National Committee on Vital and Health Statistics

Transcript

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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
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Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Rachel Seeger	HHS Office for Civil Rights	Staff
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Name	**Organization**	**Role**
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Tom Mason	HHS	
Lauren Richie	HHS	
Presenters		
Name	**Organization**	**Role**
Daniel Kalwa	Centers for Medicare & Medicaid Services	Policy Analyst

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, again. I hope you all are well, ready for day 2.

Let us go ahead and take care of roll call. Bill, do you want to lead us off?

Bill Stead: Hi, I am Bill Stead. I am Chief Strategy Officer at Vanderbilt University Medical Center. I am chair of the Full Committee. I have no conflicts.

Rebecca Hines: Alix.

Alix Goss: Alix Goss, vice president of Imprado, the consulting division of DynaVet Solutions. I am a member of the Full Committee, a member of the Executive Subcommittee, co-chair of the Standards and Review Subcommittees. I have no conflicts.

Rebecca Hines: 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. Can you hear me?

Denise Chrysler: Yes, I can. 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. No affiliation. I am a member of the Full Committee, member of the Standards Subcommittee and now a member of the Privacy and Confidentiality Subcommittee. No conflicts.

Rebecca Hines: Frank.

Frank Pasquale: Frank Pasquale, member of the Full Committee. I teach law at the University of Maryland and I am also chair of the Privacy, Confidentiality and Security Subcommittee. No conflicts.

Rebecca Hines: Jacki.

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

Rebecca Hines: Jim

Jim Cimino: Hi, Jim Cimino, University of Alabama at Birmingham. Member of the Full Committee and of the Standard Subcommittee. 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, no conflicts.

Rebecca Hines: Margaret.

Margaret Skurka: I am Margaret Skurka. MAS Consultant. I am on the Full Committee. I am a member of 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 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. No conflicts.

Rebecca Hines: Vickie.

Vickie Mays: Vickie Mays, University of California Los Angeles. I am professor in the Department of Psychology and School of Public Health in Health Policy in Management. I am a member of the Full Committee. I am a member of the Privacy, Confidentiality and Security Committee and I am on the Review Committee and Standards. No conflicts.

Rebecca Hines: Thank you. I think Nick is going to be joining us in a little bit. He had another meeting.

For staff, I see Rachel, you are on this morning.

Rachel Seeger: Hi, Rachel Seeger, HHS Office for Civil Rights. I am lead staff to the Privacy, Confidentiality and Security Subcommittee.

Rebecca Hines: Thank you. Lorraine.

Lorraine Doo: Lorraine Doo, Centers for Medicare Medicaid Services Health Informatics Office and lead staff to the Standards Subcommittee.

Rebecca Hines: Beautiful. We will have some other staff today join us as well. Maya Bernstein with ASPE. I think I will leave it there for the roll call.

Bill, over to you.

Welcome/Review Agenda

Bill Stead: Thank you, Rebecca, and welcome back everybody. Just to briefly review the agenda for the day. We are going to spend the morning working on our standards projects beginning with the updates on the NCPDP recommendation, the HITAC Task Force work with the group on the Intersection of Clinical and Administrative Data, ICAD, and then dive into the plans for the August hearing on the CAQH

CORE Operating Rule request. Then we will have an update from the Division of National Standards and then break for lunch.

And then in the afternoon, Frank will bring us back to the discussion of, I believe, the possible near-term project or the intersection of that in the longer-term project. And then we will have some time as a committee to reflect on what we have learned and as we get ready to incorporate that into our workplan update and we will also take public comment at that time and then adjourn.

Are there any questions about the agenda or suggestions for additions? Not seeing any hands, I will turn it over to Alix and Rich.

Subcommittee on Standards

Alix Goss: Well, good morning, everyone. I believe we have a slide deck and I am hoping that the team has the updated one. We did a few tweaks yesterday morning and pass that along. I believe Rich and I are going to be tag teaming. Could you go to the next slide please?

As you already have a preview, we are going to cover three topics today. We have ample amount of time to go through these updates and take questions and discussion. The three topics are an update on NCPDP, a letter, and the response that we have received really talking about where the ICAD Task Force is currently. We might even want to tip toe into some of our own convergence related discussions, especially considering yesterday's thoughtful privacy and security content and public health content that we had that we want to extend our own thinking. And then we are going to wrap it up with a discussion around the August hearing on CAQH Committee on Operating Rules that they would like to see adopted as a federal standard.

Rich and I are going to tag team through these topics so I am introducing them. I am quickly turning the baton to Rich.

Rich Landen: Thanks Alix. If we could go to the next slide please. We are going to start off this morning with just the follow up from the action that we took as the Full Subcommittee at our last meeting. As you will recollect, we approved recommendations from NCVHS to the Secretary. And this slide is kind of the high-level synopsis. We received the request from the Designated Standards Maintenance Organizations back in January to recommend adoption of an updated NCPDP Standard, specifically F6.

As a HIPAA-mandated national standard, as part of our March 24 meeting this year as a Full Committee, we heard from the industry. We deliberated the F6 standard and we voted to make two recommendations to the Secretary. First was for the adoption of F6, which is a standard that replaces the current mandated HIPAA study of D.0. And we also recommended a timeline for the adoption and implementation of F6.

Now subsequent to our meeting in March, as we were drafting the recommendation letter, it became clear to us that we needed to clarify the status of recommendations that we had made in May of 2018. At that time, we had recommended to adopt NCPDP F2 so the predecessor to F6. But we also included in that letter of recommendation to adopt batch version 10 and Medicaid subrogation. DNS and HHS have not acted. They have been reviewing, but they have not promulgated rules based on our recommendation. We wanted to be clear that this current letter of recommendation simply said supersede F2, replace D.0 by F6 instead of by F2. As an aside, F6 contains all the changes from D.0 through F2. That was the primary recommendation.

But we added a third recommendation to make it clear to DNS and HHS that we wanted to continue the 2018 recommendation to adopt batch Version 10 and the Medicaid subrogation that was in our letter back then. With that change, there were actually three recommendations in the final letter. The draft of the final letter then was reviewed by the Subcommittee and the Executive Committee before it was sent off to HHS and we sent that letter April 22.

On June 9, we received a response from HHS simply acknowledging the recommendations. That in a nutshell is what has happened since our last meeting with our recommendations for NCPDP F6. I will pause to see if there are any questions.

Alix Goss: I would also note that the letter, I believe, Rebecca, was being posted. The response letter was also posted. If you already said that, I apologize.

Rebecca Hines: Yes, it is on the website.

Rich Landen: With that, the baton goes back to Alix.

Alix Goss: The Office of the National Coordinator or ONC has a Federally Advisory Committee created by the 21st Cures and it is the latest incarnation of their FACA or Federal Advisory Committee. They have the HITAC – is the formal body sort of equivalent to what we have with NCVHS. HITAC provides guidance and input and recommendation to ONC as we do when we provide guidance recommendations and information to the Secretary. We have these two very parallel Federal Advisory Committees that have different specific requirements in that who we report to although the synergies are more in common than not about the scope of work.

A nice dividing factor is sort of NCVHS has been in the administrative wheelhouse. ONC's Federally Advisory Committees are in the EHR clinical data wheelhouse. We have realized not only from our own collaboration efforts and discussions over the years, but more especially as reinforced by the 21st Century Cures that there is a need for the two federal advisory committees to work closely together to address the trajectory for health information, policy standards within the United States.

Building on our long-lasting charge, we have been able to over the last 18 months to 2 years really work very collaboratively with the Office of National Coordinator with their charges and to be able to find a common ground on which we can try to make thoughtful recommendations to improve the overarching ecosystem in the health care.

Part of the detailed conversations that we have been having has been around the prior authorization provider burden type of aspects. We have been trying to figure out in the early days how we might more formally coordinate to fulfill the vision and our collaboration scoping document that we worked on about 18 months to 2 years ago. And through a series of public-facing, federally advisory committee meetings over the last year change, we created this new idea of a task force. The partnership with ONC has been very important and very rewarding in our ability to think about the big picture, the amount of input that we need from the industry to really have thoughtful recommendations be produced that can actually move the needle. ONC has really been able to tap into some of their resources to help us take the next step in evaluating the opportunity to intersect or converge clinical administrative data. Their resources are also helping us garner the golden efficiency objective in interfacing with the industry.

One of the things that we have done within NCVHS is our project scoping document for the convergence side of this coin. We reviewed that in March with the Full Committee. We plan to kick off a lot of that work as we noted yesterday with the trigger of getting a report from ONC's task force.

The task force, which is being called ICAD for the Intersection of Clinical and Administrative Data – I am going to give you an update on that in a few minutes. But ultimately, I just want to set the stage here for folks to understand on the Full Committee as well as in public that the end game of the task force is to produce a report that will go back to the full HITAC sort of like we do where the subcommittees do work and then take it up to the Full Committee. The task force will produce a report, submit in a draft form for feedback to HITAC. We will then be able to finalize it, having received their input. And from that point then, we would have an opportunity for the Standards Subcommittee to use that report as a piece of our larger convergence project.

We are going to first talk about the task force itself and what it has been doing. I invite my colleague participating in that task force, Jackie and Rich and Deb, to weigh in here as we go along because this as usual is taking a village.

Let us just cover some basics here. The task force's charge and our vision and charge first is to support the convergence of the Clinical and Administrative Data to improve interoperability to support clinical care, reduce burden and approve efficiency for furthering the implementation of the record once and reuse. Record once and reuse is a big part of the ONC initiatives.

The overarching charge is to produce information and considerations related to the merging of clinical and administrative data. I think it is important to call out the transport structures, the rules and protections for prior authorization to achieve the vision. Really, the goal here is prior authorization is a use case. It is a problem child of frustration and burden within the industry's ability to exchange information between payers and providers to really support the advancement of patient care and to do so in a way that minimizes overhead and cost and resource allocation by the payers and providers, but ultimately, it is really about addressing the patient safety issues and enabling a patient who has the need to get approval for insurance coverage or to understand that it will not be covered and then to be able to make good care quality decisions with their clinicians is really what we are trying to address here is that experience and the outcomes of health care being really advanced and supported by our opportunity to improve the landscape. We are using prior authorization to inform the larger conversation.

Any other kind of set up comments you might want to make, Rich?

As I noted earlier, we have several folks from the Full Committee participating on ICAD. From the Standards side of the house, Rich, Deb, and I are a part of that. And then we have been really grateful to have Jacki Monson from PCS participating and this turned out to be really instrumental in some small working group efforts that we have had in addition to the broader task force meetings.

The goal is to produce a report. We originally thought we needed to have that done by the end of September. What we realized was along the way with our check points with the full HITAC necessitated us pushing that out a month because HITAC goes into a hiatus over the summer months. We did not have an ability to get in front of them to get their review and feedback. I am extraordinarily grateful for that because this has been a pretty big lift, folks. Prior authorization is something we have been talking about for a while. Our Review Committee report that came out in 2016 really showcased the ongoing challenges and helped put more framing around the issues with prior authorization, which has been

underscored since then by the CAQH index reports that we have been also quoting within our report to congresses and it really shows a negligible increase in the ability to automate and efficiently perform the business function of prior authorization, that pre-approval for insurance coverage.

We have been – one of the critical underpinnings of the task force work is a compendium that was produced. Really hats off to Andrew at ONC who has been reporting to us as well as Michael and pulling together a lot of information to ground the task force. The compendium was built before we got launched in March. It was rolled out to help set a landscape of reference information in which we could build and we are continuing to add to that compendium through our interactions and presentations with the industry as we gather more facts.

I think what is important here to understand is to build on that efficiency of engaging the industry. We are not just starting from scratch. This is not something we have to figure out what the problems are. The issue here is what are we going to do about it this time. Why is it going to be different? How is this initiative around prior authorization as an exemplar at the larger intersection challenge that we have in front of us that we have been addressing within Predictability Roadmap and other conversations? How are we going to really figure out how to crack open the egg and get to the goodness that we are looking for, which is a more efficient process, more transparency for the patient, less burden to the patient with better outcomes and no impact to safety and addressing that administrative overhead and impact to the payers and to the provider communities.

We have not only are coming together to consolidate to get that input from the community that enables us to produce thoughtful recommendations, but we are also leveraging all that background work that the committees have – HITAC and NCVHS have been developing over the last couple of years. That was a great launch off point for us to dive into some discussions.

We launched in March with weekly task force meetings. It is a big group. We meet for 90 minutes a week. We realized early on along with my co-chair, Sheryl Turney from Anthem – she and I realized during our wraparound prep and debrief meetings that trying to do the detailed work in a setting like that was going to be very challenging. We have created lots of small offline work group meetings to address data classes and categories, business process modeling, overarching guiding principles and ideal state with an additional sub-team to that around the privacy and security principles, which Jacki and I co-led.

In addition to the task force meeting regularly, having offline working groups and Google Docs to help us advance our efforts, we have been inviting industry to come present their perspectives and views around the prior authorization topic and also soliciting any other kind of more global thoughts that they may have on the convergence conversation.

The goal at this point is to in the month of June wrap up the prior authorization nuts and bolts. To start drafting a report and we are using a template approach from prior HITAC letters and reports. We are right now compiling a number of components that will need to go ultimately into that report outline.

We will be in June elevating the body of work from the data classes and process mapping group. We have already been socializing prior authorization ideal state and guiding principle guardrails. We are taking the deeper dive on the strawman recommendations related to prior authorization and building those recommendations off of the framework of the ideal state and guiding principles. If we know where we want to get to and the things that we need to live by in getting there, we can then start to create these strawman recommendations to bring back for discussion and vetting and then subsequent

iteration by the full task force. That body of work around prior authorization will be the launch off point for the broader philosophical discussion about what it is going to take to intersect clinical and administrative data. We will need to create either additional principles or considerations. We are going to have to create specific recommendations.

With that thought process in place, hopefully in the month of July, we can get down to small group writing exercises to build out the narrative that goes into that report outline that Cheryl and I have already been working on.

From there in July, we will need to solidify not only the recommendation, but also the narrative to a very solid draft as we are expected to present those draft recommendations to HITAC for feedback right after Labor Day.

When we get the feedback, we will then turn around and use the next five weeks to produce a final report that we will then present on October 21 to HITAC. HITAC will go through their due process sort of like NCVHS does. They will need to take the report and decide how they want to advance it to the entity to which they report, in this case, ONC.

I would like to call upon Rich and Deb and Jacki to offer any additional thoughts, round out what I have said. Please contribute to this landscape of the ICAD work.

Rich Landen: Alix, my one comment is just kind of a little bit deeper into the presentations by the industry stakeholders. These presentations were to some extent about general global input, goals, objectives, problems encountered and things like that. But my take on these presentations is most of them are really reports about what industry has been trying, has been piloting, what has been succeeding, what has been failing and their attempts to bring some automation and standardization to the process within their own realms. I have found that very useful in terms of understanding pragmatically what some of the barriers are, what are some of the obstacles that ICAD, HITAC, ONC, and presumably NCVHS can help remove or get around in the future.

I am very impressed by the efforts of the industry at all these different initiatives going on. There are initiatives going on around FHIR world. AMA has brought together an industry payer/provider coalition that has come out with some agreed upon guiding principles. It is really interesting to watch how much activity there has been going on and yet there is still a long way to go before we can identify solutions to some or all of the prior auth issues.

Alix Goss: I think it is a really good point, Rich, in that in 2015 when we did a Review Committee Hearing, which had 77 testifiers at it and did a retrospective review of the HIPAA transaction standards that had been adopted and assessed the traction and value and future opportunities, we thought we needed to take on prior authorization. The industry said we are working on it and we said okay, we will wait. I think it has been really refreshing to see the leadership in the industry to try to get their arms around this because as Nick and Bill were talking about in the report to Congress – Congress, the Executive Branch, industry. It takes that trifecta to really move the needle on things. They certainly have stepped up.

Debra Strickland: Just to offer a little feedback - this is a very intense group, as you know, meaning this as a challenging effort, but I think you and your co-chair have done fabulously. We have very in-depth knowledgeable folks on this team. As they are able to present their experiences and successes and failures in areas of work, you guys are able to really gather all this information and put it in a manageable and useable source so that we can actually get to what your next steps are, which is to draft

an outline and then get that paper presented. I think the approach that we have taken here is very successful, not easy to do, gathering all the information from all these different bodies. I think that this has been a really great approach to gathering the information and maybe getting to a more successful product at this point.

Rich Landen: Jacki – would Jacki have anything to say in particular on the privacy aspects?

Alix Goss: I think Jacki may have had a conflict. Oh, there she is. She is there.

Jacki Monson: Not too much to add other than it has been fascinating for me for the different ones that I am looking at this, the prior authorization. I am mostly in learning mode, learning and taking all of the processes and all of the successes that people have tried to achieve in their own silos. I think it will be really great to see some standards.

And what I am most excited about is the idea of privacy and security by design, which we do not always get to do and in this case, we are getting to do it and have a set of recommendations that I think are close to final that really contemplate privacy and security and some of the challenges that we see with prior authorization and the idea of really wanting to standardize it and automate it and the challenges with the privacy regulations that we would run into in wanting to do that like self-pay restrictions and minimum necessary. It has been very fascinating for me to participate.

Alix Goss: Jacki, I really like that comment about the learning. I have been in this field for a while and you still pick up things along the way and you start to think about things through different lenses. It has been a process.

Rich Landen: Two quick comments before I let Alix move on. First, I want to reiterate or pick up and reiterate Deb's comment about the leadership we are seeing from Alix and her co-chair Sheryl Turney. Just tremendous heavy lifting going on to enable and to guide the group. It is a fantastic group of a lot of bright people in there. But to get them moving in the same direction, it is the old herding cats' things. Kudos to Alix on that.

My second comment is – and, again, it takes off kind of on the privacy that Jacki was talking about. In my experience in the HIPAA administrative transactions world, this is really the first transaction where the patient is directly involved in a significant extent. By and large when you look at claims, eligibility, enrollment, claims status, claims payment, those are all B to B, business to business transaction and there is no active role in the patient in that communication network. Obviously, the patient is involved in it, but it is really a transaction whether contractual or extra-contractual between a provider and a payer.

When we look at the prior auth, there is direct patient involvement. There is direct patient impact. Timeliness matters. Accuracy matters. It has been really an interesting process to bring the patient into the deliberations about a standard transaction now that actually involve the patient and to talk about setting up bilateral communications mechanisms to keep the patient informed and to get input from the patient. One of the things that I like about this and when you think not just of prior auth but how this fits in globally to the concept, the convergence of administrative and clinical, whatever mechanisms through the ICAD we set up for patient communication, those will then become available later on for additional scenarios, use cases to bring the patient into the communications loop for anything regarding the care. Once we establish the infrastructure here and the prior auth transaction, we can leverage that for other transactions yet to be identified in the future.

Alix Goss: I think it is really a good point there, Rich, in that we have been talking about not just the patient, but also the people that help the patient, the caregiving team. You have a child or you have a highly compromised partner. Often there is that need for transparency, not just with the patient and engaging them, but it is also getting data from them. It is also getting their decisions and input and that will also often include those non-clinician care team members, but still part of that family ecosystem in helping deal with disease states.

I also think along the line as we have been expanding this thought about the patient's role in all of the prior authorization steps of the process, we have been also recognizing the changes in the technology, the use of the mobile aspects. We have been talking about the changes in the capacity to automate today compared to where we may have been when we first adopted EDI standards in trying to really harness electronic health record data and discrete granular data capture at the point of care that enables that automation to happen and that you can have – if we can get to that level of automation, we can reduce burden, but we can also support some of the transparency objectives.

Before I go on to the next slide, I wanted to open it up for general questions related to ICAD because I am going to pivot after this to our convergence project. I am not seeing any questions. I am going to go ahead and move on to the next slide.

As I noted earlier, we are working with ONC to solicit input and to get a report produced that will inform not only what ONC is going to do related to their sphere, but it is also going to inform how we are going to proceed within our sphere of authorities. We developed a convergence project and presented that back in March to develop recommendations to support the convergence of clinical administrative data. We too are going to focus on prior authorization because it has been since 2015 or 2016 and something we know we needed to tackle.

It is a logical intersection point because it is a combination of administrative processes that need data from the clinical process to support the coverage decisions to be made.

It also sort of trips into some of the other data issues that we have been – data standard issues that we have been looking at, for instance, claims attachments, which we stop calling claims attachments a while ago. We want to just call it attachments because the concept of providing additional data into that administrative process happens with more than just claims, for instance, in prior authorization.

We already talked a little bit about what we are trying to do. I am going to skip to the next slide. What will happen or at least what we have been envisioning and I think we started to evolve some of this thinking a little bit yesterday, so we probably want to have some discussion around that.

We have been anticipating that we would start to do our discovery work before getting into our analysis or our drafting phase and that the timing, the chunks have been the Standards Subcommittee has been working on the CAQH CORE Operating Rule hearing for August. Once we get ourselves fully prepared for that, we can start to introduce work on this convergence project, but are really waiting for the substantive results from HITAC, ICAD to really trigger our next steps and hopefully to build off of that thoughtful work in a way that enables us to produce either recommendations, policy papers so that we can start to think about not just what does it mean to our EDI standards that we have recommended, but if there are any ancillary lessons. We are hearing things around code sets, automation, use of piloting new and better ways of exchanging this information, using emerging standards. We have heard ways of being able to support multiple standards at one time.

I think that there are a number of opportunities for us to look at within the subcommittee. Yesterday we talked a bit about where does public health reuse of the data fit into our project as we move forward.

I would propose that at the November meeting, there should be probably some philosophical discussion or updates from the Standards Subcommittee related to the convergence project scoping document and if it needs to be tweaked and where it might go. I think that November timing is good because the report from ICAD should be out or at least a very solid near final draft in October. That could probably inform the commentary that Rich and team bring back about where they want to head with this convergence project.

Are there any thoughts from yesterday's public health discussion that we want to bring in?

Rich Landen: No, I think you covered it. I think in our approach to the convergence project, we have been focusing on the HIPAA transactions meeting, the requirements that ONC is doing on the EHR and clinical side and it was a real eye opener yesterday, talking about the more global public health data collections dissemination efforts. That suggested itself that may well have a much larger place in this project than we had assumed to dates. We are going to need to go back and take a look at that and as Alix says to maybe tweak the project and bring that through the Subcommittee and back to the Full Committee for modification if that is how it pans out.

Also, just quickly to comment on the top line. We have the CAQH CORE Operating Rules hearing August 25 and 26. And unlike what we did at the June meeting for NCPDP, my crystal ball says this is going to be a lot more complex and there is going to be a lot more deliberation that the Subcommittee will have to do after we digest the written comments, after we digest what we hear August 25 and 26 in the hearing. We, as a Subcommittee, will be doing that work. Then the ICAD draft report will come out following September. We will have to take a look at that. Knock on wood. Fortunately, there is no conflict between the two. The timing is fairly complementary, not collision.

And then as we wind down the CAQH CORE work then we shift focus from ICAD over to the NCVHS convergence project. The transition there – there will be a lot of work for the Subcommittee August, September, October. But it looks to be fairly – the work seems to be very complementary and what we do in one area will be informative to the other. It looks like we will have a lot to bring to the committee in the fall.

Alix Goss: I see that we have several hands up, Rich. The first one is Vickie.

Vickie Mays: I just wanted to comment on the issue of the convergence in terms of the public health issues. I think it is a matter of not just the content, but a strategy of change in terms of data collection. One of the pushes that I have been doing particularly with CDC around some of the COVID-19 changes that are needed is really to talk about it within a bigger subset. We talked about it as public health, but we also have to realize that public health intersects with the clinical data and with the administrative data. We have been doing these as these siloed buckets and we really do have to bring them to intersect and to realize that –-

One of the examples is I have been pushing to make sure that there is a connection between the clinical specimen data for COVID-19 testing and the public health data so that you are not looking at a small problem, but you are looking at a complete problem and getting those connections to be there means we work faster and work in a way in which we have all the data. It seems like a simple thing, but it is like the lab results go over here and public health data is over there. And I was trying to work to see do we

have, God forbid, a personal ID or some kind of connectiveness so that what you are doing is looking at social risks, social determinants and its relationship to actual clinical outcomes. I want to think about this as, yes, these go together, but the strategy for having the ability to do a whole deep dive on an intervention needs to be the connection of the two things.

Alix Goss: Thank you. Rebecca, your hand was up and now it is down. You are good? Okay.

Rebecca Hines: Vickie really nailed it. We have been really focused on clinical and admin and I have been – there is this whole other world focused on public health and clinical. I really appreciate, Vickie, the way you laid it out. The challenge is these systems truly are siloed and it is going to take some really macro thinking to figure out at the level of the Standards people to me, the hell realms of all these little standards for literally moving the bits and bites from here to there – how can we somehow blow it all up without blowing it all up so that it can be connected? This is really a monster challenge. I think the tie to COVID has really made it clear that this is – now, we get it. We really see how all three really do need to – thank you, Vickie.

Denise Love: Thank you for all of your work, Alix and team, and really getting into the weeds in this so we do not have to yet.

But that said, I love where this is going. I am excited. I have been excited about convergence for 20 years. Can I just bring the cynical Denise, the Debbie Downer? Even if we get this convergence and technology, how are we going to get providers and payers to even collect the data because I have heard over and over. Public health – race, ethnicity, but we do not collect it. You are not going to it period, game over, closed. Or you want education status. Good luck. I say wouldn't it be great to get at enrollment because it is not the point of care and we do not collect it. We do not want it. How are we going to get over that barrier if we are public health, trying to converge this, but the front end is broken? And maybe I am just being too cynical.

Alix Goss: I think that there are a couple of pieces there. The data capture. I am really glad you brought that up because we have talked about a number of times within the ICAD arena that just because we can capture it, it does not mean that the workflow sinks with that and that the data is going to be captured and put in the right field so that the automation of the prior authorization request can work using the new FHIR standards or even a mapping to an X12 standard.

The point that you get at is not just about the business reasons. We need data elements. It is also will they be able to capture it, that point of care, getting the information either by the doctor or the nurse or the admin or the support staff, and somewhere has to populate the right data in the right field to go along with the right standard to get to the right place.

I think I have built on Lorraine's three rights, to now we have four rights of our thinking, and trying to mix the dynamics of data capture for our business purposes and to add on to your concern because I do not have an answer because I think it is an issue we have to tackle overall is that not all transaction standards are equal in the sense of when you have a prior authorization, you may have a very simple, straightforward, easy-peasy scenario, but there are all kinds of flavors and complexities and unique scenarios that we need to somehow have a framework that manages and can accordion to whether it is just a straightforward, I have a plan that I need to get prior authorization for everything versus I have a very complex disease state with high drugs that needs a different kind of prior auth vetting process.

How do we also not only manage the end users' need, the point of care data capture needs, but also the wide variability of scenarios that patients find themselves in?

Denise Love: Right. And then one more thing. This gets into maybe the privacy, security realm or Vickie May's realm. But how do we change that culture of fear of how the data are going to be used because one of the resistors to collecting race, ethnicity, and payer data has been – and providers too have been the fear that it would be used against them so it is better not to collect it or to silo it into a private data warehouse that the public health cannot get, but they do know. But it is not for public consumption.

I think we have to in the future talk about lessening the fear because they can get the data. And some systems are getting the SES data. But they are afraid to share it, I guess, that it could be used against them in a court of law or public opinion. I think we do not solve that today, but that is something we need to talk about making it safe for them to collect and report that data.

Rich Landen: I think Denise's comments go back and feed to Vickie's call to think through this strategically because the race/ethnicity – there are implications and applications within the medical community as we look at the COVID, the inequities, and accessibility. But you look at system wide, and the US health care system, Medicare and Medicaid aside, is primarily employer driven. Well the employers capture race/ethnicity as part of their human resources information system, and yet that data is held separately for privacy and confidentiality and for civil rights, affirmative action reporting purposes. It does not feed into the health care system. So that data exists. It was captured by the employer. It must be captured by the employer, but it does not flow through the system. Can we ask would it be appropriate to look into creating some sort of feed there? Okay. We have HIPAA mandates, but employers are not covered entities. That gets us back into the whole quandary. We have got the data that is exiting in one silo, but there are some strong reasons to keep the data in that employer silo. There are dilemmas there.

And, again, the importance of thinking strategically to recognize that government authority and public health can present some opportunities to compel compliance, but we do not want to overuse that compulsion, that mandate, if we do not have to and if there is not a compelling need to do so. There is a lot to think about. I am very glad that we have this whole group to help us think through these issues as we get into them and converge in this process.

Bill Stead: This is a rich conversation. From my perch, I am sorry that neither Sharon nor Maya are on because what we are highlighting is the fact we need a Pop Health Subcommittee.

If you go back 2001, NCVHS did a pretty good job of laying out the data landscape. That figure we have used many times in my time on the committee, and it is still, as far as I know, it still rings true with anybody that looks at it.

More recently, Larry Green really had the committee – when we were talking convergence at that time, we were talking convergence at the intersection of public health, health care and mental health.

What we now all – I will not say all. What people that live in the science of this now understand is that the root causes are all the same. There is one set of underlying mechanisms and they build on one another. Therefore, any part of the ecosystem that elects to say not part of my job, is in essence electing to try to optimize their piece while sub-optimizing the whole, which unfortunately that whole is the health of the population people, which is what we are obviously – this committee actually exists to help HHS improve. That is one level of thought.

Below that, I think we really need to keep our standards work separate from our thinking about aggregate data. They really are two very different problems. The part of our Standards' work that surrounds terminology, vocabulary, how you represent data, applies to both because that is how it is made meaningful as it moves through the pipelines. It is also how it is made meaningful when you are working with it in aggregate either as structured data or with AI.

The transactions themselves, whichever form they take, be they API based or be they push transaction based – those transactions actually have a purpose. In most cases, at least in the HIPAA world, trying to make a transaction serve too many purposes is how it has gotten too complex and how we have never been able to actually make them work. When Rich was talking about or Nick was talking yesterday about the fact we have been very successful in HIPAA with simple transaction, but not the complex ones. That is just part of that same problem. We do not want to weight down individual transactions with multiple purposes. I think the FIHR use cases have been a nice example of how to try to deal with that.

As we have this conversation, I think we need to think in those different – we are really working at several different scales of the meaning of data. I think it will help keep it straight. That is the general comment.

I happen to be looking at the slide in front of me. Alix keeps gently referring to some of the comments I made yesterday about my normal attempt to figure out how we can on one hand, use one thing for multiple purposes, on the other hand, manage our critical pass so that we get early deliverables in some cases.

I recognize the timeline that ICAD is on. I am in awe of the way you have now got that lined down. You have moved mountains since you and I chatted over lunch at the ONC.

Alix Goss: Oh, yes, the annual meeting. That was a lifetime ago.

Bill Stead: When we were actually together. So, kudos.

I do think that – and this was part of the design, the fact that we have several of our members embedded in that means that you have in your heads all of the information that is going on and being dealt with and independent of what you and your role in ICAD do. You are members of NCVHS and you have that content in your head and you know what we are trying to do, which intersects with what ICAD and HITAC are trying to do, but has a different lens to it, as you have been very careful in helping us keep straight the scoping document.

All I would encourage is that to the degree possible, and between now and the end of August, Standards is head down with no breathing room, absolutely no question. But there may be some time in September when you will have breathing room, maybe not. If you do, you might be able to move our project along, informed by what we know from ICAD, without them having to actually stay tightly coupled.

If our bandwidth that we need to leave things alone, fine. We have deliberately designed these projects collaboratively with ONC and HITAC, so they work together and leverage one another, but they do not have to be held in lock step. That is all I was trying to suggest yesterday, particularly if it helps you with a key piece of the report to Congress as you begin to try to frame that. That was the thinking there.

Alix Goss: Thank you. Vickie.

Vickie Mays: I just want to go back to Denise's point, but also now something that Bill said. While I agree that it would be nice to have a Population Subcommittee, I think that the movement that we need is not from a population health perspective, but it really is from a much more industry standard, an administrative and clinical data perspective and how, for example, we – how we wrap these issues that we have seen that is so important into just every day business as opposed to having it be a social issue.

I am convinced that right now, and that is the push that I am doing in other places that it is not about – Denise, you brought this up. It is not about the fear that people have, but it has to be about the price that people pay when they violate people's protection.

Even right now, as I said yesterday, I sit on the PRIM&R Board, we are trying to re-do and think about the Secretary's Human Subjects Committee, and what vulnerable means and what justice is, not in the social sense, but justice in the sense of the way research operations go and that you keep looking where can I build in either these consequences or protections so that things are on a path that people will begin to develop the trust.

Melissa was talking about trust a lot yesterday. I think we are putting it in people, and I am trying to see for people, they often want the Federal Government to protect them. It is like when Rachel comes on and she tells us all this stuff of OCR and the complaints and what the consequences are and how people have to pay when they have these violations. We need to move this agenda to that level and help the industry to see it is in their best interest. I really like that these issues are with Standards rather than right now at Pop Health because I do not think they are going to get very far with the social justice lens of Pop Health.

Alix Goss: Denise, it looks like you are back up again in the queue.

Denise Love: Yes. I just wanted to say, Vickie, I echo that as well. Putting it in a sidebar of Population Health has not worked for decades even though it is critical. I have heard too many times from providers and payers, race ethnicity is not needed to pay a claim. Educational status is not needed to pay a claim. It costs us a gazillion dollars to do it and we are not doing public health bidding. I do think it is a culture change and now in COVID is a time to change it.

Alix Goss: To that point, but let me ask you something, is that something that needs to come in a health care administrative transaction or is that an ancillary data set that should be --

Denise Love: No. It is in every hospital discharge dataset across the country. The problem is the culture at the hospitals – in America, we have trouble with race. The frontend admission clerks – I studied this for decades. The frontend admission clerks are shy about asking somebody their race ethnicity. They are feeling they have to ask it. It is a field required by the state. But they are very shy about asking so they code it what they observe. That field is dirty. When we try to use it for public policy that is not a trustworthy field. This is something I have dealt with since 1999. It is the culture. It is not the data. But it does come through on the administrative transactions because unfortunately we do not have very good alternative transactions for population health. Hospital data and now claims data and enrollment data are feeding these data set because there is no other alternative at the time. We do not have survey and we cannot afford surveys. It really needs to permeate into the –

Yes, I think it is a culture change and I do not have an answer. If I did, I would have solved it a long time ago.

Alix Goss: I was about to transition to Rich for the next agenda item, but what I noticed is that Lee, Vickie, and Bill all have their hands raised again. I am going to go in order and that starts with Lee.

Lee Cornelius: As I hear all this, I keep thinking about how the Office of Minority Health through the Culturally and Linguistically Appropriate Standards – within those standards, there are several that are required by law through the Office of Civil Rights. And they use that to require places around the country to comply in order to receive federal funding. It is not as though that there is not already a federal procedure in place that require things within that space. The question comes up. How do you have that conversation OMH and tying that to these data elements in the federal statistical system. This issue has been the case for a good long time in terms of the requirements that are tied to federal civil rights law.

Vickie Mays: I think we have not done a great job of helping industry understand and how to use the data. That is why I am like less in the pop health and more as a business transaction. You can plan better – ethnicity and primary language of your patient as to what services that you need for something as simple as transactions for language interpreters. You need to know, for example, if there is some drug interaction and it does have a race ethnicity base either in terms of that is a population that is likely to be taken this drug and that drug. There are many ways in which we have to make the business case. And I think understanding why you need primary language, understanding why you need education and the ways in which to avoid medical errors and mistakes because people do not understand what you told them and then they come back and sue you later because they did not understand. That is part of what needs to be, I think, within the business case that you are doing for why you are developing this.

I agree with Lee. There are already ways in which this is required, but it is not enforced. But I think the business case is much more compelling than our social justice approach.

Alix Goss: Thank you. Lee and Vickie, I am going to perceive that your hands are going to come down in a second and then go to Bill.

Bill Stead: Thank you. I know Vickie knows this. The concept of capturing race and ethnicity is extraordinarily complex. It is maybe not as complex as prior auth, but it is close. We, for example, thanks to our biobank have very good data about the difference between people's genetic race and what they view as their cultural race.

They are intersecting Venn diagrams. The idea that you have one field that means something without training the whole system, how you ask the question, the difference between self-reported race and any form of administratively required race. I am using race and ethnicity together.

We could spend a year on how to actually do this right. I would love to see us do that, it would be another work stream. To think that this is going to be solved through an administrative transaction, I think is probably missing the complexity of the data. I will just leave it at that.

Alix Goss: I think Denise has something to say.

Denise Love: I think we make it harder than it is. I was on the National Academies of Science collection of race ethnicity and state and federal data sets. Really, there are OMB standards and hospitals have the dropdown screens. The infrastructure is there. The will is not or the understanding of why to do it. I do not want to cross our chairs. I do not want to disagree with the chair because at heart, it is complex. The

way that it is used in public health in my world is we do not have to drill down to the tribe. We just need to know that maybe it is American Indian, but not that it is a Paiute Tribe in Ute branch.

It depends on how you are using it and at what level. But I just want to go back to it is part of the standard. It is being used in mixed success. I do not think we appreciate that we are almost there. I have seen progress, but it is part of the transaction standards and people are using it with mixed success.

Alix Goss: This is not your last opportunity, Denise.

Denise Love: I have been through this in minutia. It is moving the needle as far as industry and attitudes. I think COVID is an excuse and a time to even move it further. I will get off my soapbox. I am getting down.

Alix Goss: But it might also be something that we can tie in some of the privacy consideration and the cultural aspects and the thing we are thinking about and data and where it goes and that trust aspect that Melissa really introduced yesterday, I think, is a huge component of it.

With that, I am going to turn it over to Rich.

Rich Landen: Alix, let me add one more before we get off this topic. This goes back to my hospital administration days, admittedly decades and decades ago so not necessarily current. But as part of my duty as a young hospital administrator, I was responsible for both the inpatient admissions process and the emergency department registration process. Yes, there were requirements that we note and we capture race ethnicity, but there were also state regulations, this happened to be New York State and New York City, that forbade anything that smacked of preconditioning treatment on matters like race ethnicity or ability to pay and things like that. We had a conflicting sense that essentially defaulted down to the admitting clerk, having to make the determination because there were reasons that it was both uncomfortable and potentially risky to ask a patient or a patient's family to specify their race ethnicity. That was something that was compounded by the fact particularly in the emergency department, it is an emergency. You do not want to interrupt the patient flow, the patient treatment by asking questions about race ethnicity because really what does that have to do – that is just one more barrier between you and seeing the nurse, seeing the doctor.

It is not a simple process to think in terms of requiring a hospital or a dentist or a physician or their respective staff to capture this. Yes, we have to think strategically. We have to figure it out. It can be done, but we have to resolve some of the conflicts and make it a clear and compelling case and make sure that wherever the obligation ultimately falls, we have to make sure that it is clear and there are no conflicting requirements, federal or state, for that person or organization who is ultimately designated as the point at which race ethnicity is captured.

Alix Goss: I have handed the baton. Please, I think we should go to the next slide. Over to you, Rich.

Rich Landen: Okay. I have the baton. Operating Rules Hearing. As we have mentioned a couple of times, we have a request from CAQH CORE for us to consider. Three new operating rules for adoption by HHS as national mandatory standards. We have set the hearing dates of August 25 and 26. A couple of weeks ago, we made the decision to make this a virtual hearing because the availability of federal office buildings, HHS headquarters in this case, was uncertain as to can we actually get ourselves and the testifiers into the building. We made the decision early to go virtual. We have done virtual hearings before. They are not as ideal as in person, but they do have some advantages and past experience as

they are adequate – it is an adequate tool for the job. I have no real concerns that somehow going virtual is going to adversely affect the input and the deliberations and the outcome.

Federal register notice at the hearing and instructions to written comments is in process. It has been written and submitted to the government printing office. I do not know if Rebecca has an update on publication date yet or not. But while that is in the works, we, as NCVHS, the subcommittee has issued invitations to about 20 organizations to testify and in addition to those 20 organizations for testimony, we have sent letters to additional 10 key organizations, not inviting them to testify, but encouraging them specifically to submit written comments.

All the presenters will be asked to submit written comments as well as their Power Points or testimony and then submit those in advance of the hearing. We have a short list of questions that the Standards Subcommittee has drafted and disseminated.

The presenters and the testifiers will be asked to use our template to highlight themes. We have about seven minutes scheduled or allowed for each – six or seven minutes for the actual presentation and testimony and then there will be additional time after – each testifier will be part of the panel. At the end of each presentation, there will be time for questions and answers.

The template highlights certain themes. One is the anticipated value of the proposed rule. Second is what are the concerns. And then in summing up, what are the top three to five points that the testifier wants the NCVHS to consider regarding the potential adoption of these operating rules is a mandate. I think that is going to allow us to get the high-level pith of the organization's stance or opinions regarding the value of the potential adoption of operating rules. But all the detail then will be in the written comments.

Here is what the content of the hearing is. CORE has proposed three specific operating rules for adoption. The first is the 278 prior authorization transaction from X12, the data content. The second is the infrastructure rule. Data content obviously talks about what is transmitted, the data that is included in the communication and the operating rules kind of constrain what is prescribed in the X12 implementation guide and transaction themselves.

The infrastructure rule talks about the environment within which the data is transmitted. It talks about how many days and hours a week is the receiving system available. What are the maximum response times? How are the submissions, the initial transaction – how is receipt acknowledged? It talks about criteria for companion guides. That is the nature of the infrastructure.

The third rule, the one on the connectivity is a little bit different from the first two in that the first two are exclusively and explicitly about prior authorization. The connectivity rule would apply – if we recommend adoption, it will apply to all of the X12 transactions that have been adopted under HIPAA and for which there are existing operating rules. The connectivity rules would apply not just to prior auth, but to eligibility claims status and electronic remittance advice and referrals. That is a little bit different aspect. We structured the hearing. The first day is about the first two, the prior auth.

And then the second day will be addressing the connectivity rule. In our communications with the testifiers, we have made it clear that it is their discretion, their choice whether they want to have different subject matter experts present on the first day for the prior auth and the second day on the connectivity.

We also have a good list of resources, some of which are on our own website. The letter requesting the question set and we will be posting additional information up there, the agenda, the written submissions, the federal register notice. In addition, we have links to – there is some really substantive information that CAQH CORE has available on its website. We have pushed those out to industry as well. General information, specific information about prior authorization and connectivity.

In June and July, we are preparing for the hearing. At the end of July is the deadline for submitters to give us their written comments and from the end of July up through the hearing, the Subcommittee will be reading through, analyzing, discussing the input we have received in writing. From that, we will be preparing a list of questions that arise either from the subcommittee's own review of the operating rules or about issues that have been raised by the written comment. And we will prepare those questions then to ask the panels at the August 25 and 26 meeting.

In August, we will conduct the hearing. After the hearing so September and as long as it takes because, as I mentioned before, this is not going to be simple. We will have the subcommittee deliberation and the drafting of the recommendations. We will then present the recommendations to the Full Committee for review and discussion and hopefully approval. And then on approval of the Full Committee, we will draft and send the letter to the secretary conveying the committee's recommendations.

That in a nutshell is the way we see the hearings going and the timeline leading up to it and the aftermath, the deliberation and when and how we will present draft recommendations to the Full Committee.

Alix, anything to add?

Alix Goss: Really nicely summarized. It is going to be an interesting summer. The last round of operating rule review was very actively – it was a very active set of discussions and trying to raise the bar about where the industry sits on their ability to have business-to-business agreements that really help constrain the very robust functionality of the 278 and the connectivity aspects rule. I am very interested to see the industry commentary and what happens with the feedback that we receive and whether harmonious or not that feedback is.

Rich Landen: Other observations by Standards Subcommittee members?

Seeing none, let us see if there are questions from the Full Committee.

Alix Goss: I am not seeing any raised.

Rich Landen: Vickie.

Vickie Mays: I was trying to do it fast enough. Can we see the list of who you sent the request to participate or is the kind of draft of who is coming in ready yet?

Rich Landen: The letters of invitation have gone out. Rebecca or Lorraine, do we have that in the way we can present?

Alix Goss: That was not part of what we put in the deck. That is sort of the way we have been displaying things. We have had extensive round robins on trying to manage the fact that we are doing this virtually,

about how many hours we have for a virtual hearing, who is using the operating rules, how do we get the representatives from across the industry to give us feedback.

There has been a lot of effort to try to figure out how to get all those pieces to come together. That is why we also took the approach this time of saying even though – we have sent letters to say please, we want to encourage you to submit written testimony even if we just had public remark opportunity. We really are trying to reach out everybody. While Rebecca and Lorraine think about what we can or cannot display on that list at this point or how we follow up with that to answer Vickie's question.

Lorraine Doo: It is in a spreadsheet and Marietta were going to make it – put it in a nice document the way we do so. It is not pretty enough to share on the screen right now, but we could absolutely get it to the committee I would say in a couple of days for sure.

Rich Landen: We will do that, Vickie. I can just skim down the highlights. Of course, we have CAQH starting out. We have got X12, following CAQH. We have asked the other DSMO members, the SDOs, HL7, NCPDP, the DSMO and NACHO, which is another operating rules' authoring entity. We have asked them to submit written comments. We have AHIP, Blue Cross Blue Shield Association, Anthem, UnitedHealthcare. We have one of the state Medicaids. I believe we settled on Minnesota or was it North Dakota?

Lorraine Doo: North Dakota.

Rich Landen: North Dakota. We have CMS, Department of Defense, Veterans Health Administration. Did we invite Kaiser?

Rebecca Hines: I was just going to say, Vickie, it is actually in the eAgenda book. I am trying to find the page number. The draft agenda for August is there.

Alix Goss: In the agenda, it does list the organizations.

Rebecca Hines: It is page 136 of our materials. What you will see there – we did not put names of people, but we put all of the organizations that – that Rich laid out. It is three pages. It is 136, 137, and 138 of the eAgenda book. If you want to see the organizational representation, that is there.

Vickie Mays: That is fine. It is like IHS and a couple of other places I am wondering about. But let me go about. I now vaguely remember --

Rebecca Hines: In addition, Vickie, the whole world is welcome to also send written comments. That is going to be in the federal registry notice, but it is already on the NCVHS website on the meeting page. We have actually created a structure for them. I think we might have put that in the eAgenda. We did. If you look at page 134 and 135 of the eAgenda book, we have actually said to people, we would really value your input and here is a structure that would help us synthesize all of the input from however many organizations and people. There is a ton of pre-work that Lorraine and Alix and Rich have been doing. They are so organized that we have all the way until the end of July for people to send their input. You will have from July 25 all the way until August 25 so a whole month to take in all of that.

Vickie Mays: We can push it out then in terms of the request for written.

Rebecca Hines: I will send the link right now so you can send it to people.

Alix Goss: One of the things that we have been trying to do is not only look at as I affectionally refer to a group including myself the usual suspects. We have tried to really refine that to who is using it, how do we get a balanced perspective and views and also since we do not have the ability to have a weeklong set of hearings, let us use the creative idea of saying please invite people to do oral testimony. Let us make sure we have people aware and send written testimony in addition to all the public facing stuff on our website, the federal register notice. We know CAQH CORE is also doing a yeoman's lift to get their community to be prepared to give us input. They have been collaborating with us and by extension, they are bored to really help give us a better sense of what is happening in the industry and provide commentary.

Rich Landen: And the Federal Register Notices are running later so the industry will not have as much advanced notice by Federal Register as we had hoped because a lot of the large organizations monitor the Federal Register and would automatically, well, not automatically, but whoever is monitoring for them would hopefully raise it up for those impacted organizations to present written testimony.

Rebecca Hines: However, Lorraine has done a good job of getting the word out. We have been letting people know that that opportunity is here. I have been asking – Federal Register. But because of the 100 percent – status, things are a little slower than normal.

Rich Landen: And one of the other things that we did in the invitation list that we wrestled with – we know that a substantial number of the industry actors are contributing to the CORE process. We wanted to make sure that CORE's membership had an opportunity. But we also wanted to make sure that there were enough testifiers who were not part of the CORE process so we could also get that perspective as well.

Alix Goss: And I think it is also important to know that we have worked very hard to get out of the gate with all of these materials to provide the industry with as much as possible time to review these extensive rules especially the connectivity rule. That is like 50 pages of content. And giving people also the opportunity to think about where do they fit with that baseline. CORE had to do a lot of negotiation to get people to come down to an agreement of response time of two days of responding to a pen response or a final termination response. They have been doing education to also get the word out and they are going to be presenting at an upcoming meeting of the ICAD. Maybe we can use that as a way to – I will put in the back of my head to kind of stir the pot to get people to comment and come to the Federal Register or come to the NCVHS website to get those resources.

We are very mindful of how busy everyone is because of COVID and also, we are approaching the summer season. Hats off to our subcommittee members and getting their arms around the rules, getting educated, through going to webinars, reading them. Lorraine did a fantastic job of setting the stage for us to understand the basics of what the operating rules are, their authorities under legislation and regulation and what do they mean. We have been having additional discussions in the subcommittee to make sure that we are really understanding what the rules say. We have a good framework. We are such a broad, multidisciplinary team. We want to make sure everybody is set up for success to really hear what the industry has to say in written and oral remarks.

Vickie Mays: Thank you. You did great. I found it.

Bill Stead: Let me just make one process statement that plays into what you were saying, Alix. For our new members – the new members that are part of the Standards Subcommittee have been slogging through this in detail. For those of you that are new and on Privacy, Security, and Confidentiality, at the

end of the day, you are going to have to vote up or down on whatever comes out of this. It is extraordinarily important for you to be paying attention at a level that will allow you in this case as a generalist, not as a specialist in these types of standards to basically say that what the Standards Subcommittee is recommended to the Full Committee. Is it right or it does not?

As we do this kind of work, we spend this kind of time with the Full Committee, trying to help bring people along so that you begin to get – you come to grips with your question because this in particular is extremely complicated or complex content. You need to not be shy about asking questions now because it is a lot easier on the Standards Subcommittee to begin to get those questions out on the table now than to be doing with them in November when they come back with a letter we are trying to get approved.

Rich Landen: Well said, Bill. The complexity of what is in the substance of some of these rules is really over the head of the geekiest of the geeks on the subcommittee. We are reaching out for explanations to subject matter experts. We are very cognizant of what Bill was just saying about obligations to – our obligation to all the members of the Full Committee and we will do our best to synthesize and to translate into actionable terms that we can grapple with. But in order to do that, it is obviously a two-way street.

To reiterate Bill's ask, please make sure that as we present this that you keep us aware of the questions in your head and what we need to answer in order to help you arrive at the conclusions you need that we collectively make the best decision on behalf of the country.

Alix Goss: No pressure.

Rich Landen: I do not see any other questions. Final call. We can move on to the next agenda item.

Alix Goss: As our next presenter, I believe that the Standards Subcommittee is wrapping up and I believe we turn it back over to you, Rebecca and Bill.

Rebecca Hines: Dan, you are on mute. Welcome to the live meeting. Can you unmute yourself? Greg, he is on the phone. Thank you. Good morning, Dan. Can you please introduce yourself for folks who have not met you before?

Division of National Standards Update

Daniel Kalwa: Sure. My name is Daniel Kalwa. I am a policy advisor with the Division of National Standards at CMS. Our organization is responsible for writing the regulations as well as enforcing regulations around HIPAA Administrative Simplification. That includes the transactions such as claims, prior authorization, eligibility, et cetera. There is a whole host of them.

I want to thank you for giving me the opportunity to make some comments and hopefully get out some information that the committee will find useful. I am sure you are all well aware at this point that the recent crisis has thrown schedules out of whack all across the industry as well as in the government.

I will say that our primary means of communication, that is, DNS communicating to the public around our regulatory actions – that usually occurs in the unified agenda and that is on the OMB website, which is reginfo.gov. That comes out twice a year. The public information as well as the scheduling around when you can expect us to release regulation can be found there.

I will say that is the last release – was in fall of 2019 and it had not yet been updated. We do expect an update to come out shortly. But I do not want everyone to worry because this update actually contains information that we had to submit in the winter of 2019. It will not necessarily be entirely up to date. And the reason I say that is because some of the committee's most recent findings such as for F6, I do not expect to show up in this next release of the unified agenda, but I do expect it to show up in the next one.

I would like to just comment on three of our regulatory activities that are ongoing. The first is one that we did reach final in January of this year and that was the modification use of the NCPDP D.0 standard. That final regulation was put into effect for two reasons. One was around – that Medicare Part D had for reporting the partial fill of Schedule II drugs. But it was also important because of the changes to the rules around partially filling Schedule II drugs that were included in the Comprehensive Addiction and Recovery Act of 2016. Usually everybody calls that CARA. We made that modification in advance of our expected adoption of the new NCPDP standards so that when the various rules and regulations around partial fill for Schedule II drugs to get update, the standards will be able to accept the appropriate billing practices for billing partial fills of Schedule II drugs.

That is still on track. And the compliance date for that is still September 21 of this year. September 21 of 2020. That is when health plans will – the covered health plans will be required to accept the new field for billing purposes.

We have also – in the fall of 2019 unified agenda, we posted that we were working on F2. Obviously, that is a bit out of date now. We are continuing to pursue updating the NCPDP standards to F6 as recommended by the committee as well as the new batch standard and new subrogation standards.

The fall 2019, had a May 2020 release for that NRPM. Obviously, that has not happened and I will be able to share more about our expected release date once we get that information published to the unified agenda. But you can rest assured that we are moving forward with that and we do expect that quite a lot of the work we already did for F2, I think the committee already discussed it, will move forward quite nicely for F6.

The third regulation that we are working on is of course attachments, which I know everybody is both dreading and excited for, sometimes both at the same time. We listed it on the fall 2019 agenda as of May of this year, May 2020 NPRM. Obviously, that also did not make it. It was unfortunately delayed by other priorities within these last few months. We do still intend to pursue that. As we release in the unified agenda, that will include standards for using attachments with both claims and prior authorization as well as a modification to the X12 278 standard to move it from 5010 to 6020 in order to match the proposed standards for attachments. Unfortunately, at this time, I cannot give you an update on when we expect that NPRM to release. I will happy to come back in the future as soon as I have more information to share about that to the committee.

Finally, I did not send it ahead of time because I was not sure it would be released. On a separate topic, I do not know how much everyone – I am sure the subcommittee is familiar, but I am not sure how familiar everyone is. There is an exception to process in the HIPAA regulations that allows for covered entities to request and be granted an exception in order to test or if you would like pilot new standards and new approaches to the HIPAA transactions. It has been there for a long time, but we have been trying to both educate and revitalize interest in using that process.

To that end, we just recently released a memo that includes some additional information in the process as well as a new official email address that the public can send both questions and proposals should they like. That email address is administrativesimplificationexception@CMS.HHS.gov. Again, I can share all this with the staff so we can get it posted properly in the future. That memo also includes some more information for the public around how one requests the exception, what the basis for granting that exception looks like, how the secretary's response will look, and then the requirements around the organization's report on their test results and then information about how one can go about extending that exception. And that last is important because the exception process is time bounded because it is designed as a pilot and not as a permanent solution to a standard.

I am personally very excited about that because I would very much like to see some of the emerging standards get in and start testing some of these things. We could get some hard data.

One of the required outcomes if a group of covered entities wants to request an exception is an official report that goes to the secretary. And our expectation right now is that would also come to you as the Subcommittee on Standards. It would also be public. In that report, we would want to have some pertinent information that would either lends to the argument of adopting it or give us some direction on what work still needs to be done.

I know that was not a terribly large amount of information, but at this time, that is all I am able to share. Were there any questions from the committee?

Alix Goss: I was trying to officially raise my hand so thank you for seeing my – the old-fashioned way. Thank you, Dan, so very much for that update. It is great to hear that the Division of National Standards is working on a number of these items and going to be updating their unified agenda to reflect the more current update. It has been a fluid 2020 for a lot of us so I can appreciate some of the barriers.

To see the 162.940 exception process come out with some education was very exciting and very happy to see that and also to know that the Division of National Standards is anticipating that that content would be – the reports would also be submitted to us for consideration since if those pilot results actually warrant next steps. That would be a great way for us to get it in our pipeline and in our work plan to give the industry flexibility there.

A couple of things I am curious. Testing has been a longstanding issue. And this exception process is another way to test new and emerging things. I will be curious to know if you have any comments about an overarching testing strategy and what role Division of National Standards may be taking and help to advance that in the market place for any of our new and emerging standards that have industry backing. That is one question that I have. Why don't I just stop there with that one and see if you have any comments on it before I continue?

Daniel Kalwa: I do hope that the exception process can be used to test in a live environment. I know one of the difficulties has always been getting good both economic and technical data on new standards as they emerge in actual use. That is the purpose of the exception process to allow voluntary partners who voluntarily group together to test these new standards and then provide a way for that reporting to come to the public, to come to the secretary, and to come to NCVHS so that we can have some hard data on exactly how difficult is this process. Are there technical deficiencies that were discovered during the process or is it ready to go and everybody is happy with it? I can imagine a whole host in between all of those sorts of outcomes.

I can also say that DNS does not have funding for these pilot projects. It is only through this exception process. I know that it has always been an issue for the industry, but at this time, we have no funding. That would probably require statutory change.

Alix Goss: One of the things we have been talking about through the Predictability Roadmap, Dan, is this need for – how do we get as much data as possible to feed into the regulatory process to make it as efficient as possible as moving it along so that we can start to create better bookends of standards development to the industry adoption effort, which has really hinged all together from the federal processes.

I am going to stop there because I see that Rich's hand is up.

Rich Landen: Thanks, Dan. One of the questions I have is about enforcement and the context is the recommendations that we made in the Predictability Roadmap. The enforcement was intended to give information back to the industry specifically. The standards development organizations and the operating rules authorizing entities as well as industry stakeholders about what the bumps in the road were being identified through enforcement reviews and enforcement actions.

For background to the Full Committee, when the HIPAA regulations were first adopted and this goes back to the late '90s through the first decade of this century, the thought was that enforcement should be educational exclusively and not penalized. Over the decade or two since then, industry has been clamoring a little bit more for meaningful enforcement including penalties or corrective actions.

My question to Dan is can you describe for us what DNS has done and for enforcement in the last couple of years and what DNS' plans might be to the extent to talk about them for where it is going to go in the future.

Daniel Kalwa: Well, Rich, I am sorry to disappoint, but I am not actually working on the enforcement process myself. I am afraid I would not be able to comment right now.

What I could do is arrange for the staff that are responsible for enforcement to perhaps come in the future either in a future committee meeting or to the subcommittee and perhaps give a presentation.

Rich Landen: Okay, thanks. That would be fine.

Alix Goss: I am going to jump in here, Rich, if you do not have another question because we have one coming in that Rebecca and I have been collaborating on getting addressed. Back to a comment that – a remark that Dan made about what is coming out for attachments. We have talked about intended to pursue claims, attachments and prior authorization attachments and a modification for the 278 5010 to 6020. I just want to build on David Wilderman's question about adopting a new version of the X12 transaction. Effectively, is this plan in the proposed rule that we are anticipating going to actually request the industry to update the 5010 to 6020 holistically for prior authorization or is this only an attachment-specific capability?

Daniel Kalwa: No. The answer is it would be across the board. As we mentioned in the Unified Agenda, it is just across the board. We did not make that distinction.

Alix Goss: So, it would, in fact, mean that the industry would then migrate from 5010 to 6020 based upon the recommendations that we have made a while ago that you are working on. It is a great

opportunity if I am understanding correctly for the industry to weigh in in the proposed rule making process on what they think should be the next version of a 278 whether that is version 6020 or something after that.

Daniel Kalwa: Yes. And, of course, this would be an NPRM so the industry would get the chance to comment. That is what we expect the NRPM to contain.

I would also mention that as everyone reads once we do get it out to be cognizant that the Affordable Care Act those many years ago – one of the requirements when they reinforced the need to adopt an attachment standard was that the secretaries required to adopt standards "consistent with X12 5010". At least for this first pass, that is a statutory requirement that the secretary is going to have to figure out how to deal with.

Alix Goss: Just to put a little finer point on that, if 5010 is the lay of the land today for the medical transaction standards under HIPAA and the Affordable Care Act requires operating rules to be adopted in conjunction with 5010 then we are in a bit of a pickle because the version we recommended in our last attachments letter, I think, was way back to 6020.

Daniel Kalwa: That is actually the odd part. It only applies to attachments.

Alix Goss: It only applies to attachments. I am confused. If 6020 is the version for attachments, which – 275, 277 with a payload inside of it for the exchange back and forth. That version that you are talking about is 6020; yet, all the other versions we are using under HIPAA medical transactions for X12 are version 5010 and we are waiting for them to bring us the next rev, which is not going to be 7030. It is likely to be version 8010 or something thereafter. We are going to have multiple versions of basics 12 standards for the HIPAA transactions. We are looking to adopt a 6020 version for just attachment. The industry is going to have to really think through and be prepared to comment about once they see the actual proposed text, what these different versions mean to them and where they think we should go as an industry to give us that more current update about how we should do attachments, but also you have opened the door for how we should do prior auth if I have heard correctly.

Daniel Kalwa: Yes. I believe that is a reasonable point. You see our dilemma.

Alix Goss: Our new members, if that was alphabet soup and is clear as mud, you are in the right place. I am confused and I have been doing this for a long time. It is very – the version control is a very big issue.

Just to add on to this fun discussion, let us not forget that our standards version advancement process under the new ONC federal rules might be something we want to factor into this whole big conversation about how we adopt standards and advance them moving forward for efficiency and to a newer version. I think there is some other interplay for industry to think about in this –

Dan, maybe we should have had you come before the Standards Subcommittee update because I think that what you are struggling with fits into this larger conversation about the intersection of clinical and administrative data and how we are being efficient and moving forward and managing burden and overhead in information exchange to get to interoperability and how does standards version advancement fit into it and this NPRM might be a really good place for industry to be prepared to weigh in on that.

Daniel Kalwa: Yes, absolutely. That would be my hope. We really are looking for industry feedback on the solution that we are going to propose.

Alix Goss: And we do not know when that is coming out. Correct?

Daniel Kalwa: Right. I cannot even comment because right now I do not actually know. I will happy to share that with the committee and the public as soon as I have concrete information.

Alix Goss: Thank you.

Rich Landen: I am not seeing any more raised hands.

Rebecca Hines: We are an hour ahead of schedule.

Bill Stead: I just want to thank Dan for coming. We really do want to be as connected to the Division of National Standards as we can in this process. Thank you for taking the time to come and share.

Alix Goss: We just had a comment come in on the public comment box. I am just processing right now, Rebecca, before we jump from the appropriate acknowledgment.

Heather McComas is asking a question about echoing David's confusion with the version. I think that this is just underscoring the dialogue and hopefully, Heather, you can affirm that I am inferring correctly, your statement of just elevating that this is going to be confusing and industry needs to get ready about this proposed rule for the 278 and what version it will go to. I want to make sure there is nothing else I am missing in your submission.

(Pause)

She looks to be probably responding to that hopefully. I do not think it is a comment we need to address unless she comes back and affirms that there is a different nuance to what she was trying to communicate.

Rebecca Hines: She, meaning Heather?

Alix Goss: Heather. Thank you. We are on track. Basically, the AMA and Heather McComas are affirming the clear as mud confusion related to 5010 to 6020 for 278 and what that might mean in a landscape where we are thinking about moving to more current versions or alternatives in the ICAD realm.

Rebecca Hines: There is another question for Dan whether there is any update on the rescinded FAQs on electronic payments.

Daniel Kalwa: I am not sure what that is referencing. At any rate, I do not have any further information at this time. I am not actually involved in that process. But I can return and see if there is anything we can share with the committee.

Alix Goss: I think that there is also –- this is further comments upon. It is EFT and virtual credit cards related – a little more specificity. It sounds like we definitely want to have you back for our next Full Committee meeting to give us an update on a number of these issues.

Daniel Kalwa: Certainly. Any time. I am always happy to come.

Rebecca Hines: It is a date. What are you doing in late November?

Alix Goss: Hold your calendar for 18th and 19th of November.

Rebecca Hines: It is. Good memory.

Daniel Kalwa: I will pencil that in then.

Bill Stead: My only thought is it might really be worth a conversation at the level of the Standards Subcommittee with Dan or others, to really get clear what the questions are so that we could maybe bring a consolidated answer back to November, an answer that just reflected all the pieces and parts of the Division of National Standards.

Rebecca Hines: We will take that under advisement.

Alix Goss: And also, just to clarify, Bill, are you referring to not just the questions that were posed today for which we did not have answers, but possibly the other recommendation letters that we have submitted related to our Predictability Roadmap recommendations?

Bill Stead: I was actually at this juncture trying to stay in this particular space of the 5010 to 6020 and whatever else. I was just trying to make sure we got that question in a way that could end with hopefully a relatively simple answer that if – when you get confused by something, I know the rest of us have no prayer. A way to make sure we pull that together I think would be helpful because this is a big – it would fit it, but I was not trying to broaden it.

Alix Goss: We do have some time slated this summer just to make sure we have our ducks in a row on authorities and all those things related to CAQH. We have been working with Dan. We can certainly refine that list of questions and support and maybe a more robust update in November beyond the Unified Agenda updates, but anything that were hanging chads from today.

Bill Stead: Rebecca, my thought is we allow people to have a longer lunch break and restart as scheduled just to fit with the plan rather than trying to move things forward in some way. Does that work for people or would people prefer some other approach?

Alix Goss: I like that approach. I think we schedule according to our agenda when we get our breaks.

Rebecca Hines: Bill, that means we are going to reconvene here at 1:45.

Bill Stead: That sounds like a plan.

Rebecca Hines: Very good. That will mean the staff involved will also be available. Good call.

Bill Stead: Thank you.

(Break for Lunch)

PSC Subcommittee Project: Privacy, Confidentiality and Security Considerations for Data Collection and Use During a Public Health Emergency

Rebecca Hines: Bill, looks like we are ready to start the afternoon.

Bill Stead: Yes, my thought is we do that by handing the baton to Frank.

Frank Pasquale: I hope everyone had a refreshing break. Now we're going to be going into our short-term project for PCS in terms of this Privacy, Confidentiality, and Security Considerations for Data Collection and Use During a Public Health Emergency. We already had some good discussion yesterday, I really appreciate everyone's contribution, I took some notes on that, and I've used those notes to inform these slides.

So where I'm hoping to go with this is to pretty quickly run through some slides, maybe the first six or seven that I have by 2:00 PM, then to leave it open for us to have discussion, if the discussion, in terms of what I took to be the main learnings from the discussion yesterday, and some of the things that resonated.

Because what I was really trying to do yesterday was to figure out what resonated with the committee and with staff and other stakeholders and what was something that seemed either beyond our ken, too ambitious, not ambitious enough, et cetera. So we're going to have that time carved out for discussion. And then some time for next steps. And I think the next steps are relatively clear, but I'd love to hear more in terms of that work.

So just to review this potential short-term project, the key overarching theme was from yesterday what should happen with data during an emergency, are there ways of adopting FIPPs for pandemic in terms of data to be collected, what data should we be offering guidance on, is it being collected or should be collected, the rules that are all right to override and how long those overrides should last, what should happen to data gathered, collected.

And used during an exemption, a waiver period, because that was part of I think a theme of both PCS over the past spring and then in our March meeting was the problem of waivers and then data collected during waivers and not having adequate guidance as to what is done with that data during the emergency, level of edification of data, and other issues about how to harmonize or how to recognize the useful divergences between local, state, and federal levels of law.

Again, the key element here in terms of updating this 2015 toolkit was what guardrails also can we put on this information. We really want to think about guardrails, we want to think deeply about what are the ways in which there are unprecedented opportunities for both advantages here and for incentivizing important levels of inference about public health and about individual health from the nature of the COVID19 pandemic.

And we're learning things every day, it's kind of amazing how medical practice has changed just in a matter of months in the US. I think for example ventilator use, the prevalence of that or non-prevalence of that, other issues. So in terms of being able to help create the data liquidity necessary and access necessary for this incredibly important on the fly research, we really want to be in a role of enabling that, but also enabling it in a way that was respectful to privacy, confidentiality, and security.

So here is where the rubber hit the road yesterday. I won't go over what didn't seem to resonate with folks or what people thought was too ambitious, but what I think did resonate first of all was the idea of updating the extant toolkit. Because as Nick said yesterday it's great to see the committee having continuity with respect to what it's doing. I know as a professor of administrative law that it's often encouraged that agencies work from within their prior frameworks and are updating and elaborating upon them rather than starting something entirely new, and so we have laid that groundwork.

One thing I really heard from lots of folks yesterday including Vicke, Nick, other members of the committee, was the mention of data use agreements was something that would be worthwhile to dig a little bit deeper into.

And depending on our ambitions and our capacity with respect to the research we're able to conduct and help that we're able to get, one thing, the most simple aspect of providing further guidance for the extant toolkit with respect to data use agreements is what should be in them.

That could be one thing that would be sort of a very important thing we could try to think about, is just laying out on the table here are the list of considerations you should have if you are approached by an entity that has some interest in using your data or collecting new forms of data and doing analysis on it.

The most ambitious version of this will be to have a model data use agreement, and that is something that has sometimes been offered by agencies, when you think about business associate agreements, what would be a model BAA, but it's also something that is probably difficult to put together in such a small timeframe.

So I think on the spectrum there's sort of on the one hand side the simplest version of this, what should be in a data use agreement, the most complex version would be here is a sample agreement that you can use as a template, adjust to your own purposes but use as a template. And maybe looking at this we'll come in the golden mean, we'll be looking for something between those two possibilities.

The third theme of yesterday's discussion was about practical popularization of settled data protection principles. Lots of us have a long term, decades of experience in dealing with health data, so to us an idea like de-identification is second hand, but on the other hand there are many people out there now that really have not grappled with it, so there is demand for expertise here, and there's demand for just some popularization of these concepts.

And I think of how difficult it was for me to first get my head around differential privacy, those more complex concepts of fuzzing data and doing other things to reduce the risk of de-identification. I think that there's lots of work to be done here in terms of bringing forward these ideas.

And I think there's also the practical impact of a principal like data minimization, because if we really think deeply about data minimization, ultimately de-identification is one part of the toolkit toward a data minimization framework, but I think there's also far more that one can do and we can address in data use agreements with respect to limitations on further reuse of the data, data destruction guidelines, in terms of very sensitive data, other sorts of issues that could be brought up there.

And then finally one of the things that we talked about was contact tracing yesterday. And I really appreciate the input with respect to the controversies now raised by contact tracing in many states, both in terms of states that want to get more ambitious, and states that are passing legislation that is in some ways hamstringing or otherwise standing in the way of some forms of contact tracing.

And the more that perhaps the traditional venues are foreclosed the more you're going to see demands for alternative sources of data of the type we saw addressed by both professors Nissenbaum and Rothstein yesterday. I thought that was just such a great discussion and I really appreciate the committee members' very frank questions for both Helen and Mark yesterday.

And I think that one of the things that I really want to be sure that we are able to concentrate on in terms of thinking about contact tracing is something very practical that Vicky brought up, what is adequate training with respect to data protection.

She brought up courses that range from six to 20 hours with respect to states that are beefing up their contact tracing abilities. What would be adequate training there. And even if we can't directly affect what's going on with respect to requirements there, we can at the very least provide something that could become a good standard document that would be considered by contact tracers.

So the different directions of this, if I had to think about two very practical things that we could probably contribute in the timeframe that Bill had mentioned, which was single digit months, it would be topics that are within data use agreements and some model language or some proposed language in those. And secondly, the elements of what a contact tracer should know with respect to data protection and what are some of the options there, in terms of what would go on there. So those are the proposed focus areas from yesterday's discussion.

Now here are some of the subjects that could be brought up in data use agreements. One is de-identification when appropriate, and introducing people to concepts of de-identification, and if we have time I can get into later slides about these concepts, limited data sets, other issues like that. But that at least is just to put that on the agenda, I think that is helpful.

Second is determining retention schedule. If you have some sort of retention schedule that would be something that would help I think build public trust in the idea that increasing data liquidity was being done in the service of combatting the public health emergency.

A third is requiring an impact assessment. So I know there is very good literature in this computer security area on potential risks of data. And so sort of bringing that, the best of that type of literature to individuals who are in these very critical roles of deciding on the breadth and depth of data sharing to do in a pandemic would be helpful.

Also in terms of IRB and institutional approval, to giving some sense of where that is appropriate, and also giving perhaps some language that might be of interest to IRBs or institutions that might want to address some of these privacy concerns.

And then prohibiting or limiting third party data sharing. And that's a tricky area, and it might need to be very specific. For example, third party data sharing with respect to longer term research on the nature of respiratory illness might be something that would seem relatively uncontroversial.

Other forms of data sharing, for example to entities that might be using the data to classify and evaluate individuals for employment, housing, credit, other legally protected categories, that might be much more troubling. And I think being able to distinguish between those types of secondary uses or third-party sharing is something that needs to be on the agenda of these data use agreements.

And we talked a little bit yesterday about data use agreements and a single point person and accountability. And I think that the other thing that I just wanted to put out there is one of the big challenges I think over the last five to ten years of data policy, at least going back to Facebook, Cambridge Analytica, and perhaps before, is a concern that there is privacy on paper, and then there's sort of data sharing and practices that exist in reality.

And for example if you look at the empirical work of Ari Ezra Waldman, who is both a sociologist and a law professor, he has talked a lot about the problem of making sure that the policies on the books are actually followed in real life, and how we often lack capacities to really ensure that.

And so thinking more deeply about that, making that part of the decision making process, how would you know if your policy had actually been violated? That I think is something that is not really a big part of the conversation right now in many areas and could be quite constructively added to it I think by an intervention that we're contemplating.

And I just mentioned Ari, the other, Ari's work Privacy as Trust is his big work on this topic, but the other issue that I think is really critical here is that on the one hand we want to see a lot more cooperation between non HIPAA covered entities and HIPAA covered entities on many of these topics. For example, we've talked a bit about the data flow from the HIPAA covered to the non-HIPAA covered, there also might be potential data flows in the reverse direction. I think recently of very interesting studies on sewage, and sort of being able to attract COVID patterns by fecal materials and other matters in sewage, and how that might inform policy makers' decision making. But there's very little work on that area in terms of what are the proper standards there.

And so I think one of the things that the hearing that we would potentially have in September could canvas is what is the full range of data flows that are now being contemplated or are in use or are actually underway in these areas, and the other issue too is that this could be a way in which a leverage point for when we talk about the transfers of data from HIPAA covered to non-HIPAA covered entities, this could perhaps be a leverage point for some of the recommendations in the beyond HIPAA report that we released last year. So that's another issue, and then also sort of teaching people about continually evaluating and reducing security risks in transmitting this COVID data.

Woody Hartzog's book, Privacy's Blueprint, I think is excellent on this type of issue. I'd hope that we could invite perhaps him and others like him to this sort of meeting. I'd also note that Hartzog and Julie Cohen and one other author, just published something really interesting in Brooking's paper yesterday that I'll try to share with the folks afterwards, on COVID data sharing and on sort of some of the topics that Mark and Helen discussed yesterday.

So with that I wanted to try to keep to my original plan with respect to allowing ample time for discussion for any of these. If we could go back just a few slides to sort of the focus areas. That's the one, Proposed Focus Areas Based on Yesterday's Discussion. I just wanted to first throw open the floor to say this is what I heard, is this what everybody else heard? Are there any other additions, subtractions, any other things? And I see Rachel's hand is up, so Rachel, would you want to comment on that?

Rachel Seeger: No, sorry.

Frank Pasquale: Oh, I see, it was from the roll call. Any other hands, anyone else want to comment on these proposed focus areas based on yesterday's discussions?

Melissa Goldstein: This is Melissa. This is more of a clarification question. When you say practical popularization of the data protection principles, what do you mean by practical popularization?

Frank Pasquale: Thanks, it is not self-evident from the phrasing there. I think that when we think about privacy in health data there are many levels of abstraction. There are people that know inside and out all of the most recent guidance's and cases and corrective action plans that have come out of OCR, et cetera, and they have this sort of really deep level knowledge. There are those that have a level of knowledge of the regs, privacy rules, security rules, et cetera. There are those that know the statute, roughly what it looks like, and there are those that know health privacy law.

And I think that part of what this is about is to give entities a chance to give the overworked general counsel, particularly entities that don't have the type of support that probably very large providers do, some sense of what they need to be thinking about with respect to these questions.

I guess that's another aspect of this, I'm glad you asked this question Melissa, because I presume that one of the reasons for this ask was that a lot of authorities were getting questions in this area.

Now I assume that the authorities that are getting questions in these areas, the questions are not coming from, to use my neighborhood, the University of Maryland Medical System or Johns Hopkins or massive centers, I assume that many of the questions are coming from relatively small entities, that this is new to them, they do not necessarily have a dedicated staff on hand, a full-time HIPAA person or something like that.

And in fact, that would actually be a very interesting sort of sociological question area for empirical research, of what is the capacity of many entities with respect to their ability to process health data and the regs here. So I think that that is sort of where we're going from. Certainly, if staff have a different view, I'd love to hear that, if you think that I'm presuming wrong here. But I would guess Melissa that would be a potential audience there.

Another potential audience could be the people in tech firms that are gathering some of the more unusual or data sources that we heard a little bit about from Helen and Mark yesterday. That would be another thing where we may not necessarily have those who are running certain apps that might be quite useful for some of these purposes being very aware of the overall framework here. And a lot of times they don't have a legal staff at all, they just maybe have some that they call on one-offs. So I think that would be one rationale for that practical popularization.

Now, on the other hand I could certainly hear from my experience as an advocate for professions and an advocate for proper training that maybe it's not our role to offer that sort of thing. But I think that in general more information and more thoughtful condensation and summarization of critical information is better than less. Because on some level this could be the document that alerts people to the fact that maybe they have to invest more in understanding the underlying dynamics and requirements of data sharing.

Melissa Goldstein: I had one other thought. I'm not sure that this is the right time, so you tell me to postpone it if it's not the right time. It's about data use agreements. I don't actually know that much about their enforceability and how often they're actually enforced by one of the parties. I would assume by the party sharing the data, because if the party receiving the data does something, I can't imagine why they would try to enforce the agreement, unless they're not getting the data they were told they were going to get.

I don't know much about their strengths and enforceability and how often they're enforced. I know a lot more about confidentiality agreements. I think I'm always really hesitant honestly to rely upon outside private contracts essentially as I think it's a step in the right direction but I tend to be hesitant to rely on it as our only stop-gap, our only way protecting something. Does that make sense?

Frank Pasquale: Absolutely. I think that is something, hearing that, I think that we may need to expand the scope a bit, and to talk a bit more in this project about a potential audience being regulators. Because essentially that could be something that if, I absolutely hear you Melissa with respect to the weaknesses of data use agreements. I adverted to it indirectly by saying what is your audit plan, how do you make sure these data aren't being misused.

But one of the leading examples of data use agreements we have between Facebook and Cambridge Analytica and numerous other app developers that sort of had free reign for lots of data in 2012-2013, one of the most sophisticated and powerful companies in the world, apparently didn't do very much at all to sort of vet the actual abidance by these data use agreements.

And so that is something where I think in the healthcare sector thankfully there is thanks to the good offices of OCR a much more developed mode of trying to ensure that there are audits or other forms of substantive accountability with respect to actual adherence to the terms of business associate agreements.

But I think to the extent that the audience of this type of project would include entities that are not covered, it would be a particular interest to complement an interest on data use agreements with some frank warnings about both the reach and the potential application of FTC rules on unfair and deceptive practices and on state level unfairness UDAP unfair and deceptive practices laws and confidentiality laws.

Because one thing that's really interesting here, I haven't even brought up human subject research yet. But one of the things that is inspiring this is the idea that there is a lot of opportunity for types of interventions on individuals that ring some alarm bells to those that are concerned about human subject research.

To give a very practical example, that Facebook once had an experiment to see if it could change people's mood by adding or subtracting positive or negative words. On the one hand they thought they were home free in terms of not having to worry about human subjects research, but actually thanks to the Kennedy Krieger case in Maryland, Maryland has a relatively aggressive law with respect to expanding the definition of human subject research beyond federally funded research, and they had a complaint lodged against them. Ultimately nothing was done. But this idea, it's a very interesting one to sort of think further about.

And so the Illinois Biometrics Law is another very aggressive state level privacy law that entities may know nothing about. Many people when I talk to journalists about privacy mention that law, and people just shrug their shoulders, but it has actually led to some relatively hefty judgments. I also think that the CCPA in California and further iterations that are possibly coming down the pike are interesting too. So all of t hose things could be, just having a sense of the implication of those laws could be something that's quite valuable.

The balance that I think we have, this is something that I've been thinking about a lot in terms of a project that I'm working on now, called incentivizing and quarantining medical inferences, is that on the

one hand we're trying to incentivize a lot of medical inferences that could be used for the public good and to promote public health.

But we also I think want to, and I think the language of quarantine is appropriate here, we want to quarantine and keep apart certain inferences about individuals so that they do not affect the rest of their lives, because that's a part of how outside of healthcare that's a part of how we build trust. Many hands up, this is great. I didn't see who was first. Rebecca, did you keep track of that or did you want me to keep track of the hands?

Rebecca Hines: Vickie is next, she has had her hand up for quite a while.

Vickie Mays: Thanks. I just actually wanted to follow up on Melissa's comments, because when Linda chaired the committee, we actually did look at it, not a deep dive, but we began to look at this issue of data use agreements. And it was really thinking about the business associate case.

But it was also thinking about the consumer, and the extent to which consumers, and I remember Maya's comment about, I think we had come in to use the IT or something in HHS, and we just clicked the box that said yes, and Maya said how many of you have read it, and I think none of us did. But it really is from a consumer perspective helping also to bring awareness for them about the fact that data can be used in these other ways if they don't need it.

So I think that I agree with you about the strength of enforcement, but I think that if we can put regulators, and that's what Frank was saying, we can put regulators on notice that they need to have less jargon, clearer, sooner in the information, that they need to say what the sharing will be, and then also consumers to have a sense, I think we'll do better. But enforcement, that's a hard one, but education and change by regulators I think would be useful.

Nick Coussoule: Can I respond to what Vickie just said? I think it raises an interesting question, and it's a bit of a perspective on my point. As an advisory body, and we're trying to figure out how we might inform and influence the secretary to help make other things happen, I think what Vicky just talked about was a really interesting one, as far as if our end game is to try to influence policy or rulemaking, how can we do something like that.

In the case of the consumer side of it I think it's a relatively straightforward kind of problem that we're trying to address and how we might get at that, to be able to have an influence. So I just wanted to say part of it is, I'm also trying to make sure we keep in mind what our end game is and what we're trying to influence both from a general audience perspective but also as an advisory body to influencing rulemaking and policy.

Frank Pasquale: It is tricky, and I see lots of hand so I will be quick, just to say that I think when the ask originally came, the ask seemed to be focused around advising, advising sort of entities that might be a little confused. But I think, this is something that has been part of my thought process on this the whole time, also it's got to be about policy, because there's such a gap here. There's such a gap in terms of expectations.

There's a gap between, Helen Nissenbaum mentioned yesterday a study she did that was on what people expect to happen with their data. And according to Nissenbaum's study, I think most people or at least a very sizeable plurality think that HIPAA applies to health data. They don't know this concept of covered entities and then having a whole bunch of health data totally outside of covered entities.

And so just trying to bring the law more into line with people's consumer expectations is something that is quite a challenge, but I think could be really valuable, and certainly fits within the larger intent of a project like this. I'm sorry, I'll let others speak.

Rebecca Hines: Alix.

Alix Goss: Thank you. Building on some of this commentary from your introduction where you're talking about the real life capacities and the aspect of trust, when we talk about these data use agreements, and I've participated in developing a number of them from a statewide health information exchange perspective in particular, and I'm currently working on the FHIR at Scale Task Force within ONC looking at directory type of information.

And there are some assumptions being made in a lot of portions of our ecosystem that we build on HIPAA framework, the efforts that have come before, that established trust, that legal framework, and often it's very entity to entity focused.

And I feel like where are we as the citizen in the middle of it is a really big issue, because even though I'm in this business I'm not even sure how I'd ever even know that there had been a violation of my data, and more especially if I did figure that out what I would actually do about it, and how much money it would take to try to go up against an organization with lawyers and resources to try to prove my case, and that I had harm. I mean that's a steep climb for a citizen.

And so this is an aspect of the education that I think is lacking, back to your HIPAA covered entity nuance kind of aspect, it's about trust and how data is being used, how we're going to be able to harness the data for the common good while trying to get to the individual health outcomes and maintaining the trust along the way. So I think this is a very complicated issue, I think there's a lot of layers of assumptions building on the frameworks that we have today.

I think this is part of the conversation around the intersection of clinical administrative data, I think that as we look at ONC's objectives for trusted exchange and common agreements that enable a health information network across our country to have a common set of principles in a federated environment is something that we really need to step back and think about as a part of this equation, because what we're getting into is bleeding into a whole bunch of other things that are happening under ONC's leadership in response to 21st Century Cures, into what's happening within just our regional efforts to better share information to support patient outcomes.

And so there's this aspect of data use agreements, the education about what those agreements provide as far as protection and how the citizen fits in are all things that I feel like we could tease out a little bit better.

Frank Pasquale: I agree. I was just taking a lot of notes because there is a lot going on there. I mean a couple of things just in response to affirm these points and elaborate on them a little bit more. The point about not knowing even how to figure out whether there was a violation I think is such a critical one.

I, a few years ago, had the pleasure of reading this book by Mary Ebeling called, Health Care and Big Data. What happened to her was she wrote an entire book about an experience where she had a miscarriage, but she was marketed baby stuff, items for a baby, for five years, and keyed to like each month.

So she would have had the child I think a month after the miscarriage or two months after, whatever the time frame was, and at that point she was being marketed soy milk, and then she was later marketed baby clothes, and she was later marketed these other sorts of things. All sort of on this presumption that she had this child somehow.

And she felt like she had never spoken about it to anyone but her doctor, and maybe a couple other emails and things like that. But the effort to try to understand where that data flowed, how it got out, how it affected a profile of her, and how it led to continual re-traumatization about her miscarriage over and over again, it's a very compelling story, and I think there are mysteries, despite years of trying to research data flow and she never found out.

So I think that that question of looking at that level of capacity within the health data ecosystem that has been mapped by Latanya Sweeney and others is really helpful to sort of really get a sense of the scope of the problem. And it's something where to be honest about that system we may have to have a section that says there is much we do not understand about the current health data ecosystem, and there are risks that cannot be quantified or even known given that. That's part of an honest disclosure.

Alix Goss: And I think to build on that honest disclosure is the fact that the business models continue to change as the data gets harnessed, the technologies advance, and just because we might be able to, we don't know what we don't know today, boy it's going to be even a bigger bucket tomorrow.

Frank Pasquale: Right. I think that's a big part of it. And also thinking creatively about the future, Sharon Brown just today proposed legislation called the Data Act that would essentially move entirely from a notice and consent model to a model of regulators watching out for misuse. And it's a very interesting model, it's a very well-developed act that was just released today.

I think you have legislative interest to the extent that we have some duties to advice legislators, that's something that's in the hopper now, are thoughts about how to move beyond all of the responsibility being put on the individuals, because I think we all have an experience of being overwhelmed by that responsibility. Other hands?

Rebecca Hines: Denise is up.

Denise Love: Thank you, this is a good discussion, and I have to bail for another call soon, but I just wanted to insert my experience of data use agreements, not direct to consumers but to data users. It is only one leg on a data protection stool and should never be considered to be the only protection of the data.

When we work with states who have regulatory authority to release the data, data use agreements are one tool, but statistical and management controls of other sorts are also the other legs of the stool. I find that data use agreements, rather than being an enforcement issue, it is an education issue.

The user has to read through, and a good data use agreement has the appropriate uses, limitations, and stipulations that go beyond enforcement, but they agree and read, that may be the only time they really take the time to know exactly what those stipulations are. So I just wanted to put that in as standalone data use agreements are not effective.

And I do want to say that post COVID, Alix, you hit exactly what I'm trying to imagine in a post COVID world, say we get there, is we will have novel datasets and private sector interest like I've never seen in the public data uses and repurposing.

And I had one person running an HIE say to me can't we figure this out to more effectively use timely public data, or the private sector is going to eat our lunch. The public sector seems more handcuffed, the private sector seems a little more free to do some novel things. So I don't have an answer for that, but that was something that was said to be on a sidebar that I don't know if that's going to be true, but that's just something to think about.

Frank Pasquale: Thank you so much. I will keep in mind that stool image is very helpful to me, the three-legged stool, in conveying to people that there's much more to this than the DUA. I think I was trying to use the focus to try to focus to doing something, it's a narrow part of it, but you're right, it can sometimes get too narrow. The other privacy protective measures you mentioned are very helpful.

Denise Love: And I think the risk of not releasing sometimes is worse than the risk of those marketing or other uses. I just don't think absolute privacy is something we can expect in this world. I just won't believe that that's the gold standard. And so what is the tradeoff we're willing to make. But I also am a firm believer, I wouldn't do that I do, that some risk taking is essential if we're to really tackle the problems that we have today. So I'll stop there.

Rebecca Hines: Deb.

Debra Strickland: Yes. I do think it could serve a purpose by way of education in this regard, because as we have mentioned before with these data use agreements and the fact that people just click on through and whatever, I think that people should be well aware that they need to sort of slow down and actually read the agreements, because you could be giving away your first born or something like that, you have no idea what you're agreeing to with those, especially when it's an app like your exercise or your health data and all that kind of stuff.

I really do feel like the general population does think that all health data is covered by HIPAA, and I do think it would be a good information point for people to be educated and understand that it is not covered by HIPAA, and if you sign that agreement and it is a bold statement that they can share it wherever then your data is theirs.

I think getting people, the general population to trust, like just through this COVID thing, people were commenting about there's no way anyone is going to be tracing me, there's no app that's going to be on my phone, I'm not going to let them use my GPS, people are just anti-tracking, so I think that's going to be an uphill battle.

And part of that is things like you go on Amazon to search for something, maybe you're going to buy it, maybe you thought you'd buy it for someone else or whatever, then all of a sudden you pop over to Facebook and the ad is over there already, in seconds, and that speaks to the story that Frank you told about the poor woman who had a miscarriage and all of this baby stuff is there. Well she probably went shopping on Amazon for things to prep for the baby, and now everybody and their brother knows that she was expecting.

So it's a trust thing, the general population is going to be a tough nut to crack, and I don't know, unless we really get to a different paradigm with trusting and reading these things and understanding their limitations, the general population is going to be very hard to get in tune and in step with these things.

Frank Pasquale: Thank you.

Jim Cimino: I was wondering where we fit in the arrangements that occur between outside researchers and institutions that have data sharing or data use agreements, in terms of enforceability and sanctions and that sort of thing.

And to give you an example, we're wrestling with this at UAB right now, but at NIH anybody can be a special volunteer, and if you're a special volunteer you get a badge and you get access, somebody vouches for you and then you're kind of in, you can get access to patient data and do research with it, that kind of thing.

If the person who vouches for you leaves, as far as I know nobody is tracking that. So what happens to the institution, NIH of course is a special case, but you could see other places doing this. I assume they do when an outside researcher wants to collaborate with an inside researcher and they establish some agreements, start sharing data. Where do they fit into this?

Frank Pasquale: That is something – that example is a very interesting example. I think that it is something, in my original scoping for this, I had done a little bit of in the Data Toolkit for Communities from 2015, there is some material that would seem to be relevant to guidance with respect to arm's length transactions, but this idea of the sort of special visitor, what was the term again?

Jim Cimino: Special volunteer.

Frank Pasquale: Special volunteer. That is something that I have not seen yet. Just to follow up a bit on that, is that something where they can get access to individual case level data, or is it some level anonymized?

Jim Cimino: They are treated like an intramural investigator. So they have to do the training and that kind of thing. Another example would be something like DB Gap for instance or some other database where there's a data use committee.

I'm an adjunct at Columbia, when I was at NIH, NIH didn't have a data use committee to get access to DB Gap data, which was kind of weird. But fortunately, I was a Columbia adjunct faculty, and I went through their data use committee, and I got the data. But suppose I leave Columbia, I've still got the data, I could still even query for more data in DB Gap under that arrangement.

It seems like there needs to be some sort of formal check and balance, not just because it's a good thing to do, but to protect the lenders of the data, because they can't ask you every minute, hey, do you still have the right to this data, there has to be some way to manage that, give access without being onerous, but that still protects the originator of the data, and of course the human subjects.

Frank Pasquale: It is interesting to me in terms of just thinking back to maintaining transparency with respect to the full range of data flows that may not be expected or the institutions may not be adequately keeping track of, it does remind me, I'm very sorry to bring this up, I think this was in our parking lot at some point, it was the question of accounting for disclosures, further guidance on that,

elaboration on it, et cetera, that idea. I do think that there's something to be said though for maintaining for some, for audit trails that have been described in a number of contexts along those lines, at least to keep track of who has what, who accessed what when.

I'm glad that you brought that up Jen, because I do think as we move to a world, especially a post COVID world of people doing more work at home, or needing access, more remote access, more far from the institution access, that's yet another potential point of vulnerability, that these should be something that is of some interest here.

But I want to also, we've had so many interesting contributions recently, I just want to pull back a little bit to say that given the bandwidth of the committee what I worry a bit about is I don't want to pack too many things into this, but what I also want to say is that after our conversation today, if you want to send me either literature on or expertise, like experts that you would love to hear more from about your particular angle on this problem, that would be great. Because I see it's already 2:35, and I just want to be sure to move to the last slide or so. Taking the next two hands, but then moving to the last slide or so just to give you a sense of what the next steps are.

Denise Chrysler: I am listening to this with interest because I'm usually the person who is working with somebody to direct a data use agreement because I'm trying to get the data for public health where the data is not required to be reported by law, but from entities that are voluntarily providing it. And I have my own list of data components that may or may not be used. And I read data use agreements all the time that can go from one page to 40 pages.

And one of the parts that's so important though is the legal authorization, because that helps the parties think through can this really occur. There are things that are more contained, more limited, and I'm not sure if this has all been done before, than actually drafting a model data use agreement, because what is needed depends so much on the situation and the sensitivity of the data, et cetera. And that's like providing components and why they're important.

Sometimes ownership of data is an important component of a data use agreement, sometimes it isn't. And sort of more of a menu of components, and explaining the value of data use agreements whether or not they're legally enforceable and the best way I see them as legally enforceable is if you cross somebody don't plan on getting data from them again. It's just been my experience.

Frank Pasquale: I love – that's great. Just to ask one follow up question. Do you think you or those in your role in other institutions, would they be helped by a database of data use agreements or some sort of publicly available grouping of them, or do you think it's something that's always so one off.

Denise Chrysler: That actually has been on our "to-do" list for about 10 years. Years ago we worked with, I was part of a workgroup with CDC, to develop mutual aid agreements. And what we did was we developed a web-based sort of menu with pick and choose components, and it really illustrated what kind of language folks use and what might fit you.

So you could just start downloading your different components, and what needed to be in a mutual aid agreement, and really covering why these are important, and that's the kind of dream. But that's actually a big project.

A smaller project is what are the various components, what purpose do they serve, rather than actually, when we envision this kind of project we envision collecting data use agreements, and I have collected a

number of them, so that we could post examples, and I send people examples, and I'm always looking for people that have good examples to help me with my own drafting.

Rebecca Hines: I am really glad to see Maya's hand up, because I think it would be very helpful at this point to have ASPE's thoughts on the discussion to help guide where the subcommittee ends up putting its effort and focus. Maya?

Maya Bernstein: Of course defer to Rachel about the direction that she and Frank, and to Frank about the direction they want to go, but just for an ASPE perspective, and I join the conversation a little bit late, I was in the budget briefing, but with regard to data use agreements it turns out that ASPE does have an ongoing project on this, and we are working with GSA which has some bit of funding, something similar I think to the conversation here, which was to gather a group of data use agreements as examples, and actually to come up with either a library, not a model data use agreement that would be one agreement for everyone, because that I think would never work, but to have a template with example or blessed clauses for each of the different categories that you're going to have to cover in a data use agreement.

So something that would be like what we used to call semi-structured, what categories there are, and then maybe for each category there are five to ten possible clauses that you would put in there depending on what you actually wanted to do with that particular category.

So there might be something that says you will not attempt to re-identify, or it's okay if you try to re-identify, we don't care, because this data is not really identifiable, whatever it is, this data is completely public use data and you could try to do what you want. So that we'd have like a library of clauses and maybe a tool to go with it like TurboTax for creating a data use agreement.

From our point of view of course counsel will always have to sign off on whatever data use agreement we agree to, but it would be, the idea is to have a starting place where it would cut down the amount of time on the regular routine parts of a data use agreement, and allow the parties to focus on that part that is more difficult or unique to a particular project.

So I feel like there is something already going for a government on that issue, and maybe that particular aspect is not the best use of the committee's time to develop, but I think there are issues about policies and how they're used and other things that are not creating the content that could be useful.

Rebecca Hines: Maya, I am thinking back to Sharon's questions from a month ago around what happens, sort of pandemic times and non-pandemic times and what happens to the data when the pandemic winds down. I just want to make sure that you think that we're going, that the subcommittee is going in the right direction to address that request.

Maya Bernstein: I am not sure I know how to answer that right now, partly because I missed the beginning of the conversation and I don't want to derail, because I'm not quite sure exactly where you are truthfully. I didn't remember us talking before about data use agreements in particular, that piece is new in this discussion to me. I was thinking about the toolkit, and maybe are you thinking about it as part of a toolkit or in terms of that updating, or --

Frank Pasquale: Just for me to realign the conversation a little bit, I think that what basically happened was the first kind of data use conversation was a lot about updating the toolkit. And then when I was hearing from individuals, the consensus from the first day was it's a lot to try to update the whole

toolkit, but here are four things that would be quite useful for you to try to focus on in terms of there are things the toolkit references but are not fully elaborated in the current toolkit, with respect to particularly public health emergencies that have led to greater than normal gathering collection analysis and use of data.

Maya Bernstein: So you are thinking about a data use agreement particularly for a pandemic, like that would be ready to go in an emergency, that kind of thing?

Frank Pasquale: Yes, that could be part of it. That could be the very specific element of this, and that would also apply to all four of these other bullet points on the slide that is up right now.

Maya Bernstein: I can tell you from experience literally I got today, we've been working for more than a month on, not a data use agreement exactly, but on an MOU with FEMA about how we're working together with FEMA using their existing, they have a responder system that collects data in an emergency, and we're using it to do, they now have a special section called COVID responder which has data on testing, and they have been collecting data on testing through us. It has been happening on the ground in fact, but there was no memorandum of understanding between agencies until like today or yesterday I just got notice.

And so it's because we're just doing what we need to do during the emergency and trying to catch up with the authorities and the paperwork and whatever. So it might be that we have some things like that setup for something like this, that you could pull on in a time of emergency, without having to wait.

And we're doing everything kind of one off at the moment because we've never done this before. FEMA hasn't had an emergency that's not a hurricane or an earthquake but that's a health thing> it's not exactly in their bailiwick, but we're just working it out. And so maybe it would have been useful to have some kind of tools like that so we wouldn't be scrambling. I'm just thinking off the top of my head.

Frank Pasquale: That makes sense. That all makes a lot of sense, and I think it's one of the things that, I think going back to the PCS discussions and maybe even after, because I think this was lobbed to PCS in March and April, and I think for our initial discussions we grew somewhat organically out of the March general committee meeting which was precisely about the problem of the fire drill during an emergency, that's the problem. It's sort of like on the one hand you can say an emergency is an emergency and it's always going to be a completely unique, new, one off situation. On the other hand, certainly hurricanes seem to happen at least once every five years.

Maya Bernstein: Apparently, we are going to be in a particularly bad hurricane season, on top of everything else. One thing I will say is if you're talking about looking at the toolkit and updating it, I think it is worthwhile to narrow to those things that are particularly important now for the pandemic, and that will allow you to scope the work of the subcommittee to be more reasonable, and just more feasible, within the resources of the time that you have.

So if you could pick out those few things that would particularly be advantage in a pandemic, and focus on those three or whatever things that they are, I think that could be useful, instead of redoing the whole toolkit. The more you can focus your attention on the highest priority things that you believe are useful for a pandemic I think will be a benefit to the department.

Frank Pasquale: Great, great. I know we are out of time, but I see a couple, Deb's hand is still up.

Rebecca Hines: I think that is left over, she didn't put it down.

Debra Strickland: Sorry.

Frank Pasquale: That seems to be about – let me give you the last slide. If we can move to the very last slide of the presentation that will be quite helpful. So here we go. I think this is the scoping document that I conceive of as a literature review that could be done, that's one possibility that we can go forward on. It's not necessarily something that PCS itself has to do, but it's something potentially, there could be support from HHS or potentially from an extern or someone to sort of scope through some of the documents, literature review there.

And then secondly a September hearing to canvas experts' views that are not reflected in the literature, because I think one of the things that we saw just yesterday was that people have put a lot of time into thinking this material through, but they haven't published yet. Or things are just popping up, like the piece by Julie Coleman and Woody Hertzog that I came across just this morning.

So those are the next steps, and I think that they will be very helpful in terms of informing the actions here. So with that, I don't want to eat into the next portion of time, but I just want to give everyone a sense of that was where we were going. And I'll turn it over to Bill or to Rebecca.

Bill Stead: Thank you, Frank. You have got a lot of interest and impact that you and the subcommittee can boil down. So I think you've done a wonderful job of advancing our thinking, so thank you.

Committee Reflection – what have we learned?

Bill Stead: We are now at a point, what Rebecca and I were thinking we would do is to basically do a round-robin, that we haven't done in a while, to get each member to share their reflections on what we've learned over the past couple of days as a way of sort of crystallizing it, in a way that can be carried forward into the work plan discussion. Rebecca was going to share her screen so that she could actually jot things down as we've done from time to time when we were doing that. Is that a fair introduction to this block, Rebecca?

Rebecca Hines: Absolutely. Just going to just basically try to capture what you say, so go ahead and instruct me and guide me if I don't have it right.

Bill Stead: I made a list that just was the order of things that were on my participant list, we don't need to go in that order, but it gives me a way to check off so I can make sure that the introverts in the group speak up in addition to the extroverts. So everyone is going to need to share, say a couple of minutes with us, of what the big take homes are from their perch that we should consider. Who would like to kick this off?

Vickie Mays: I guess I am in the introvert group. Just kidding. The big take-home for me has to do with Pop Health making a business case for standards. And it's like really thinking a lot about the population health issues as they relate now to not just public health but to clinical and administrative issues. So how do we best do that, I think it's the business case.

Bill Stead: Neat. Who wants to step up next?

Lee Cornelius: Actually, a reflection. I was actually fascinated yesterday with the discussion about natural language processing as it relates to this discussion of validation of the things that are coming up, the death records and so on, and I thought about that and the Federal Data Collection System, I think it's good that there's thought and we have that conversation about, for lack of a better word, artificial intelligence, because you have this going on in the business community anyway, and I think it's going to shape the nature of future discussions of federal data.

Bill Stead: Thank you.

Nick Coussoule: Bill, this is Nick. I can weigh in again. I apologize for missing most of this morning. But if I could go back to yesterday, I think the good news and bad news parts of these, having very smart people come in and talk to us, is it oftentimes raises as many questions as it provides answers.

And when I look at some of the discussions yesterday in regards to the data gathering questions and data sharing questions at the federal level with the federated system, and then even how that translates into things that we talk about from a privacy and security perspective, it makes me realize how intertwined a lot of this is.

And I think part of our challenge, even to get back to what Vicky was just talking about in regards to population health and regards to standards, I think if we're thoughtful about how we frame these up with our subcommittees, there are certainly some things that are independent in each subcommittee, but there's a lot of potential overlap, and I think we may have an ability to try to leverage some of that over time.

I know that's a little bit vague but is it just in my head as to how some of those come together. It is difficult oftentimes, to truly create in isolation, so I think it's worth thinking about how those intersections work effectively.

Bill Stead: Perfect. Who is next?

Alix Goss: I will offer some reflections. The primary word that keeps coming back to me is something that Melissa said yesterday, she started off with a reference to trust, and the criticality of trust. And as I think about the cultural shift discussions that we had earlier today, we have a lot of cultural implications related to our data, to trust, to communities. I think we have to continue to have trust as a beacon, as a goal, and I think it is challenging to establish trust depending upon the perch from which you look at an issue.

And that we have a lot of, if I just take this, I agreed with Nick, sort of this idea that everything is interrelated and we need that bigger picture view of what we're doing as well as the deeper diving things, but if we think about yesterday's comments from Chelsea about the data superhighway vision and the mixed realities that we're really living in of these paved, beautiful interstates that lead to dirt roads and to driveways across our country, there's a lot of complexity in what we have to address to make it work for our entire nation, and that to me is daunting.

And a good aspiration to try to address in our work, especially as we think about the difference between the public facing end state, the applications, the web browser, the experience that we have as individuals in contrast to what it takes under the covers with data standards and vocabularies and frameworks and agreements and ecosystems that know how to play together to make it work in the day-in day-out lives of our citizens.

There's a lot of complexity there, and the more we build a digitized world with lots of layers of electronics on it, those underpinning standards are really important, and an everyday person shouldn't have to worry about them at all.

But somehow there has to be some level of trust in how that's built, in how they're rolled out, and what they mean to us and the impacts on us, and COVID is giving us an excellent opportunity because there are people who are trying to understand how stuff is really connected, even if you look at social media and how things are connected.

And I think we're coming into a new wave, and it has been really heavy in the standards discussion the last couple of years, and I really feel like there's a pivot to the philosophical privacy focus, we've done a lot of work to try to understand where was HIPAA, what's beyond HIPAA, and now we're opening up the next phase, and I'm disappointed not to be here with you Frank and your team to take it to the next level.

I'll be paying attention, don't worry, and hope to participate in September, but I think that there are some real opportunities here and some real service that we can do to tie up a lot of the work that we've done to date and extend the work that we've already got in the pipeline with our federal partners, and I think that collaboration is really important as we move forward in providing service.

Bill Stead: Thanks, Alix. Rich, is your hand up because you're ready to go?

Rich Landen: Hand is up and ready to go. I think I have four main takeaways, and the first is just how many different lenses we are now able to view a lot of what we do through, given the light of COVID. A lot of new perspectives on old problems and seeing interdependencies and gaps that have always been there but have not been as visible.

And COVID of course is a global pandemic, but scaling that down, then you've got regional disasters like hurricanes, and then local disasters like tornadoes or fires, and just how all our data flows need to be somehow robust enough and redundant enough to supply the data needs within the privacy, security, reasonableness parameters that we've been talking about.

Which leads to my second point, and that's Vicky's comment about how we need to think through this strategically, and our strategic thinking has to take into account both the I think some of us have used the term pragmatic, it's got to be based in reality, we can't go too far toward the theory and redesigning the world from the day of creation, but we've got to be able to make progress in the near future that leads to a sustainable long-term more strategic solution.

Going to point three then is the ONC-DNS presentation makes clear that the work of the Standards Subcommittee and the predictability roadmap still needs more work, because here we are 25-27 years after HIPAA and 20 years after the first set of rules, and we as a country are still struggling and confused with how these rules get updated to reflect current technology, current business needs. So again, we're looking for solutions.

Point number four then is specifically for the Standards Subcommittee I think that our day to day tasks, the operating rules, hearings, ICAD and then the larger data convergence process is still, with respect to the foregoing three points, we're still very well framed and I don't see any disruption to the basics of that, although we need to argument the convergence to take into account some of the public health data issues that we talked about yesterday, and again this morning.

But I think the subcommittee is on a good glide path there, but then remembering that there's still upcoming work to be done around ICD, and that landscape has changed as well, so not for the rest of this year or the first part of next year, but the second half of next year there's going to be a lot more on our plates too.

So overall a lot of new perspectives from COVID. Anything we do related to COVID is going to have a limited window in which there will be a lot of receptivity, a lot of funding availability, but at the pace at which NCVHS works I'm not sure the window is going to be long enough for us to get everything done that we really need to get done.

Bill Stead: Thank you. Deb.

Debra Strickland: So I really found the speakers yesterday about the COVID reflecting statistics, I found it interesting that some of their statistics were not really in line with what I'm seeing, which raises its own questions.

I also was really pleased to hear ASPE is taking on the data use agreement and creating models. I think we talked about this a while back, and I think it was around the time we were looking at using death information and so forth and around that topic, but I think that this is a great way to use the data and to create a model for people who need the data use agreements.

And trying to drive good data use agreements that are solid and that will also help to educate the consumer to say hey, this is what you're signing up for when it says X, it will create sort of a glide path there to say okay well we can create this model and then we can in layman's terms explain to people what it means, and is your data protected, is it not protected. So I found that was a really good thing to know that they are doing. Those were a couple of the points I took away from the last couple days.

Bill Stead: Thank you. Frank, I believe you are next.

Frank Pasquale: Thanks, and I just wanted to say thanks so much with respect to all of the comments so far. I've certainly learned a lot from the learnings. I think that the big thing that I am really seeing now is a need for PCS to also engage a bit more with the clinical administrative data sharing proposals in terms of just thinking further about how does that fit into the models of data sharing or lack of models of data sharing that we are trying to promote, or at the very least trying to recognize and popularize via the toolkit updating.

And so that's something that I think is really going to be very critical. On the one hand I think that my time on the committee, I've only been here a little over a year, and what I've been seeing over that year is a lot of work going to the subcommittees, a lot of trust in the subcommittees.

But I also think that there are so many interesting opportunities for cross-pollination and learning in terms of bringing a standards perspective to the privacy area, bringing a privacy perspective to the standards and data exchange area. And I also do hope that eventually we will have back the population subcommittee, because I do think that there is a real need for thinking further about how not just the individual level impact of data sharing but also how it affects groups and communities. So all of those things are on my agenda.

The last thing that I think is something that will be very useful is perhaps for future agendas to think further about what is the conversation going on in Congress right now, because I think one of our

themes has been that the existing frameworks are just now working. I'm noticing consent is being a framework that really is failing so many people in so many ways.

And there are now I think just a very interesting bubbling up of perspectives on future privacy legislation happening in Congress, and to think about how to sort of have further conversations about this longer term view would be really helpful, because I know that a lot of staffers in Congress are quite interested in expert consultation in all these areas. So thanks.

Bill Stead: Very good. Thank you. Jacki, I think you are next.

Jacki Monson: Sure. I think the most exciting thing is I followed all the conversations for the first time in three and a half years being on the committee and think I generally know what's going on, so that's some progress. I think privacy and standards have monopolized the last two days, and I think as Frank commented on and others have that there is a lot of coordination, correlation, connection between the two, particularly as we talk about the topics we have discussed in the last two days. I think there has been a lot of talk about privacy, and it's really hard to figure out what to focus on. Sort of the biggest bang for the buck.

It seems like we've had lots of dialogue about various things the last two days, and it's hard to figure out how to narrow the scope in such a way that we can do meaningful work, because we certainly can't take on the world, even though it feels like we should, based on the conversations in the last 48 hours. And I think my last note just is we need the Pop Health subcommittee back.

Bill Stead: Denise Chrysler, I think you're next.

Denise Chrysler: I have been trying to figure out what I have to offer in the sense of a perspective, my area of experience. And it has been very obvious to me through the meetings that I am with very learned people.

And I think what I have taken away from the last two days, combined with what experience I may bring is about public health, its special role, its broad powers to collect information, and today the concern about what information then gets pushed back out to the public.

And I think we have seen a lot of questioning about whether data is being shared or not shared for political reasons, and one of the big challenges is our tension between privacy and informing the public in this connected world.

So as I listen to the discussion of how we continue to navigate that, it raises for me to what extent we need to reevaluate our risk tolerance. And in this connected world where are we going to draw the line, because it seems like with a possibility, and maybe one of the issues is what are our options, I know Denise Love mentioned synthetic data. And it has some plusses, it has some minuses.

But just thinking, I believe ASPE is raising what are the guidelines for sharing information with the public, and just wanting to make sure that our focus, our tradeoffs, our balance is not too much weighted on privacy that we lose track of our special stewardship of data, that we get data for a reason, and that's not to put it under a bushel basket or to hoard it, but that we still have our stewardship relationships of protecting it. So just that continued balance, and I do feel now like I am rambling, so I'll just leave it there.

Bill Stead: Thank you, very much. Margaret, I think you are next.

Margaret Skurka: First of all, I have the greatest respect for all the people on these calls, and with really smart people in it, I'm doing better, I'm getting it better, I feel much more confident in what I'm hearing in this meeting than I did in a previous meeting. It's hard to be a newbie and not have met most of you face to face. I did reach out to Alix via email, and she was very encouraging and said things will get better, and they are.

I'm glad I'm on the Standards Subcommittee, because that has given me a new insight into that world. And Rich has reached out to me also. And I am excited about ICD-11 sometime next year, because that is my strong suit and where I've spent my work life, so I'll be able to be a much better contributor there. My parents were immigrants, and they told me you learn more from listening than talking, so I've tried to be a good listener here.

And just one other thing with ICD-11, some time on our plate there should be what I think is just a real quick change in that there's a procedure system that was inappropriately named ICD-10 PCS, so when you guys talk about PCS it's different than my world, because I think of PCS as the Procedure Classification System.

It has nothing to do with ICD-10, it's a US product, and it should be renamed and just be called Procedure Classification System. It's updated yearly, it's nothing to do with the WHO and ICD-10, it got the wrong name I think when it was developed in 2015 when we went to ICD-10.

Bill Stead: Thank you. And on that we did make a very clear recommendation that stated that despite the name it was totally decoupled from ICD-10, and therefore did not have to be dealt with in the ICD-11 process.

Rebecca Hines: I will say that when we did that there was for some reason the discussion at that particular moment when the committee was finalizing the recommendation, I think it got watered down to the point that it was not clear what the committee was saying. Whereas Margaret just said it very clearly. And I think our recommendation was watered down so much that it doesn't actually say that. And someone like me who doesn't live in that space wouldn't have any idea that that's what we were recommending.

Rich Landen: My recollection is we did two things in our letter of recommendation, we pointed out that PCS is not related to WHO, and we did call I think for the renaming.

Bill Stead: That can be revisited. Thank you for raising it. Jim, you're next.

Jim Cimino: It was good to hear Jackie say she's just getting the hang of it after three and a half years. So I'm three years behind her, and it feels like it. So I've been very quiet, and it has been because I'm in learning mode. But I did learn a fair amount, I did hear a lot, I'm still synthesizing.

I was struck by the COVID19 data collection and CDC's issues. One of the things I'm struggling with is trying to understand the reach and scope of this committee, and how much we can help something like the ability to standardize and collect, not only standardize the data but standardize the processes.

You're probably following COVID19 data one way or another. And you may notice that people tend not to get sick on the weekends, or they tend not to die on the weekends, so you see this saw tooth pattern

in the data. And of course, that's a reporting anomaly. Or you see one day where they had a very low number of cases and you're going wow, it's dropping, and the next day there's double the number, because of course all the people that didn't get reported the day before are there the day after.

You may also be hearing about some of the national efforts to bring data together like N3C, All of Us Consortium, and others. And the thing they all struggle with is identifying patients with COVID19. And it's not that it's a mystery, when you're looking at the patient you're seeing that patient and the patient has COVID19. The mystery is trying to tease it out of the electronic health record. Because despite the presence of ICD-10 codes, those codes are often not assigned until after the patient has left the hospital.

And we're trying to get data now in real time, this is a pandemic, and we're trying to get data much more quickly, and we can't wait for the billing office to decide what the ICD-10 code is, and then there are other issues of well in terms of the level of severity we don't care that somebody had COVID19 so much as we care about how severe their disease was, and we need to find ways to help our public health community be able to get a better handle on these data.

So I'm not sure where that comes. For instance, can we originate recommendations, or are we completely responsive to requests for recommendations. I probably should know that in the hundreds of pages of stuff I've been sent to read about this committee. So that's kind of where I am. Hopefully I will have a more coherent statement to make at the end of the November meeting.

Bill Stead: Jim, thank you. And we can and do originate recommendations. I think that Melissa has not yet raised her hand, so I will call on you Melissa.

Melissa Goldstein: I was trying to be the quiet one, which doesn't happen very often. I think the most vivid thing in my mind right now is what we've experienced in the last six months, and I can't believe it's six months honestly.

And listening to Mark Rothstein yesterday talk about how he was so amazed at how compliant everyone was at the beginning of the quote-unquote, lockdowns, and how people were staying home, and how we would see the videos of Italy and everyone in their houses and not out on the streets and think about wow, even in Italy, before we were locked down, right? And people were really good. And then now watching what's happened.

And public health law, the repetitive thing we say all the time is there is this balance between doing things, the duty and power of the government to do things for the public's health, and then the balance with the individuals and the limits on what that can be. And we are now seeing the blowback.

We are seeing people angry, we're seeing politically elected or appointed officials taking away the power from public health and saying no, we're not going to demand masks. We're seeing it at the local levels, we're seeing it at the state levels, and we're seeing it at the federal level, almost a declaration that the (inaudible).

So it's fascinating to me from the perspective of what we should and what we can recommend from the perspective of what is practical and what is doable and what is going to be the most useful. And if we are facing so much blowback, and some of it is framed in privacy terms, some of it is framed in strictly I'm going to do what I want to terms.

But when we're talking about sharing data, when we're talking about the privacy, when we're talking about the standards, when we're talking about all of this, we have to remember that balance, and that yes, we want to be able to access data for the public's health, but there are limits to what we could and should do. I think that's what I'm thinking.

Bill Stead: Thank you.

Rebecca Hines: Do we have Denise Love?

Bill Stead: Denise is not back on, I don't think. She had to drop off, and I've scanned and don't see her. So I'll just close out the loop. The only thing that hadn't been mentioned that was on my list was what I think is a very fresh lens that Brian Moyer is bringing to the National Center for Health Statistics with his, if you will, outsider view, and I think a real interest in cross-sector approaches to putting together things that matter, and alternative data capture strategies and so forth, in a way that at least I have not heard being put forward by NCHS at that level.

So I think that is a good direction, and I think it suggests that since that is our space we really should figure out a member that can afford to do the extra duty of being the liaison to the BSC the way that at one point Bob Phillips was doing for us. I think that that's a bridge that we shouldn't let lay fallow. So that's my major thought that one of the others of you did not catch.

Rebecca Hines: Bill, I don't think most of our members, especially the new ones, know this. The Board of Scientific Counselors was actually I think it's in a biological term it's a spinoff, it's a shoot of this committee when this committee was given extra duties through HIPAA it didn't have time really and the bandwidth, and so BSC was created by the NCHS director in the 90s to focus more on NCHS specific topics, programs, guidelines, and yet we're still here, probably I would say if you look at our charter it's a much broader, longer charter.

So what we had was they had a liaison to the committee, and we, this committee, had a liaison to them where you'd attend each other's meetings. Oh joy, you get to go to more meetings. But it was really great, Bob Phillips did a wonderful job, he was local to DC, he rolled off in the last year, but he would go to the meetings and he would do updates on the committee's work so that the board knew what we were doing, and then he'd come back. So if there's anyone who is even remotely interested, let's talk in the next week about that opportunity. And you don't have to be here in DC, it just so happened he was and it was a good fit.

Lee Cornelius: Rebecca, could I give a pitch for the BSC?

Rebecca Hines: Please. You were the former chair of the BSC, correct?

Lee Cornelius: Yes. Before coming onto NCVHS I was on the BSC for six years. It was delightful. Because you're right close to all the data sources, involved with the expertise, what they're trying to do, balance survey development and the science of it. Also you have these one on one meetings with the senior management of NCHS, and even being the liaison you provide that context back and forth between NCVHS and what the Board of Scientific Counselors is about. So you'll find that would be a joy to do.

Rebecca Hines: Thank you. Wow.

Vickie Mays: Could I also comment about the BSC? Because I was the liaison from NCVHS to the BSC. I think the last time we brought it up I had asked if we could replace Bob. But I think the critical thing is some of the directions that we're moving in and some of the directions that they're moving in, particularly in terms of the data that they've started collecting and worrying about is instead of us being on parallel tracks I think we should be sharing back and forth, because I think we need to know changes that they're making, we need to be able to influence inclusion of some things. And if we're going to bring this public health agenda and align it with the clinical and administrative, then that's the perfect relationship.

And then can I add one more thing to my comment? And it's something that Bill said that I don't want us to lose, and that is Bill was talking about the difficulty of the collection of race data. And I've just been thinking a lot about it because it's something I even teach about. The complexity that is there, it actually, I think, is starting to help us make the case as we start to use genetic testing for example for certain things.

It would really be helpful I think to think more about the collection of the data on race and ethnicity as a business case for the very things that Bill is talking about, and to help clinical settings to understand when they bed can use that information, and when they might for example need to actually do genetic testing. So Bill, I really like that. That was great.

Bill Stead: Thank you, Vickie. That completes our round robin. And that's really a rich set of thoughts, and thanks to Rebecca's careful scribing we'll have it in a way that each of us can have access to as we think about our next steps forward. Now I believe what we're going to do is to stop and see if we have public comment. Is that right, Rebecca?

Public Comment

Rebecca Hines: Yes, thanks Kim for putting up the comment slides. So for those of you who were on Zoom in the attendee mode, please click raise your hand, which has now been enabled, to request unmuting from your Zoom audio if you're on the Zoom phone, which I'm not sure we even have anybody on Zoom phone. But if you did press star nine to request unmuting. You can also send email to NCVHSmail@cdc.gov, and I can check that right now too. So let's take 30 seconds to see if we have any comment from the audience or on email. Nothing from email. Greg, anything?

Greg Richards: Nothing yet.

Rebecca Hines: Why don't we move to the next agenda item and we can just monitor for any –

Bill Stead: Perfect. I think we did a pretty good job of picking up the questions through the online question thing and dealt with things that people frequently would otherwise have to keep to the end. I think that's a major upgrade to our capability. Rebecca, we were going to switch to where you were sharing your screen so we could pull up the workplan.

NCVHS 2020/21 Workplan Review

Rebecca Hines: Here is the NCVHS Workplan. This should look familiar, it's also in the e-agenda book. And I've finally remembered to add row members. Bill, do you want to have each subcommittee member go through, or what do you want to do?

Bill Stead: I think what we basically want to do is to let the appropriate subcommittee co-chairs as you go to each row comment briefly and most importantly say given whether the things we've learned and gone through the day whether there are any changes. Because again for the new members what now happens since we're nearing the end of a quarter, we will after this meeting delete the Q1 column, and we will delete the 2020 Q1 column after this meeting, and that will allow us to open up a new column for Q1 of calendar 2021.

So we're always working this kind of rolling multi-month lens of our work plan across the subcommittees. Subcommittees do things that aren't on this dashboard. This dashboard are the things that are at the level that they want to engage the attention of the full committee, and that we therefore are developing scoping documents and working through sort of our full committee process for subcommittee work. So with that, row one, Alex or Nick, Rich, do you want to comment?

Rich Landen: I think we are on schedule right now. We have completed what is in 2020 Q1. We've done the update here in Q2. We're still on track to get the ICAD update and begin the analysis and refining the scope in Q3. Q4 we will be performing the data analysis. We may get to drafting recommendations in Q4, or more likely in 2021 Q1 bring them to the full committee. Alix, you concur?

Rebecca Hines: Can I just add, because we did talk about so much, the expansion of this to include public health data, when you say refine scope do we want to put a note there Rich to remind ourselves?

Rich Landen: A note or a sub-bullet, yes.

Rebecca Hines: Okay. This is you guys again, Rich and Alix.

Rich Landen: Alix, do you want to take the lead on this?

Alix Goss: I am happy to help you with it. So in the collaboration with ONC at this point I really think that we've completed the necessary updates at this meeting, and we really are probably going to need to revisit in Q3 sort of what's next after ICAD to map that out. And I think there could be some long-term horizon work plan issues for the sub and full committees to think about for 2021 and beyond.

I also think that there will be a number of things that happen in the ONC sphere, and possibly even within federal rulemaking that could influence where we want to take things, thinking about the Trusted Exchange for Common Agreement Framework, ONC has a private sector industry group trying to really advance a lot of those things, we've talked about that a little bit on and off throughout the last two days. So I think that, and probably make that a sub-bullet to revisit next after ICAD, map it out. That's all sort of one thought process or a sub-point. So thank you Rebecca.

Bill Stead: Alix, don't we want to remove the final results anticipated to October?

Rich Landen: Yes. That's as we reported in the PowerPoint today, and that would of course shift it into Q4.

Alix Goss: Actually, what I think we want to do is move what you all had in Q3 and move it to Q4.

Bill Stead: What you are doing – the way Rebecca split it is right. You're doing the current work in Q3, and the final results will be Q4.

Alix Goss: I am at the next bullet, the revisit what's next after ICAD I would put in Q4, not in Q3.

Bill Stead: That is where I was actually trying to persuade you to do a little bit of that thinking in advance, but maybe it's one more bridge too far.

Alix Goss: No, not really, because it's not me that you have to persuade my friend.

Rebecca Hines: My friend it won't be you doing the persuading.

Rich Landen: Part of this will also depend on the feedback that ICAD gets from its parent, HITAC, and ONC.

Bill Stead: You all are keeping this more tightly coupled than I would, but I've had my piece and you all can work it out. Predictability roadmap, isn't that where we need to plop in our 5010/6020 conversation out in Q3 maybe?

Alix Goss: When are we going to get a proposed rule?

Bill Stead: I thought we were going to at least have the conversation to clarify what the current lay of the land is - the conversations that we had with Paul.

Rich Landen: That would be this coming quarter.

Alix Goss: Paul or Dan?

Bill Stead: Dan, I'm sorry.

Alix Goss: I think I am just in denial we're already in the middle of June.

Rebecca Hines: Less than two weeks we'll be in July my friend.

Rich Landen: Summer solstice.

Alix Goss: I am sorry, can you please go back to that, because I think what we need to say on the predictability roadmap, it sort of fits there but it doesn't. It's attachment specific, so I think we need to clarify that the 5010 versus 6020 is attachments and related to their NPRM.

I think you also at some point want to come back and take a look at have we gotten responses to the work that we've done so far in predictability roadmap after we get through the other work rows above, till we can figure out what might be next, and it might be that it's appropriate to just let it sit for a bit, because I really do think a lot of these privacy, security, sort of larger population health may kind of drive some of those things. But I would hope we could continue to make some progress or have progress made in response to that body of work.

Rich Landen: Alix, do you think we should slot that in the beyond column, or be a little more conservative and put it in Q4?

Bill Stead: I think you are going to have to do the review response to PR focus letters and recs to be able to do the Fourteenth Report to Congress. That's smack dab in the middle of what Nick was suggesting was in that scope, unless am I wrong Nick?

Nick Coussoule: I think that is right, Bill. The challenge of this is we'll certainly reflect on any feedback that we've gotten, but to a large degree we're kind of waiting.

Alix Goss: So to Rich's point, do you want to put it in Q4, Rich, or do you want to put it in beyond? Because I think we were going at what we want to say that goes into the report to Congress is separate than what do we need to do to advance the ball or go back to the well or rattle the cages or something.

Rich Landen: I am thinking of it in that sense, too. So why don't we compromise and put it in Q4?

Rebecca Hines: I don't think we have any changes to the report to Congress, do we?

Nick Coussoule: I don't think so Rebecca. I think it's pretty straightforward. The only thing I would highlight is for the other committee members to provide any feedback based on our discussions yesterday or their work. We would love that and we'll be kind of running it pretty regularly, certainly through the executive committee and then other members as appropriate. We welcome all the input we can get.

Alix Goss: I really like the idea, Nick, that we get some advanced planning in the work queue for the subcommittees if they're going to be asked to do something more than just outlining.

Nick Coussoule: I think Bill said a week or two should be plenty of time.

Bill Stead: I must admit it will be fun not to spend this year's winter holidays doing the Fourteenth Report to Congress, but I'll be thinking about you.

Nick Coussoule: No you won't.

Frank Pasquale: So are we up to PCS?

Rebecca Hines: We are.

Frank Pasquale: So I think in terms of the work plan this looks reasonable to me. I think that we've done a pretty good job of this meeting to, in the 2020 Q2 box, the third box, to define the project scope. Or I'm sorry, the second box I should say, the 2020 Q2, I think we've done a good job in sort of dealing with the ASPE request, and defining the project scope.

I think in thinking about Q3, following through on this project scope will be our goal during our meetings, and so we'll definitely be going through that and building on the consensus with respect to those slides that I presented today, reflecting yesterday's discussion. I also think that we'll be spending time in getting that literature review commissioned, and also in terms of getting the hearing for September. So the lit review will be a big part of this, organizing the hearing for September will be a big part of this.

And then that's going to be all Q3, and I think Q4 is going to be about holding that hearing, and at least I think trying to relatively rapidly get something small done, some small update or small type of guidance that is in line with what ASPE wanted. And then I think after this year then it's onto the building the trust in public health surveillance infrastructure.

And to pick up on a point that Lee made about natural language processing and AI, I do think that that's going to be a really important shoot. Because I think that's also an area where the rubber sort of hits the road when we think about data quality and integrity and what's going to be feeding these systems, and most importantly. the right to a human in the loop.

Because I've heard a lot about automation in today's meeting, but I have to confess I also have a book coming out this fall that's all about the limits of automation, and particularly problems that have run into computational approaches to data transfers is something that I've written about and published work and looked a little bit into in this work. So I think it is an area where sort of the intersection will be a very interesting one, and our focus on AI and making sure data is quality data and has integrity will be part of the ongoing work plan. So thanks.

Vickie Mays: I had some questions about the hearing in September. I know we are going to be remote. Are we talking about one day or two day? I think there's for you Rebecca some budget implications.

Rebecca Hines: One.

Vickie Mays: Only one day. Is it going to be open to the public?

Rebecca Hines: They really need to be. And the two dates we're honing in on are September 14 or September 11.

Vickie Mays: Well, 11 is better for me. I'm running a boot camp on the 14th.

Rebecca Hines: So that is a question for the next subcommittee call.

Frank Pasquale: We will try and schedule that next call.

Rich Landen: On the incoming change request I think no changes here. Recognize we can get new requests at any time, but we are not expecting any imminently. We know X12 will be coming through the DSMO eventually, but there's no certainty around that date so there's no sense in trying to predict which quarter at this point.

Rebecca Hines: What do we want to do? Right now we just have a standing item there that says monitor results of HHS action for further steps.

Rich Landen: I think that is still probably an accurate description of what our next step is.

Rebecca Hines: Okay. I have been monitoring the Wellbeing in the Nation Network for the data access work that the committee wrapped up a couple years ago. There's no obviously actual work to be done there. Probably we ought to invite them to a meeting for an update when it makes sense to do so. Anything in the recurring/ongoing or the parking lot?

Rich Landen: Nope.

Bill Stead: I think we are in pretty good shape, because you've got the rich set of notes about future thoughts that can begin to drive a next generation parking lot that can eventually get then elevated back up onto the workplace. So I think we've done that. Before we quit the sort of public part of the meeting,

I wanted to share a few closing thoughts as chair. And while I do that Lee and Alix might think about some similar closing thoughts so that we can leave the committee with some of our thinking.

Rebecca Hines: Bill, before you do that I just want to make clear for the public that this is the last full committee meeting for our Chair, Bill Stead, for me, Llewellyn Cornelius and Alix Goss who has been Co-chair Of Standards for a number of years. And so although we may likely have one or two hearings while they're still here, this is their last meeting with all of us as a full committee.

Bill Stead: Thanks for the clarification. When I was thinking about this I reflected back to my orientation where Debbie Jackson said that the NCVHS is a family. And at the time I didn't feel that way, I felt a little bureaucratic and other things. But as I reflect back, it clearly is a correct statement.

During my first couple of years Larry Green was a supportive parent, urging us forward. When I came onboard, I planned to join the Subcommittee on Quality, but it was discontinued, and Larry then talked me into co-chairing population health.

And therefore Bruce Cohen became my older brother, and with his background in public health and people skills and my background in biomedical informatics and process skills, and Susan Kanaan's unbelievable writing expertise, we began to get traction on what became the Health Data Framework and Community Level Core Metrics.

Early on in Walter Suarez's watch Alix and I partnered on the first draft of what became a strategic plan for the committee. I remember we did this while riding the metro from Hyattsville to Silver Springs, between the long committee meeting and non-virtual group dinner.

The ACA Review Committee tolerated my naïve questions as I began to immerse in the HIPAA Admin Simplification Standards for the first time, and our work on core metrics evolved into the measurement framework for community health and wellbeing. In the process I really learned the power of working through an environmental scan and the sequential iterative convenings to find a common ground.

In 2016 I accepted the appointment as chair after I was unsuccessful in convincing Linda Kloss to step up to that challenge. In exchange she agreed to sit next to me at the head of the table and help. Most of you know she did that with unbelievable poise. Rebecca and I bonded effortlessly as she and I worked toward our first full committee meeting and worked the 12th Report to Congress.

As chair I've had the privilege of supporting the subcommittees as pop health worked through the Next Generation Vital Statistics work, as standards worked through Predictability Roadmap, terminology, vocabulary, ICD-11, and as PCS worked through privacy beyond HIPAA.

So Debbie is right, NCVHS is a family. We collaborated and learn from each other, we work hard, and we've really provided a very important long and short-term guidance. So I just want to thank each of you for your collegiality and the experiences that will stay with me far beyond NCVHS. So thank you. Lee or Alix, would you step up with a few thoughts?

Lee Cornelius: I will step up. What I would share, and I would say both for the committee and the staff and the persons who have attended the hearings, it's clear that there are so many players that go above and beyond the call of duty and really dive in.

The work that we get to do and that we've witnessed, there's just so much behind the scenes, that the public face of what happens is the classic tip of the iceberg, but you wouldn't get to see the iceberg if it wasn't for, it's like an orchestration. I think about skating on an ice skating rink at Rockefeller Center during the holidays, it's a nice orchestration, and that people we dovetail, we push, we pull back, we reflect, and definitely it is a family, it's like once you're in we never let you out.

So I will not be shocked if Rebecca calls me up and says do you have a minute, you really need like three days. So that has been wonderful. And at the same time some of the work that takes place in the committee, I just don't know about, it's not in my space. So being part of the meetings and reading the narrative and then contributing, I learned a lot and was glad to be able to be part of this.

Actually, the last thing I'll say is actually something that I mediate a lot on in my life outside of the committee, and that's the notion of sustainability and institutionalization. And one of the things I'm very appreciative of is the long-term legacy of the committee way before this time and way after. I always worry about things that happen one shot or do not have sustainability, so I will carry with me that notion of what do you need to do if you need to plant a bug that it has to be revisited 10 to 20 years from now.

And the last point, and I think of Alix in listening to spaces where you're like we talked about this 10 and 20 years ago, when are we going to get on that dime? And hearing that in real time in the committee I'm like oops, we need to come around the corner on that if we're really going to have transformation. So I really enjoyed the time, and I'll look forward to spaces where I can be of service.

Alix Goss: You both have said so much of what's in my heart. I can build on the family theme. The good, the bad, the ugly, and the silver bullet. And to know that this is a group of people that I'm going to dearly miss, the debates, the intellectual roundtable. There it is, the infamous silver bullet. We always heard you had one in your desk.

So I think that this intellectual exercise among really good hearted, very smart, very hardworking and dedicated individuals, it has been an honor to be a part of this cool kids group, and to be able to build on the work of those before us, and to help maybe those that come after us to be a little wiser and to take our work even further.

I had the pleasure of being a testifier on the other side of the table, long before I was invited to submit my candidacy to NCVHS. And when I was in the role of as the standards community and the alphabet soup, I was often sitting in the seat to try to get to influence all of your thinking.

And the work that we do here on this side of the table in listening hard, in learning from those who are on the ground taking care of those that we love and those that we hope will be safe and sound, is a great responsibility, and it's an opportunity to craft thoughtful short and long-term recommendations and try to influence where our nation is headed. And I will pay attention and listen to your calls in the future. Like it was exciting to see Debbie Jackson listening in today. You are part of the family, you never can quite leave. It's Margaret's comments about the in person dynamic.

For me right now, it hit me two weeks ago in a subcommittee call, I may not be physically able to hug any of you for a very long time, and to sit down and break bread and laugh, share bizarre family stories and friend stories, and to just take greater appreciation of who you are beyond the think tank work that we're charged with. I thank you for helping me grow as a professional and as a colleague and as a person. I feel so much better as a person for this experience, and I will miss you all.

Denise Love: And Alix you still have not finished that story we started in DC. We heard part one and two.

Alix Goss: It all fell apart. Two weeks ago it all fell apart. So that's for another conversation.

Denise Love: We will miss you all.

Bill Stead: Let me do the closing, a little bit more formal thank you's to the subcommittees for the thoughtful planning and work that led into such a productive committee. Back to Lee's point about the tip of the iceberg, it has been a busy few months, and especially thank you to the staff of the subcommittees, Lorraine Doo and Rachel Seeger, and also a thanks to the NCHS team, Mariette Squires and Geneva Cashaw and to ASPE staff, especially Maya Bernstein and the leadership.

I also want to recognize the logistics contractor, RLA. Greg made this thing work perfectly in supporting such an effective, smooth virtual meeting. And last but not least, Rebecca Hines for the help she gives each and every one of us at all hours of the day.

So thank you all very much. I think that gets us to where we can adjourn. Then we'll have some sort of notice about something to follow. So we're formally adjourned and leaving this meeting.

(Whereupon, the meeting adjourned at 4:00 p.m.)