

He is past president of the ASLME, the American Society of Law, Medicine and Ethics and also served as Public Health Ethics Editor for the American Journal of Public Health from 2011 to 2019. He has authored 19 books and over 250 articles. I just am so glad to have both Helen and Mark here to present today. We really appreciate you making the time for us today. And with that, Helen, if you could begin, we would really appreciate it.

Helen Nissenbaum: Thanks so much, Frank, and for inviting me to this really interesting committee meeting. I have some slides.

Pasuale: While that is being queued up, I just wanted to also – I guess a further introduction is that part of our meeting in this area could include Helen's co-authored work on privacy disaster or disaster for privacy, which I think is quite relevant in terms of thinking about data in the context of emergencies and other areas, but also data misuse and how we have to balance an awareness of those two things.

I see the slides. Thank you.

Helen Nissenbaum: I am going to take as my mission because I know you are having this meeting and it covers lots of topics and so that I wanted to briefly introduce you to the theory of contextual integrity, which is the way of understanding privacy and then explain very briefly also, how contextual integrity shapes the way we ask questions relevant to privacy and in particular in relation to digital technology. I am going to use the disaster app study as a jumping off board, but also this discussion that is being ongoing about COVID contact tracing and in particular the Google-Apple's APIs as well, because I think the contextual integrity can offer a different way of querying what is going on in those cases and we have found it useful in the disaster app case.

The idea of contextual integrity, also just to give you a bit of background, is not necessarily a definition of privacy that answers questions of academic legacy. There are generations of work I would say starting from the 1960s, which tries to understand what is privacy in relation to this emerging computational technology, and nowadays, information technology, now digital technologies and AI?

Contextual integrity does not necessarily want a conceptual, philosophical definition that follows that tradition, but rather it wants to ask the question of when you see the disruption that these technologies have caused and you hear people complain and say my privacy has been threatened or is at risk or even violated. What is it that they are trying to say?

I want to offer as I mentioned, an approach to thinking about take assisted health surveillance and again, I am not here to give you a solution to say oh good, bad, but rather just a way of approaching that might yield more productive solutions.

And using as a jumping off point, the mobile phone enabled contact tracing and it is really again merely an illustration, because the theory applies across the board to a lot of digital information technologies and it is like the byline, how to avoid Trojan horses because I think a lot of what we are being offered to accept are Trojan horses and we should be careful.

We have what Apple and Google have proposed. I got this graphic off a BBC story. I believe they got it from Google and Apple and maybe they developed it based on the description. But you can see. It is very simple. A and B meet. Their phones exchange a key code. Then AB becomes infected, the update to status, gives his consent to share the key with the database. These phones regularly download the database to check for matching codes, and it alerts her that somebody she has been near has tested positive. That all sounds so wonderful and just so simple.

And when I started trying to understand it because I am not a technologist, but I know that there is just a devil in the detail. I started asking my colleagues. Well, who knows the connection between the key code and the phone IDs and who creates the connection? How does A's status get inserted into the system because of course you want something to be legitimate and verifiable? Where is the database? What or whose models inform the decision to alert B that she has been infected and so forth? And can public health authorities – presumably, they are the app developers on top of the API, can they benefit from this knowledge that the system is accumulating?

Now, a lot of the questions and of course I asked all my technical colleagues. I did get answers to some of the questions, but I was sort of interested that some of the questions even some of the experts who are my colleagues at Cornell Tech, just actually did not know the answers to. I found that heartening, actually. But anyway.

Then some of the folks said well, okay. You are asking all these questions. They are not all about privacy. And I did not think that was correct. But it is true that if you consider a traditional understanding of privacy, I want to call it the predominant definitions that are out there, right to control information about ourselves, which leads directly into this is the way we protect privacy. We get people's consent. Or the right to have information about ourselves withheld, which means secrecy or maybe it means anonymization. If you have those narrow definitions of privacy, then it is true, not all those questions, which are considered really important, are relevant.

And a third variation on these two is to say we have control or yes, secrecy, but only with regards to private or sensitive information, not so-called public. So the world of information is divided into this dichotomy.

Instead I want us to think about privacy differently. I am going to do like a race through the theory of contextual integrity, just the highlights, and hopefully it will interest you enough to dig a little bit deeper.

Instead of secrecy and instead of control, the proposition is that privacy is appropriate flow. Definition of privacy, right to appropriate flow. And what that means is that it is flow of information that conforms with legitimate, contextual, informational norms. And this is all the theoretical construct. The key terms here are context and informational norms, and then this concept of legitimacy, legitimate informational norms.

The idea – the worldview of contextual integrity is that the social world is divided into differentiated social spaces or social – I do not want to use the word space because it is not really a space. It is a domain or a sphere such as nothing mysterious, health care, education, politics and so forth. And it is governed by rules and all sorts of norms and most importantly, it is defined by goals. What is the goal that makes health – what are the goals that makes health care, health care, education, education? And of course, they are highly contested, but this is really important and this is what defines these different domains.

Among the norms that govern behaviors are informational norms, and the proposition here is that in order to assess whether a given information flow either respect privacy or violates it, you need to match the flows in terms of five parameters, active parameter. You have the data subjects, sender recipient, information types, transmission principles. And the transmission principle is a little bit tricky, but it is basically the terms or the conditions under which the information flows and it can be quite complex. We could say if a police enters a house and does a search, it is acceptable only if they have gone in with a warrant and control of the information or consent is a transmission principle, but it is only one because some terms under which information flows can legitimately override an individual's consent such as a witness in a court of law, such as when we file our tax returns in about a month. We are not asked to consent to provide the information, but we are compelled to.

And the legitimacy of informational norms is due to the fact that the norms protect the interests of all concerned. I am going very fast and feel free to challenge, ask questions, and so forth. They do not conflict with important societal values. It is a freedom of speech, autonomy and so on. And most importantly, the norms of information flow are important in promoting the contextual ends, purposes and values. Of the constraints on information flow in health care are legitimate to the extent they promote whatever we think the goals of the health care context are. It could be alleviation of pain or curing disease, and they are values such as equity that we consider important in the health care domain.

The question now is how does one apply the theory of contextual integrity in any given circumstance? In many of the cases, what is going on is we are looking at technology. We are looking at technical systems and we are saying, does the system – it could be anything, Facebook, Google, Google Street View, we have to ask whether the flow conforms with legitimate contextual informational norms. And the heuristic that we are proposing is that you need to map these flows in terms of the five parameters. I am just reviewing. But now it is actual discovery.

We compare these flows, actual flows, with entrenched informational norms, and what these norms are is an empirical question. And in my group and colleagues, we have been doing quite a lot of work to try and understand what people's expectations are to come to some kind of systematic understanding and sometimes actually law will inform us of what the normative expectations are.

And then we need to –- if there is any difference, we assess legitimacy of flow versus the norm in terms of which one better promotes contextual ends, purposes and values. This is very brief.

And I want to do maybe just – it might help to see this in the context of the study that Frank referred to, where we actually utilize some of the structure of contextual integrity. My colleagues, Madeline Zanfaleipar(phonetic) and Yan Shvartzshnaider, were both at Princeton as fellows at the time, and they became interested in these disaster apps.

We did then altogether an assessment of 15 disaster apps and we wanted to understand what the privacy status is of these 15 disaster apps. And what you see on – I think it is also your right-hand side is the list of the 15 disaster apps that we looked at.

We performed a static analysis to understand what are the data flows in these apps, code, and permissions. We utilized this amazing system that Serge Egelman and his colleagues have developed called AppCensus to get an understanding of the dynamic analysis where we mapped information through actual information flows in terms of the five parameters of contextual informational norms.

And then we measured the flows against norms. What were the norms that we used? Law and regulatory guidance, endogenous privacy policies, and then we also surveyed user comments. And what we found was – this is again, I invite you to look at the paper, but just a couple of things is that Red Cross, which is such a trusted institution, their emergency and hurricane apps are non-compliant with law and guidance and they are also non-compliant with their own privacy policies. And furthermore, two apps, my hurricane tracker and my earthquake alerts, even following the emergencies, they continued tracking the location of people who had the app.

When we come back to the contact tracing apps that are being proposed in the APIs, it is important for us – this is why these questions are about privacy. We need to have enough information about how the apps work, how the APIs work in order to be able to answer the question so that we can map the flows and get at what the risks are and in particular, and this is the thing I am most passionate about, whether the public health authorities can benefit from the knowledge and update their own models by understanding how contact affects whether people are infected or not because it might be fine to protect one or two individuals, but it would not be satisfying if we could not update our understanding the epidemiological understanding of how something like COVID works.

This is before my recommendation, for those of us who are interested in understanding what these apps provide and how contextual integrity can guide our better understanding and what questions to ask. Thank you.

Frank Pasquale: Thank you so much, Helen. That is really clarifying and I really appreciate the application of the theory of contextual integrity to these very fast developing and rapidly evolving technologies for contact tracing and exposure notification.

Now, Mark, if you could present, that would be terrific.

Mark Rothstein: Frank, can you hear me?

Frank Pasquale: I can hear you. I cannot see you. Is your video on? Now I see you. Great.

Maya Bernstein: I do not see him, but it looks like his camera is blocked.

Frank Pasquale: I cannot see him.

Mark Rothstein: How about now?

Gregory Richards: It looks like your webcam is on, but that something is covering it because it is only getting black.

Mark Rothstein: How about now?

Gregory Richards: We still do not see anything. It is registering that you have a webcam, however.

Mark Rothstein: I am very pleased to appear before the NCVHS at least in audio form. Today my remarks are coming from a forthcoming editorial that I have written for the American Journal of Public Health that should be posted online in a week or two. The print version will be out in September, and actually briefly to tell you the history of this piece. When I was invited to give this presentation, I thought this is really important. I need to write something about this. I quick wrote something and AJPH is going to rush it through the publication schedule. It will be out shortly.

Just to backtrack a little bit, the fundamental, ethical, legal and policy challenge in all of public health is to balance public and individual interest. This is often conceptualized as the conflict between utilitarianism and libertarianism. And during the COVID-19 pandemic, this struggle has evolved the imposition of extraordinary levels of government mandated social distancing to protect public health then followed by impassioned efforts to lessen those constraints in the interest of individual liberty and economic renewal. The same type of conflict long has existed between individual interests in health privacy and public health interests in the collection use and disclosure of health information.

The COVID-19 pandemic presents these issues in a stark and unique way because it is the most deadly disease outbreak since the 1918 influenza pandemic and it is also occurring at a time when new technologies permit an unprecedented level of information gathering, aggregation, analysis, and dissemination.

The fundamental ethics and policy issue are how can we decide whether to permit the uses of these technologies and if so under what conditions and with what if any restraints. And to try to analyze that, I developed four criteria that I think policymakers should use in trying to answer this question. And those four criteria are first necessity and effectiveness. Second, proportionality and minimal infringement. Third, purpose limitations. And fourth, justice. These come from the public health literature as well as the literature dealing with data protection.

First, necessity and effectiveness. No public health intervention should be introduced without compelling evidence of its necessity and effectiveness. However, we are not in ordinary times and faced with a novel, lethal pathogen with no vaccine or highly effective treatment, clinicians sometimes have adopted measures without persuasive evidence of effectiveness. And public health officials sometimes have implemented information-gathering techniques without adequate evidence of necessity or effectiveness.

Let me just go back to 2003. During the SARS epidemic of 2003, the WHO recommended exit and entrance screening of all international travelers. Unproven thermal screening was used for maritime crews, passengers on cruise ships and ferries, and land border crossings. Canada used thermal screening at the airports in Toronto and Vancouver and they screened 2.4 million passengers. Of those 2.4 million passengers, only 832 passengers were singled out for further evaluation and none were determined to have SARS.

This experience demonstrated that thermal screening for coronavirus at least in this setting, simply does not work. Yet here we are 17 years later. We still have no evidence of its effectiveness. Nonetheless, thermal screening for SARS-CoV-2 often accompanied by oral questioning about symptoms and possible exposures, is widely used in the US, perhaps because it is fast, cheap, non-intrusive, and gives the impression that something is being done to protect people.

Neither the thermal screening process nor the data it generates poses a significant threat to privacy. But I think the stakes are too high and the support for public health interventions too tenuous to employ measures whose main value is symbolic.

Second, proportionality and minimal infringement. Public health interventions should be proportional to the risk. In a pandemic, extensive and intensive public health measures can be justified, but not every public health information activity is necessary and can be accomplished without substantial infringement on individual privacy rights. The proportionality of the response considers the value of the information to public health and often this is not clear when data collection has begun. The degree of infringement analyzes such factors as the sensitivity of the information whether there has been any type of consent including the ability to opt out and whether the information concerns minors or other vulnerable populations. An initial step should be determining if other alternatives can produce similar results using less intrusive means.

Data minimization protects privacy by limiting the amount of information collected and used to the minimum necessary. And of course, everyone hearing this talk knows that the principle of minimum necessary is one of the hallmarks of the HIPAA privacy rule.

Other relevant data protection principles that should be applicable in a public health emergency are that information ought to be collected, maintained, and disclosed in the least identifiable form, consistent with the intended use. Sensitive data should be retained for the minimum amount of time necessary and then destroyed. And security measures should prohibit access by unauthorized users.

The third consideration is purpose limitation. Data collected for a specific purpose should only be used for that purpose and should not be repurposed without the consent of the data sources or compelling public justification. Purpose limitations may conflict with big data analytics and other health surveillance technologies that feature massive and diverse data collection, machine learning, and algorithms that identify associations from disparate data sets.

One way of assessing the appropriateness of aggregating multiple data sets is by considering whether the data were collected for a public health purpose and used traditional public health methods. For example, public health laws in every state require reporting of specific infectious diseases to public health agencies.

Similarly, contact tracing is an established public health tool used to control sexually transmitted infections and other diseases. The public considers the use of these traditional public health methods as generally acceptable and ethical to use in a public health emergency, but there could be concerns if it is not voluntary, it uses technologies that are seen as invasive or it leads to a stigmatization or other harms.

It is especially problematic when data are repurposed for public health from other sources including Internet search terms, social media posts, geolocation information, sensor data, cell phone records, credit card transactions, health check apps, and proximity data generated by apps on mobile devices.

Some of these data sources have proven valuable in other countries during the pandemic and they should not be prohibited summarily, but they should not be presumed to be effective or ethically acceptable in the United States especially if they involve the collection of sensitive data.

Furthermore, collecting data that can be used for purposes other than public health such as population surveillance or law enforcement is likely to be viewed with great suspicion by the public.

And fourth is justice. The coronavirus pandemic is raising societal concerns about justice at a time when racial disparities and criminal justice, economic opportunities, and other areas are being critically reexamined. Black Americans are 2.4 times more likely to die of COVID-19 than white Americans and 2.2 times more likely to die than Asians or Latinos. Justice demands assessing the benefits and burdens of all public health policies including neutral policies with a disparate impact on certain groups.

For instance, the burden of closing non-essential businesses is more onerous for low-wage service workers who cannot telecommunicate and who have modest savings. Other public health interventions may adversely affect other individuals and groups such as people with disabilities or preexisting health conditions, those experiencing homelessness, senior citizens, people with cognitive impairments, and immigrants who lack English fluency.

Health privacy, especially informational health privacy, is rarely included in discussions of health equity. Fairly allocating the burdens and benefits of health information policies requires consideration of information practices in the broader context, including the impact on vulnerable populations.

For example, if contact tracing using mobile apps is deemed effective and acceptable, what measures are needed for lower income people who are most at risk for COVID-19, but who are also more likely to lack smartphones? Is the release of public health data more likely to result in discrimination against certain individuals and groups in employment, housing, or access to health care?

Finally, will any health benefits derived from collecting and using health information extend to all members of society?

In conclusion, ethical issues including health privacy are especially important to keep in mind during major disease outbreaks when exigent circumstances may lead to aggressive public health data collection and dissemination policies. These practices should be continually evaluated during the emergency using the four criteria I mentioned earlier or perhaps other criteria as well. Then after the emergency ends, intrusive health information practices initiated during the pandemic should be discontinued unless there are compelling reasons to continue using them.

Finally, in this Sunday's New York Times Magazine, there was an article by Steven Johnson of epidemiology and he wrote, "eventually, medicine will protect us from SARS-CoV-2, but for the time being, vital statistics are the best defense we have." Our challenge is to use these statistics with appropriate regard for essential, ethical principles, including privacy and justice. Thank you.

Frank Pasquale: Thank you so much, Mark. It was very clarifying, very helpful. And I think that these two presentations are such a good complement to our earlier discussions today because what we are doing here is we are really seeing both sides of the – we have been talking a lot about the upside and the positive affordances of automation of good data, but now we have also heard about some real problems here.

I do want to moderate the larger discussion. But before doing so – please do raise your hand if you have questions for either of the panelists or for the committees as a whole.

But one thing I just wanted to start with the panelists is – and this comes especially in discussion of proportionality and the relative risks and burdens of the implementing of technological solutions here or technological assists to contact tracers.

On the one hand, I have been hearing a lot from privacy activists and some affected groups that the key to contact tracing is very human intensive. It is professional intensive and that technology really has a relatively small role to play and therefore that the emphasis that we have often getting on exposure notification and contact tracing apps is a symptom of techno-solutionism of an effort to run to a technical response rather than doing some of the hard and difficult work of revitalizing county, local public health agencies or national public health capacity. There has been a lot of cuts to public health capacity over the past decade, especially with the national crisis of 2008.

On the other hand, what I have also seen in my comparative analysis – admittedly, this is rudimentary and I have not done a formal analysis, but I have been trying to keep track of what is going on in countries where a much more effective approach to COVID has taken root.

And I would say looking at the record of South Korea, in particular, Taiwan and Germany, that they do have some reliance on these apps. I think South Korea, in particular, has relied on technical assists to detect and to help bust clusters of cases and to do other – and to help. I think Taiwan also there – there was some emphasis on using the use of electronic data for maintaining quarantines.

I guess the question would be – to frame it at the most general level, do you think that there is something to be learned from the comparative experience first that we go in the direction of saying techno-solutions – problematic? But second, are there comparative lessons that would lead us to think that we have to give a second look to and to try to develop guidelines for apps be they exposure notification contact tracing? And to make this particular concrete, your answers will help inform our project scoping for the work of the PCS, the Privacy, Confidentiality, and Security Subcommittee as we think about our work plan for the next two years, tomorrow – subcommittee meetings. Comparatively speaking, do you think there is much to be learned comparatively or not so much? Either could go first. Helen or Mark.

Mark Rothstein: Let me say Frank, one of the things that we need to compare is the social milieu of the country and they are not all the same. I think some of the countries that you mentioned have a lot more comfort with technological solutions than we would in the United States. What works in South Korea may not be acceptable in the United States. We need to come up with a whole variety of strategies.

Having said that, we might reach a point where it is just totally infeasible to do in-person traditional contact tracing because there are so many people who are exposed at the same time. If we have a bad spike or a terrible second wave of COVID-19 then we may have fewer options. But I would not be comfortable saying okay, this is a problem that can be solved by any of the technologies that we have talked about and that should be our first choice.

Helen Nissenbaum: Just following on with what Mark has said, the differences among the different cultures and the way the difference societies are constituted is very important, absolutely critical, in fact. And I would say that, for example, there is a fear – this is really interesting because there is a fear and often, we look at China and we say you see. There is function creep. Once we have this whole

system of contact tracing for pandemic, now, we have an ability for the government to be able to follow people's social networks and do all these other things. I am nodding away, but I am thinking wow. What about all these disaster apps that carry on functioning in the ways they do even after the disaster is over? I do not know that we can point too many fingers. But it does depend on whether the country in question has laws that are appropriate.

For example, if the Privacy Act passed in 1974 that precisely was the purpose of it, which is to say we have different governmental agencies in order for people to entrust data with these agencies. We need to ensure. We need to give them assurances that there is not going to be one single governmental agency that is going to be able to aggregate all that data. Some of these were also broken down.

But I think legally, we need to be assured that if we have to go the way of technology and comprehensive contact tracing through technology, we are going to have suitable constraints that are in place and maybe this is something the committee can grab on to.

But I do want to say something about the first question you asked about techno-solutionism because among the various people that are asked about these particular models of contact tracing, there were some who were especially computer scientists who were very cynical and they said the first wrong step was to place contact tracing on top of the mobile platform. That immediately is hugely problematic because Apple and Google dominate the space, completely dominate the space and there is so much going on under the hood that it is unclear that placing – it does not matter how great that app is or how many protections are inserted into the app itself, what Google and Apple are doing underneath that at the API level and operating system level is what we all know to call a world garden. It is not techno-solutionism that is a problem in general, but it is making that first step into the mobile platform. In my more optimistic moments, I think maybe this is going to break open the mobile platform issues because this is so important.

Frank Pasquale: Thanks so much, both Mark and Helen. That is really illuminating. And I think you are right to say that that is the black box problem in ways is something that is – and the power problem. It is both an opacity, but even if the opacity is remedied, the power of governments vis-a-vie some of these very large tech platforms is in doubt.

I see hands up from Nick and Melissa. Nick first and then Melissa.

Nick Coussoule: Thanks for the discussion so far. It is interesting. I want to pose a little thinking problem. Those of us who have been in the technology realm for a long time – there are certain things that technology can do that people just are not very good at. In the contact tracing example, going and asking people who they have been near, they are going to get it wrong often versus if you happen to have the right technology whether it is mobile phones and they can trace it, there is likely to be at least objectively better data on some of that. I do not think most people would argue that in a very limited use case if that would be interesting information.

Part of what I am getting to here is a little bit – I really like the way Mark frames up the different considerations. Because if we take a look at the purpose limitation to that one component and question, I think most people would say if that was the only reason that that data was captured or ever used for, people would be pretty good with it. But unfortunately, it is a little bit like the barn doors are open and there is no way to actually get the animals back because they are already gone. It is an interesting way to frame it.

I get less – maybe less question about the techno solutionism because I do think that there are interesting ways that technology can be leveraged that become impractical without it. At the same time, it is very difficult to create that limiting factor both from a time perspective and a scaling perspective.

I guess I would open it up to other questions or comments about that.

Helen Nissenbaum: Are we doing lots of questions and then coming to the answers? How should we do it?

Frank Pasquale: Let us have Melissa's question and then you can – both you and Mark can choose – can address both at the same time. Melissa, if you could ask your question that would be great.

Melissa Goldstein: Sure. Can you hear me? Great. Thank you to both of you for coming. This has been very helpful to me and I really appreciate it. I am interested in the idea of public acceptance or on the other end of the spectrum public blowback and cooperation with public health authorities, cooperation and trust in the government in public health authorities in measures to contain the virus and to test and hopefully we will be doing more testing, more contact tracing, more isolation in the future than we have been although we are opening up at the same time.

I live in Washington, DC. We are anticipating moving to Phase 2 on Monday. We have had tremendous blowback and a lot of protests recently. I am wondering about the two models that you presented so Helen's model and context focused and Mark, which the model reminded me of Jacobson's four categories and also of course reminded me of the FIPPs.

I guess one of them is a thought exercise that probably is not fair like had we paid more attention from the beginning on this balancing idea, would we be in the situation we are now of blowback.

Perhaps the more apt question would be how do we move forward from where we are with perhaps a bad taste in the public's mouth about where we have been and how things have been proposed and the kind of willy-nilly helter-skelter way and how do we gain this back so that we can actually approach the virus in the way that we need to and gather the data that we need to moving forward.

Helen Nissenbaum: I am happy to go. Nick, I am not as optimistic as you about technology. It is true what I have read about why the contact – automation of contact tracing is a good idea because people have faulty memories and especially when you are in contact with people you do not know. It is definitely the case that your phones might be talking to each other and yet you might not be aware of that.

It is not just that I do not see any advantage to it. I see that there is potential, but there are also worries in the current application that have been – which is in particular. I worry about the model. What is the magic that is happening that goes from – you are coming into contact with so many people, but then you are going to get these alerts that say someone you were in contact with is COVID positive. What is the model that takes all this information and pops out and says Frank was – we were close enough for long enough time and now I must be worried. Unless we insist on that model being publicly available and I think it gets to something that Melissa was saying about public trust.

Unless we understand what is going on under the hood and I am not saying every single user needs to understand, but unless we know that public – the experts, the epidemiologists, the public health authorities and so on understand how these models are working, I am concerned that tech could go

wrong, maybe not in the same ways our faulty memories, but it could go wrong. And I think Frank in his work on black box decision and discrimination shows us that there can be hidden ways in which technology can make errors and the errors are not necessarily evenly spread apart across the population. These are the conditions that I would insist on.

I think the barn doors are open argument, which is like the justification for every kind of function – I think we have to really reject that and every time someone says that to me I say so many people would love to see Donald Trump's tax returns. The IRS has it. How come we have not all seen it? How come there is not barn doors are open? Someone has the data; therefore, everyone has the data. It is interesting the convenience with which we – that argument.

Nick Coussoule: Helen, just to be clear, this is Nick, my point about the barn door was that if you stipulated that this information would be useful for one particular case, unfortunately, pulling that back is almost impossible because at that point, even though you may be very well intentioned, you basically have already opened the doors. I am not suggesting you should open the doors. My point is that once you have picked the use case even though the best of intentions, you have now created that difficult situation.

Helen Nissenbaum: Got it.

Mark Rothstein: I would like to answer Melissa's question. You cannot see me, but there is a dark cloud over my head. I wish I could be more optimistic. When we had the first month or six weeks of the lockdown, I was amazed at how compliant, unified, together the people were in this. It just sort of blew me away. But then we know what happened after that. Our country is not known for its social solidarity the way that some of the Asian countries that Frank mentioned are or even Canada. Now we see that where we have the rugged individualism is coming to the front. You cannot tell us what to do. We are independent and so on. That really conflicts with public health. It always has. It always will in emergency situations. The country is crying out for leadership that can unify us and to face this really existential threat. Until we have that, I am afraid it is going to continue in its present course, which is not good for anyone.

Frank Pasquale: Yes, Mark. I just wanted to build on that because part of what my vision here is there were at least four plans for reopening the US that were released by very high profile prestigious thinktanks. There was an AEI plan that Scott Gottlieb co-authored. There was one from Danielle Allen in the Harvard Safra Center. There was one from the Center for American Progress. All of them very well thought out and extremely compelling in terms of the vision for – country, which could include or not include the tech. And one of the things if you look at the Vox article on these four different plans, there is a spectrum of tech-ishness to them of like how much they would rely on automated exposure notification, contact tracing. Both sort of governmentally enabled, but also within private companies. Lots of universities now are being told you are going to need to reopen and you are going to need to reopen with a very high-tech surveillance of student clusters of cases, other things like that.

I think the problem now in something that I had certainly not foreseen is that we seem to have a real lack of leadership right now.

And I think the other issue that I think I really want just to think deeply about is that I think culture – on the one hand, I do think that cultural arguments are important in recognizing that we are not X country. It is a very important thing to bear in mind.

I also though, really have to worry though that – I know there is at least one governor I think announced today that that governor was going to forbid every locality in his state from requiring mask wearing. This is to me a strangely – and to me, it is like at that point perhaps we have to ask does the culture need to change and what role do experts have in stepping forward and identifying the mass loss of life that could result from certain cultural commitments, which is now at the point of six Boeing 747s crashing. That is about the number of our death toll. It might at some point get to the point of a 9/11 per day.

That is where I wonder sometimes that even if there is only an incremental gain from certain forms of data gathering to the finding of the pandemic that it has to be taken very seriously. That is where I am coming from here, but I also recognize though that there are some very powerful critiques in all of our work of techno solutionist plans that really do not deliver what we want them to deliver.

I see Rich and Denise now have their hands up. I think I saw Rich first and then Denise. Rich.

Rich Landen: Thanks, Frank. Lots of interesting threads here. I am not a deep expert in privacy, but I certainly have been exposed to it through EHR work and my – five years on the committee now.

One thought that I have not heard raised is what is the role of the generational differences in the culture here. Our conversation, as I have been listening to it this afternoon, has been fairly on the conservative side. But I have been exposed to several venues where particularly in the EHR world when focus groups were charged with here is the advantage of yielding some of your privacy or consenting to some privacy disclosures that you would not necessarily agree to on a general basis. But when you look at a specific value, the trade-off, you would be willing to trade this off to get some advantage. There is that aspect. And then there is the generational. Are we around the table – are we tending to be a little bit more conservative than some of the younger generations? I have heard that from the focus groups as well where the generation has grown up on the smartphones and the Google apps and the social media just do not have the same concerns as some of the older generations. I want to recognize that thread. I do not have any particular questions or particular challenge or answer. But we need to recognize that too as part of our discussion of the culture. There are those that say hell no and those that say no big deal.

Frank Pasquale: Thanks. I think we will do our practice of maybe having two or three questions because I see Rebecca's hand is up. If we could do Denise and then Rebecca and then have a response from Helen and Mark.

Denise Love: Thank you. Rich, you took the question that I had too about generational differences and what denominator did we play to, the lowest or the highest, but relevance, the information that is not relevant and those tradeoffs and risks to make it relevant leads to a vacuum and others will fill it outside of public health.

But I just wanted to register a concern that Mark raised. I really loved these presentations and I wrote a lot of notes. But I kind of have a hiccup here on repurposed data because I have made a living on repurposed data. If you really think back to vital records, they were just to register births and deaths and now they are the public health infrastructure. Hospital data is built off billing data that is repurposed over and over. And now we have linked files and population databases that go into such linkages that we could not imagine. And we are spinning that straw of administrative data into gold through repurposing data, data that we collect for one purpose today. We cannot even imagine that in five years that maybe something that we are so glad we did collect, and it answers questions, we cannot even anticipate.

Other than saying a single purpose data, maybe guardrails around or rephrasing that. But that just was a red flag to me that says I do not think repurposed data is bad at all because that is how we manage our public health and we cannot afford single use data sets anymore.

Frank Pasquale: Thanks so much, Denise. Rebecca.

Rebecca Hines: I wanted to circle back to this whole question of public trust and culture. I was intrigued. I did some of the background reading and the article on Iceland, a statement really sticks out with me. They were talking about why they had such an incredible success with quelling the virus and getting back to normal relatively quickly. It was because – there was sort of a somewhat snide remark in the article about the politicians managed to just put themselves off to the side and turn the whole affair, the whole operation over to the three public health gurus, our equivalent of Fauci, Redfield, and Birx. They had their three. And they let those three run the whole thing and the country agreed and everybody did what they said to do. It was sort of equivalent of our Ohio Amy Acton. Many of you might know about how she managed to communicate, and the governor really seeded to her the communication strategy in Ohio. They had a much lower incidence than Michigan next door.

It seems to me there is a culture, an opportunity here around getting people educated on public health. Obviously, some Americans are already on board with that. But that is another way of looking at it is depoliticizing when you are in the middle of the situation and that is the way you can move things in the right direction. I just wanted to speak to that article and how that was all discussed and fleshed out.

Frank Pasquale: Thanks so much, Rebecca. I would also note that Taiwan had a vice president who I think was an epidemiologist before becoming the vice president. It is really something that I think – also looking at Germany and Angela Merkel's exceptional fluency in science and being able to explain the R nought factor in both accessible and rigorous way. It just makes a world of difference. It is a world of difference to leadership and also respect for expertise.

It is actually a theme of a book that I have coming out this fall. It is on defending human expertise both from – politicized interventions against it.

I know we had some great comments here. Any closing remarks or thoughts from Helen or Mark?

Mark Rothstein: Frank, if I may, I very quickly want to address the three very interesting comments. First with regard to Rich's comment. I have been very interested in this so-called generational difference in health privacy and did a detailed study of this. I will give you my conclusion. There are differences between people in their 20s versus 40s or 60s. I am not sure it is a generational difference. I would argue that it is a life cycle difference and that when young people become middle age, they are going to have views of their parents. We can talk about that offline.

On Denise's point, it is not the repurpose so much as it is the repurpose of sensitive data for uses that the individual had no possible understanding of beforehand. Maybe we need an asterisk to repurpose and not prohibit all repurposing but the kind that people could legitimately object to.

Rebecca's point about be politicizing. I think that is absolutely the case. Another piece that I have written I have gone off on that particular point. You cannot do public health in a partisan, political arena. We are seeing what happens.

Helen Nissenbaum: I also wanted to pick up on these really great points. Here, I think contextual integrity forces a different kind of thinking. And Rich, I was so interested in learning more about the kinds of studies you are doing.

When you talk about the focus groups and you offer people tradeoffs and you say you could get this and that, one of the – I have a series of three studies with Kirsten Martin. And what we show is that when you ask the questions and you are inserting values for the different parameters like you would say this data to these recipients and under such and such conditions, you might at first ask people about how do you feel about disclosure of information end of story. But then when you add the recipient field, you get just huge variation.

There are these hidden variables that are affecting people's responses and my view is that unless you present these questions and flesh out all the values for all the parameters, the results are going to be ambiguous. That is my one comment.

About the generational differences, I think it is not so much a matter of some people – young people do not care. But it is the case that maybe young people care about different things. That is one thing. And they may not be as wise as older people. They may engage in, as we know, risky dangerous habits and all the people might not. I think in the data space, there is a lot that people do not know about what is going on with the data and how it can come back to affect back. Very few people are applying for mortgages when they are 20 years old.

This comes along with the question of privacy again, a contextual integrity commitment when we are trying to assess privacy risk or privacy threat. It is not a question of preferences. Privacy is not a preference. We need to assess what the acceptable information flows are. And when we do that, it maybe that because preferences are very fickle and do depend on lack of knowledge. These are my concerns in response to Rich's comment.

I think Vickie's point also to me shows why the FIPPs, the Fair Information Practice Principles, are really problematic because what the FIPPs allows is for purpose specification to be anything and then the uses simply need to be according to the purpose specification whereas I think the question we need to ask is is the purpose of these legitimate. Are the uses of the data legitimate uses of the data? It does not matter if the new uses of the data do not conform with the original purposes. I think Mark and I – there is a lot we agree on, but maybe that one not necessarily because it is not all about what people consented to.

But if the purpose changes, but the goal is still achieved, and it is a pro-social goal then the problem is not – then the repurposing is not problematic according to my view.

Frank Pasquale: Thank you. Thanks so much for that. I think Rich's – I think your hand may have been left out. If not then we can jump in. Vickie, I see your hand is up.

Vickie Mays: This is actually addressed to Mark. Both of them. Mark, this issue of when you talk about generational differences, to me the issue really has become in COVID-19 these racial ethnic differences because of this concept of vulnerability and people not having either the resources or the knowledge sometimes for protection and whether or not that puts the Federal Government or the state or someone with a greater burden to ensure that as that data is being used that that person is protected. I now on the PRIM&R board and we have been talking about this relative to the collection of data and research and this issue of both justice and vulnerability. And the vulnerability is greater, the poorer you

are, the less knowledge you have, and you do not have a capacity to fight back. Whose responsibility is it to do those protections? Can we have differential type protections under some of our policies and procedures? When is your paper coming out?

Mark Rothstein: Any day. I can send you a copy.

I think you raised some very interesting questions about the vulnerability of the individuals and the groups. One thing that occurs to me is how much of the difference between the 20-year-olds and the 40-year-olds is based on the fact that there is evidence that the 20-year-olds are not as likely to become infected. And if they are infected, they are more likely to have a modest case than someone who is in their 60s or 70s.

I think probably they would be more of a risk taker even if the risks were aligned on an age basis, but the fact that there is evidence that it is the really old people or the really sick people or those with preexisting health conditions that are most at risk tends to skew the difference in ages. And then when you layer the different ethnic and racial groups on top of that, it gets even more complicated. The issues that you raised – we obviously need to try to get a handle on it.

Vickie Mays: There is new data out that just came out on Monday that really is talking about these age differences. And in racial and ethnic minorities, they are looking as vulnerable as people in their 60s and what have you in terms of the disparities of how sick they are getting. It is kind of like the issue of race ethnicity is – which is I think in embedded in poverty and all this other stuff is trumping some of these other things – that is why I am saying this issue of vulnerability – we are really struggling with that relative to the impact of what that data you collected can do to that person if they are undocumented, if they doing something. Too many people living in the household for their landlord. There is all this stuff that people are really getting slammed. There are cases of people put out of their apartment because the density issue has come up relative to COVID-19. How we use this data when a person is vulnerable has to almost be a little different, I think, in terms of degrees of vulnerability or something. I do not have the answer. We are struggling with it in PRIM&R right now around research.

Bill Stead: I think with that, Frank, you probably want to begin to bring this to closure.

Frank Pasquale: Yes, yes. I realize our agenda. We are set to adjourn for 5:15. I just wanted to – I see that – I think we have our hands – have all participated. With that, I just wanted to again thank Helen and Mark for some really illuminating presentations. We hope we can come back to you for further input as we develop our own approach because we so highly value your perspectives. Thank you.

Now, I will turn it back over to Bill.

Bill Stead: I will just add my thanks. The presentations were unbelievably clear and the contrast very helpful and the rich discussion is really going to help move the subcommittee and work board and help the full committee understand where we are.

With that, I believe, we are at the point that – Rebecca is nodding her head yes that we can adjourn. We will see you all with your faces bright and smiley a little bit before 10 Eastern tomorrow.

Rebecca Hines: Yes. If everyone could log in five minutes early, we can start on time. That would be great. Thank you all for your patience on a virtual format. I hope you have a good evening. We will see you all bright and early if you are on the West Coast tomorrow at 9:55 Eastern.

Bill Stead: Just remember. We have to enjoy the dinner we are not having together.

(Whereupon, the meeting adjourned at 5:17 p.m.)