National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

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

Presenters		
Name	**Organization**	**Role**
Steve Posnack	ONC	Deputy National Coordinator for HIT

Call to Order/Roll Call

Rebecca Hines: Okay. Let us go ahead and get started. It looks like the attendees are all coming into our virtual space. Good morning, everybody. Back to Day 2 of the fall meeting of the National Committee on Vital and Health Statistics. My name again is Rebecca Hines. I serve as Executive Secretary and Designated Federal Officer for the Committee. We had a rousing day yesterday and we have lots of good new topics for this morning. And then we are going to actually spend the afternoon – Nick will get into our revised agenda. With that, let us move to roll call beginning with our chair.

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

Rebecca Hines: Deb Strickland.

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

Rebecca Hines: Thank you.

Denise Chrysler.

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

Rebecca Hines: Denise Love.

Denise Love: Denise Love, independent consultant. I serve on the Full Committee. I co-chair the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Jacki Monson.

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

Rebecca Hines: Jim Cimino.

Jim Cimino: I am Jim Cimino, director of the Informatics Institute and professor of medicine at University of Alabama at Birmingham. I am a member of the Full Committee, member of the Standards Committee and I have no conflicts.

Rebecca Hines: Jamie Ferguson.

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

Rebecca Hines: Margaret Skurka.

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

Rebecca Hines: Melissa Goldstein.

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

Rebecca Hines: Rich Landen.

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

Rebecca Hines: Tammy Feenstra Banks.

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

Rebecca Hines: Thanks, Tammy.

Valerie.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I work for the University of Pittsburgh as associate professor and vice chair of education. I am a member of the Full Committee and I also serve on the Subcommittee on PCS. I have no conflicts.

Rebecca Hines: Wu Xu.

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

Rebecca Hines: Thank you. We have one member who I believe will be joining us shortly, Vickie Mays.

Let us turn it over to staff. We have our lead staff with us this morning starting with Lorraine Doo.

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

Rebecca Hines. And Rachel Seeger. Rachel is lead staff to the Subcommittee on Privacy, Confidentiality, and Security. I think that is who is with us this morning.

Let us turn it over – before we do that, let me just briefly mention, we do have public comment today. Thank you for putting up the slide. It will be at 12:45, we think. Please do stay attuned to the agenda in case we are running early or behind. But we will try to have the public comment fall around 12:45

Eastern. In addition, you can send your public comment by email to NCVHSmail@cdc.gov. We can read it into the record alternatively to a live comment.

Nick, over to you.

Welcome Remarks/Agenda Review

Nick Coussoule: Thanks Rebecca. Let me quickly go through our agenda for today. The morning is going to be filled with mostly our Standards Subcommittee work. We will have an update from Rich Landen and Denise Love, our co-chairs. And then we will spend some time with Steve Posnack, who is the deputy national coordinator for HIT at ONC. And then we will have – Rich and Denise will give us an update on the listening session from August that we conducted as well as an update on the Convergence 2.0 project. Some more to come on that one later. We will have public comments, as Rebecca indicated earlier. And then we will break for lunch.

We will have a first session in the afternoon with Sharon Arnold from ASPE, talking about health equity update and some potential work for the committee. And then we will have two follow-up items from yesterday in regard to the ICD-11 letter as well as the PCS follow-up work in regard to some potential priorities for the PCS work. I will review the workplan briefly and then closing remarks and adjourn hopefully at 4 o'clock this afternoon. With that said, let me turn it over to Rich and Denise.

Subcommittee on Standards

Rich Landen: Thanks Nick. I am going to take the first part of this. Denise will cover most of the report out on the listening session.

I am going to talk a little bit just some general background about what the Subcommittee on Standards has been doing. That will lead us into our conversation with Steve Posnack.

For the benefit of those of you who are not familiar, let me just summarize the charge of the Standards Subcommittee. The Subcommittee monitors and makes recommendations to the Full NCVHS in the following areas: identify issues and opportunities and health data standards. The Subcommittee provides outreach, liaison, and consultation with and serves as public forum on health information technology standards for industry, federal, state, local, and tribal governments, makes recommendations related to electronic standards and operating rules under HIPAA, privacy and security standards, and health terminologies and vocabularies.

The Subcommittee makes recommendations on strategies to promote continuing process of developing, coordinating, adopting, implementing, and maintaining standards. And these strategies include public information and educational efforts as well as research and development.

We participate in the development and publication of the Report to Congress that we worked on yesterday for the HIPAA Administrative Simplification. And we collaborate with other federal advisory committees on cross-cutting issues as appropriate and when delegated by the Full Committee. That in a nutshell is the scope of the Subcommittee's focus.

Our current work, the largest single body of work is what we are calling shorthand Convergence 2.0. The official title is the Standardization of Information for Burden Reduction and Post-Pandemic America. We will spend the bulk of the latter part of our session this morning talking about that, the listening session. In my piece this morning, I am just going to deliver a real high-level overall of that.

Besides the Convergence 2.0 work, we have other ongoing collaborations with ONC around the convergence of data streams in the health and wellness world. The universe of the data streams has expanded since the original charge to NCVHS and the Subcommittee around the HIPAA transactions. It is expanding more from just information flows between and among covered entities, now including a lot broader. And we will talk about that a little bit later.

We have worked in the past with ONC in the HITAC. HITAC is ONC's advisory committee, their FACA. Last year, HITAC had a taskforce called ICAD on which we participated, several members of the Standards Subcommittee. We will continue to work and collaborate with ONC on the results of the ICAD work and any follow up and ongoing work that is of mutual interest to ONC, HITAC, and NCVHS.

Another piece of work that the Subcommittee, as we talked about yesterday, is the preparatory work for ICD-11. I will not say more about that since everybody is familiar with that.

And then finally, as the Subcommittee, we focus on HIPAA transactions, code sets, operating rules, updates, when submitted by the Standards Developmental Organizations, the DSMOs, designated standards maintenance organizations, and CAQH CORE, the Operating Rule Authoring Entity.

Just a high-level overview of the Convergence 2.0 process and project. It is a two-year project. The project plan is up on the NCVHS website for anyone that wants the full details. The projects break down into two phases. Phase I is kind of establishing the landscape, get a good sense of who is doing what, what the challenges are, what are the opportunities are, and as part of the centerpiece of that Phase I, we held a listening session last week at which we had panelists representing different segments of health care and other industries. We will talk much more about that later this morning.

Phase II is the analysis deliberation report and potential recommendations that will be coming from the Subcommittee after we consider and look into what we learned in the landscaping effort and assuming we will be talking more to different industry representatives to drill down on some of the things we learned in the listening session.

The Convergence 2.0 project builds on earlier Standards Subcommittee work, specifically the Predictability Roadmap, which we have been working on over the last four or five years. That envisions a more industry-driven standards development adoption process. It envisions more timely updates. Those updates will be more frequent, but smaller, more digestible bites. It includes enhanced pre-adoption testing. It includes building in return-on-investment determination. I stress that that is not just a financial, that is a lot more than just the dollars in return on investment and also gets into the area of enforcement and/or conformance.

Additional opportunities that may be considered for evaluation during the project are FHIR and APIs, all-payer claims databases, APCDs, common data layout, consistency of reporting and exchange of social risk data. As I mentioned, conformance and enforcement. Those are two are similar, not necessarily

synonymous. But what opportunities are there for improvement for the industry. Looking into some sanctioned exceptions and alternatives to the current HIPAA transaction standards and processes. Looking at health data flows beyond the traditional HIPAA and HITAC trading partners. That includes social and structural determinants of health, patient social services programs, public health, infectious diseases, vital statistics, pandemic-related lessons learned and patient consumer-driven data.

In all this, we stress that the Standards Subcommittee and NCVHS is not an operating entity. We are an advisory group. With industry and government agency input, we establish visions, goals, priorities. We make observations and recommendations. We produce documents that serve as guides of frameworks for others to do the development, to do the regulatory, to do the legislative or the implementation work. That in a nutshell is who the Standards Subcommittee is and what we are working on currently.

With that, I would like then to transition over to introduce Steve Posnack and have Steve talk a little bit about what ONC is up to, ONC and HITAC. It is a lot of parallels, a lot of overlap. The charters of both the NCVHS and HITAC are fairly clear. There are lines of demarcation, but there are a lot of areas of mutual interest and a lot of opportunity for collaboration, coordination, and sharing the workload.

Steve Posnack is the Deputy National Coordinator of Health Information Technology. He has been with the Office of the National Coordinator for – I think it is over 16 years now. Is that right, Steve? Steve has been involved in all the major efforts of ONC, including promoting interoperability that used to be called meaningful use, USCDI, TEFCA, ISA, Health Level 7, CCDA, and FHIR processes. Steve has master's degrees, plural, one in security informatics and one in health policy. Steve has his CISSP certificate in the information security area.

Steve is going to talk about current ONC and HITAC work in the space adjacent to NCVHS' areas of interest and then we will have a discussion around the opportunities for collaboration and alignment. Steve, over to you. Thanks.

Steve Posnack: Thanks very much, Rich. I will take you and Nick if you guys want to moonlight to do intros for me anytime. It is a pleasure to be with all of you. As Rich mentioned, I have been with HHS and ONC for quite some time. For those of you who are health IT historians, you may recall that ONC did not have an advisory committee attributed directly to us in the beginning. I had the great fortune and privilege to work with and support NCHS at that time with some of the work that we were doing. I have a soft spot for NCVHS in the work that you all do. I am happy to give you some updates today on what we are up to, as Rich mentioned, areas of mutual interests, convergence, cumulative impact and effect that we all can bring together. The role of an advisory committee is one that HHS tends to leverage to a great degree. The long tenure and stature of NCHS is certainly something to be proud of as well. I think it is probably one of the HHS' longest standing advisory committee – steeped in history and a pleasure to be able to present to you today.

I am going to run my slides, which I did put together for you. I felt that pressure to have some slides available. They should have come up now at this point. Here I am. Let us dive in. I wanted to give folks just a brief orientation to ONC and what we do and how we approach things, again, from a historical perspective. There have been many incarnations of ONC since 2004 – jump over to my next slide.

We obviously are part of the Department of Health and Human Services. We are part of what is called the Office of the Secretary so similar to ASPE. We are a staff division that is part of HHS. And we were created by President W. Bush, as I liked to call him, in 2004 under Executive Order. For those of you that have tracked ONC's mission and work over time, it has certainly evolved as the health IT landscape has evolved. You may recall in the early stages of our work, very much focused on EHR adoption, health IT adoption in both in the ambulatory and inpatient setting and that let up to the passage of the EHR incentive program that was part of the HITAC Act, which is part of the American Recovery and Reinvestment Act in 2009.

And a lot of work in the early stages of the 2010 was spent on increasing EHR adoption with a future promise of all of the great things that we get to talk about now, which I think we would have preferred to have as challenges years or if not a decade earlier. But I am happy to have them now and happy to be chipping away at some of these issues that we knew were on the horizon and now have reached a level of maturity in both business, practical and policy implications that we can do something about them.

Just to fast forward in terms of our brief statutory history, you may all be familiar as well with the 21st Century Cures Act, which passed at the end of the Obama Administration. That included a whole new suite of authorities that my office is now attributed to and associated with. Things around reducing burden from a clinical et al perspective, the Trusted Exchange Framework and Common Agreement activities that we are involved in that Rich mentioned earlier. I will try to use words first and phrases before I use the acronym. I am sure I will slip into acronym speech, and you can forgive me later.

We also made significant modifications to our certification program as a result of some of these statutory charges and also have implemented now provisions associated with what are call the information-blocking exceptions and general policies that now encourage and expect information sharing to occur among the health care ecosystem and specifically among certain actors, as we call them, that are covered by the law. I did not go into a deep regulatory dive as far as these slides, so I wanted to give you a full office portfolio orientation and certainly get to places where we see and just simply with the collegial work that we have done thus far with NCVHS, opportunities for us to continue to work together.

When we think about ONC, we really focus on three specific subject matter expert competencies as well as our broad role in general as a coordinator. Largely, as Rich mentioned, as part of some of my work, we do a lot with the standards community. I have some more details in terms of examples of that. We obviously run the ONC Health IT Certification Program. And that also has an expanded scope and breadth effect where there are a number of programs across HHS as well as in the private sector that reference ONC Health IT Certification in one form or another. We work to provide consultative expertise and subject matter expertise to either sister agencies or other organizations in public-private consortia to understand how to best leverage the certification program and what its fit for purpose and in some cases, not fit for purpose.

And then lastly, we focus on health information exchange, the verb. I try to emphasize that there. This is a multi-layered, multi-dimensional approach, working with in some cases, health information exchanges and networks, the noun, and different types of policy issues. The Trusted Exchange Framework and Common Agreement is certainly one of those. If you have been tracking that project, we have recently

released a timeline with our partner, the Sequoia Project, who serves as the recognized coordinating entity. They are under FACA's agreement with us to help steward the general process to reach a version one of what is called the common agreement, which will be that government document, the contract that would facilitate broader, nationwide exchange.

And then it is often intangible. I know many of you are somewhat closer to government in some cases and maybe pathfinding your career of being part of a federal advisory committee. We do a lot of work behind the scenes with our federal partners, with our state and public sector partners to keep things moving and to sharpen our own perspective, help sharpen and coalesce different ideas together.

I would be remiss if I did not highlight that later today, which is why I need to leave you all at 11:30. We are running the first day of our tech form that we call it. There is a session this afternoon for a few hours and then another one next Friday that you can catch as well. That is publicly accessible for anybody that has dialed in here to flip over to if your schedule allows. We do opportunities like that in terms of overall industry convening.

We do more specific targeted workshops on particular issues or advancing group-oriented thinking around a particular solution set or other challenges that we may face that we feel multiple stakeholders across the industry share. We often try to keep our head up and looking for those to say we see a few different organizations doing these things a bit differently. Maybe it is more efficient. Maybe it is more effective. Maybe there is another way to advance the issues that we face together by bringing that group to have that conversation and to initiate some of those connections. We do a lot of that behind the scenes. And to recognize our staff at ONC, they do not get enough credit for a lot of the behind-the-scenes work that they do. I know they are not here to listen in. I will give them those props and then remind myself to tell them the next time I do that –

Ultimately, we are driving towards two main objectives, which are there to the right on your screen. Advancing the development and use of health IT capabilities, which ranges an entire spectrum of work, and establishing expectations for data sharing. A lot of these plug in and flow towards from left to right into these tangible impact areas, investments, and coordination opportunities that we have with the health care ecosystem at large. We are really driving those from both the technology and policy perspective.

If you heard me talk before, we approach that mixture, those proportions in different ways. In some cases, we may need a higher proportion of technology-rated work, standards and testing infrastructure and reference implementation. That is really what maybe a greater than 50 percent level of effort to get something moving or to move something to the next stage of maturity.

In other cases, there may be a policy regulatory misunderstanding of interpretation type issue that goes along with health IT and interoperability. We have to spend a lot of time working with our colleagues at another federal agency. The Office of Civil Rights is one of our key partners and we work a lot with them despite HIPAA being the HIPAA rules, being out for 20 plus years now, it is still probably one of the most widely misunderstood and widely intentionally misunderstood regulations that exist out there as well. We do a lot of work.

As Rich mentioned, some of our regulatory work now has intersected with the HIPAA rules. We are finding new opportunities and new ways to work with OCR and explaining both how the information blocking exceptions fit into the larger HIPAA paradigm and provides a new fresh look at explaining some of the more detailed concepts that exist in the HIPAA privacy rule, in particular.

That is a brief overview of ONC, how we approach our work, where you can find us toiling away on a day-to-day basis in any one of those four main categories.

When it comes to standards certification and exchange, I just wanted to highlight really across the board a number of activities in which we are engaged in. We do a lot of – I describe it as multi-level work with standards development organizations. In some cases, it could be syntax level related standards work for implementation guides and new ways of building recipes and packaging things together to satisfy a business purpose or a use case.

And then in other cases, we are working directly with more semantics-oriented organizations. We have a cooperative agreement with Regenstrief to do some work on LOINC. We certainly partner with our colleagues at NLM who steward many different code systems, RxNorm, SNOMED CT, a couple of examples.

And then equally, we work with industry in general to share best practices to make sure that we are highlighting the availability of new ways to do things and solve new challenges. And we also work on industry alignment. One of them that I call Project USA – I hear a lot of folks call it Project US@. That is okay too. But it was originally trying to be a play on words with the "at" symbol that also looks like an "a". And clearly, I was too clever and confused a lot of folks, which led to a lot of different pronunciations of our project.

But that one in specific was patient matching still remains an issue and an area where I would like to see greater benchmarks and transparency and greater understanding of the industry progress.

One of the key areas that has been highlighted in terms of I would not say an impediment, but it certainly is something that is frustrating to the patient matching process is simply around address and consistency in terms of how addresses are formatted. For many of you that work in the health care ecosystem – you know that this includes both workflow and processes and human labor upfront upstream for just that initial registration all the way down to data normalization and other approaches for the eventual either export or interchange with that information.

We set out a year ago right at the end of 2020, to push forward and initiate with industry to standardized and come up with greater constrained rules around how addresses should be formatted in health care settings. That is standard diagnostic. There are many HL7 standards, X12, NCPDP, key partners, all of them that I mentioned among many others that are part of the standards community that are working together on this, equally partnered with our colleagues at USPS because they have tools and interests around address standardization. A lot of that is just real in the trench work.

I want to say thank to everyone that has been participating in that activity because we did put out for public comments some initial versions of the implementation guidance and got feedback and we are still working on track to get something out by the end of the year.

The other thing that we administer is called the Interoperability Standards Advisory. I like to refer to that colloquial as the standardopedia. If you want to know what is going on from an interoperability needs perspective or use cases or different kinds of models that may exist, we try to represent everything that we possibly get feedback on into the Interoperability Standards Advisory so that as you are approaching something new within your organization or you just want to find out what the current status of certain standards that are being used, you can go to this as a resource. That is updated 24/7, 365 throughout the year. And we also do some public comment processes at which there are some open now. I would encourage to HealthIT.gov to check those out.

The one thing that we have added as part of this overall platform is, as was mentioned earlier, the United States Core Data for Interoperability. This is something that we have adopted as a standard for data policy in our regulatory paradigm. It is applicable to our certification requirements. Health IT developers are now approaching updating their systems for compliance by the end of next year to get those systems out that now include support for USCDI and I should mention Version 1 because this summer we also put out a guidance version of USCDI Version 2, which starts to lay a predictable and transparent process and pathway for the industry to go down, relative to standards and expectations. I know that is something that NCVHS and the Standards Subcommittee has been discussing as well with us. But how do we give more predictability to industry of the future for both regulatory decisions as well as where there is just mutual interest there in terms of the industry moving forward? We have been looking at ways to be more transparent and to add more predictability to our policies as well.

As I mentioned, we administer the ONC Health IT Certification Program. This includes under the coverage, supporting numerous testing tools. We have one that we – in the FHIR space, you always have to come up with a full name. We call our testing tool Inferno. That is FHIR-based testing for fire servers. The code is available online. The infrastructure is available to go beyond just certification-based testing through our certification criteria. It is a general FHIR-based testing resource for anyone out there that is looking for those types of tools. We have many that really span a wide spectrum of electronic testing tools that are available as part of our certification program but can also be used in more general sense as well.

And then we do standards work, health information exchange related work across many different programmatic domains. I am happy to discuss these in more detail with you all, but I just wanted to highlight a few there. Certainly, right now in the midst of the pandemic, looking at public health modernization, there is an Executive Order from President Biden and in fact, multiple, but one that we are focused on in particular with our colleagues at CDC is around public health data infrastructure and modernization and we are invested in that. There will be more work coming out of ONC and CDC over the next few months as we continue to work together within the Federal Government at this stage.

Certainly, this has been overshadowed by the pandemic. There is still a lot of work going on in terms of opioids and the opioid epidemic and the sharing of Prescription Drug Monitoring Program information and making sure that people are effectively treated, and interventions are brought to bear in this particular area because it is still an issue and unfortunately, as different nationwide crises come up, some of them get put out of the spotlight. But it is something that across the board, staff at ONC, as well as the department are continuing to work on.

Certainly, a lot of work that we do across the board can help feed in the research. This includes coordination, opportunities, standardization opportunities, new health information exchange, modality opportunities with our colleagues at NIH and FDA in particular, just in terms of how we can leverage the digital foundation now that we have with electronic health records in particular being widely deployed across the United States.

And that also feeds into quality and safety-related activities, continuous quality improvement. Equity has become very much a front and center issue that has been highlighted by this administration. There is lots of work going on in standing up new projects and new expectations around how health IT has evolved with respect to equity.

Similarly, a close sister or brother to that is going to be around in social determinants of health, SDOH. And then as I mentioned, patient matching, privacy and security, all of those are issues that intertwine and become infrastructural and are inherent dependencies to all of the work that we are doing and making sure that we have those built in as part of our running model of work.

And then lastly, as I emphasized there, exchange as a verb, patient access in terms of using apps, getting access via the web through what maybe referred to as patient portals, still a major work area for our office and both from a technology and policy perspective, building nationwide capacity through the work that we have done through the Trusted Exchange Framework and Common Agreement, TESCA.

And then equally looking at – a lot of the interoperability focus areas that we have had to date have been around outbound-related exchange activities. I just highlighted one here in terms of patient-generated health data. That is more of an inbound focus. We have also been looking and partnering with the community and better understanding right related API capabilities, which opens a whole new area of work for both the health IT software developers as well as for policy setting and the like. All of those are future-looking areas that we are starting to spend more and more time on as the standards and the policy understandings improve.

Last year in the overall work products and activities that we are involved in, Health IT Advisory Committee, as was mentioned. This is, I guess, your sister federal advisory committee.

We are down to one federal advisory committee. Those of you may remember when we had two: the Health IT Policy Committee and Health IT Standards Committee. The HITAC now serves as our primary FACA. We have had a number of different task forces, which is generally what we call our draft subcommittees in a FACA speak. We have had an interoperability standards priority taskforce that issued recommendations. We have had ICAD, which I know you are familiar with more intimately. We have also had those providing feedback on the USCDI overall.

With respect to the ICAD taskforce, I wanted to address this upfront. We can certainly have more discussion. We received a number of recommendations and appreciate your partnership and feedback along those lines as those came up.

We are going through those recommendations. We are talking to our federal colleagues that may be implicated by them or have mission interest in them and as I talked to the team, we are equally interested in following through and following up on the Phase 1 of the standards work and inquiry that

you all are doing now too to look where there would be future synergies for the two federal advisory committees.

I would note as well that we are partnering with and working with certain federal agencies on implementing some of those recommendations in ICAD that the ICAD taskforce came up with and that HITAC ultimately referred and recommended to us. But that is going to be an iterative process. There were quite a few recommendations. As you may know, the agencies that get them have to fit them in and prioritize them and look and see where timing is right and especially where there are regulatory-related changes. Those tend to have a life of their own in a different timely stream that we have to dip into.

As I mentioned, but I will state briefly again, we need a lot of federal agency coordination. This includes alignment on data requirements. That, as I mentioned before, spans for public health related or research related or quality measurement and overall, just programmatic understanding, if there are payor alternative payment models like what the data landscape looks like from a standardization perspective and in that regards, provide a lot of technical advice. We also play a role behind the scenes, working with some of our federal partners that have larger procurement levers. This would be the agency that do a lot of grants or do a lot of contracts. We helped build in different health IT provisions into those procurement-related activities.

And then equally, we do a lot of policy alignment regulatory. There are CMS rules always coming around the corner. We do a lot of work with them, and they are great partners in terms of policy alignment and health IT interest. CMS, as a whole, has been instrumental in advancing a lot of interoperability progress across the nation as a whole.

We do a lot of collaborative work with the software development community and innovation communities, both to understand what our rules say from a colloquial interest and then equally to hear from them where are these pain points. And sometimes it is not things that ONC has particular jurisdiction or authority over, but we can take in our coordination role back to some of those other agencies or initiate certain conversations where it may be relevant for us to have a conversation with the FTC or our colleagues over at OCR, DoD, VA, and the like.

I am sure many of you are familiar with the Federal Health IT Strategic Plan. That is something that right now it is currently set between 2020 and 2025. We will be looking to refresh that as government agencies do in the next couple of years. But that is something as well that we use as a guidepost and sets a number of goals for federal agencies across the board with respect to health IT.

And the last thing we do is a lot of public-private consortia related work. Ton of expertise among our team at ONC. And as much as we can get them out there into the wild, we try to do so. Making sure that everyone are up speed on what our ONC staff and subject matter experts are working and then taking that feedback back into the agency as well.

This brings us to your NCVHS, and you are here to help, and I say that affectionately as a subtitle. As I was trying to put this together and your colleagues there helped prepped me a little bit in terms of what to seed the discussion with and thankfully, I think I left plenty of time for us to just have some open

dialogue. There are lots of opportunities for let us talk about data and the use cases that are available to us.

Something that has come up and I have noticed an observable trend on is that as we have now had greater adoption of health IT software across a lot of different stakeholders, there are still some among the care continuum that you could say are behind or have experience, a bit of digital divide and we can talk about that too across that care continuum.

But in a large sense for ambulatory health care providers as well as hospitals, we have a lot of data now available that is in digitized form. And how to make best use of that and make sure that the quality of the data, which is one thing I am sure you all have discussed at least in your day job is that there is a lot of work that goes on for normalization. There is a lot of work that goes on to make sure that correct semantic standards and bindings are used, or value sets are used consistently. And in some cases, it is really important. That is necessary for the data to be fit for purpose.

And then in other cases, our tolerance for not having the data explicitly coded and really fixed with discrete findings. That may not necessarily be as important for certain use cases as others. It would be really interesting, I think, as NCVHS looks at broad mandate to look at areas and perhaps provide input to the ecosystem as a whole about when is the right level of quality of data in particular important. I know that ranges from the spectrum of we are just going to do free text analysis. Just shove us over whatever data you have and we will work it out. That is kind of the large search mantra. And then all the way to the clinical research and sometimes you hear research grade as a hyphenated word data. I am not sure that means the same thing to all people. But it is supposed to mean like super high quality, super finely tuned, very discrete information, as far as I understand. In that case, that requires a lot of work upfront to make sure that the data is captured appropriately.

That kind of fits into I think what we have experienced to link together pandemic response. You all have as part of the name and the mission vital and health statistics as well. That is clearly an area where greater standardization attention could be paid and opportunities for merging again as I kind of flow into my convergence area.

These are things when people ask me like what do you see in the future? I get the crystal ball out and I wiggle my fingers and I say I think the larger three or four dimensions that we are approaching over the next decade. One is around – I previously mentioned that ICAD has already started and NCVHS has already started. The streams of clinical and administrative data are blending together for a number of reasons and seeing more and more convergence there, efficiencies. The potential now if they are getting so close together or if they are intertwined that we may have a little bit of duplication in terms of how things are being done. That is creating friction, creating burden that did not previously exist because they were these isolated processes. But as we are looking and emerging them together, it does require us to take a holistic view and take a step back and say what is a fresh look at how these streams are going to be handled.

Clinical and research, I touched on a little bit, but definitely see convergence opportunities there.

And then because we are – say this as a reminder. We are part of the Department of Health and Human Services. There has definitely been I think a great awakening in terms of merging together the health and human services experiences and both from an individual citizen services and providing them more efficiently and more effectively all the way to their understanding of how to create a policy and how to serve populations that may be seeking care outside of the traditional health care system. And that blends again into the social determinants of health-related work that is ongoing and the like. I am debating whether or not to put equity as its own separate convergence category. But I think we do see a lot of opportunity there both in understanding the data that is being collected, how the data is being used, and where and when certain information is being exchanged, all have impacts and effects on equity as well as the privacy and security policy that may be applied to the data, which was not necessarily traditionally collected several years ago and is now being more collected more and more.

All those convergence areas blend into perhaps another passion of mine, which as a computer scientist by initial training and approaching it through health IT professional work environment. As we look at burden reduction, as we look at why we have gotten into this field, what we think the benefit of using health IT is, it is to make things better. In the automation context, that is an area where we can put computers to use so that we can do higher functioning, higher value activities as professionals, as humans. And let the computers do the redundant tasks of computationally dense activities and then come back to us with insights that we can use to do a little bit more of those higher cognitive related functions.

As we look at automation and how – getting back to the level of data, where we see different convergence opportunities, how that feeds into automation opportunities for our work overall. I wanted to highlight that, not to say that NCVHS should say these are things that need to be automated, but what are the underlying ingredients. What are the underlying foundational support structures from data from how we talk about the level of quality of data that may be used, where we can pinpoint the right areas for transparency around the algorithms that may be used? All of those and that gets a little bit into data governance and data use expectations. I wanted to highlight there a note for myself. All those get into new dynamics that we need to consider, making sure that as we change workflows and that is both the cultural and systemic change that we have a good understanding of how automation fits in or how we are going to use these algorithms that are part of artificial intelligence and machine learning and what that is going to mean to the future of health care delivery and interoperability and data exchange.

Lastly, we are always in the market for metrics and benchmarks about how we can measure progress. I think we have talked with HITAC a bit about this. But if there are specific areas that flow within NCVHS' purview or that you all have a greater finger on the pulse for, I definitely would be interested in having discussions about ways in which we can manage and better understand the industry progress overall.

With that, I think that is my last slide. Different ways to contact ONC. Different ways to get engaged. If you are not already signed up for our weekly Listservs, you can do that HealthIT.gov. If you want to give feedback or provide information or questions, if you have an information-blocking related complaint, you can access all that through HealthIT.gov/feedback. And then certainly, we are on social and LinkedIn and the like. You can track us down there as well.

With that, I flip off the slides and head back over to the main grid here. I am happy to engage in some dialogue now. I will turn it back over to you, Rich.

Rich Landen: Thanks Steve. That was an impressive distillation of a ton of a half of work and history and all that. I have one observation and I have an initial question for you. While we are doing that, the members of the NCVHS can start formulating their questions. If you have a question, use the raise your hand feature.

My observation is that looking backwards, the nation has gone from single digit or low double digit adoption rates of electronic health records back when American Recovery and Reinvestment Act was passed in 2009. Now, we are in over 90 percent adoption rates and that is primarily because of the meaningful use now Promoting Interoperability Program. That was a major enabler of the digital data exchange and ONC was of course the – along with CMS was the focus for accomplishing that. That was – essentially, that built the foundational infrastructure that was the enabler that was the sea change for the exchange of digitized data.

That, however, looking farther back – that was enabled, the whole adoption of EHRs was enabled essentially as an outcome and unforeseen outcome of HIPAA in 1996, which introduced the concept of national standards to the health care community. One event, ton of work done leads to another event sea change and this is getting us into today where we now have this electronic, this digital infrastructure in place that we are looking to continue to optimize to meet more and more of individual and social health, individual and societal health and wellness needs. Quite a history there. Your last comment is about the benchmarking and measuring success. I think that is one of the measures.

My question. Patient matching. You talked about standardizing of addresses and there is an RFI to which you got responses and will probably publish by the end of the year. But my question is is there a preliminary glance at what the industry commenters have suggested. Are we looking at a standard unique identifier as the solution or are we looking at a more algorithmic approach? Algorithmic then would combine name, data of birth, address, and other factors and do a probability type prediction of the correctness of the identification.

Steve Posnack: First, I will do a quick observation on your observation. I think you are entirely right. A lot of us have had pieces of paper, post-it notes where we have tucked into the pocket or we put on the chapter of the notebook like when we get here, this is what we are going to do. Now, we are like finally. Flip to that page. We have gotten here. There is lots of work to be done.

On patient matching in particular, those of you who may be familiar, we had a congressional request to produce a report and recommendations on patient identity and patient matching. That is in the works. And certainly, I will let you all know and send you all information when we actually publicly release that report.

That was work that we did – much of last year, as you mentioned, Rich, we did an RFI. We did some public workshops to gather input. As many of you know, given the 1996 HIPAA law, it did include unique identifier requirements for many and the prohibition is still in place although I know many stakeholders have been pushing Congress to make changes to that.

I think we have heard from a growing audience that they feel that having a unique identifier for patients would be helpful. There is a lot of split opinions in terms of whether or not that should be mandated at a federal government level or that it should generally be supported in a national infrastructure type perspective. But at the same time, I think there is general recognition that an identifier alone as helpful as it may be to make things more efficient is not going to be sufficient. It will likely be in a probabilistic environment in general even with an identifier if one were to be used.

Let us remember ecosystem wise the Medicare beneficiary ID shifted from the Social Security Number to now unique identifier for Medicare beneficiaries. The last I checked the Medicare beneficiary number was increasing year over year. There are a lot of people in the population that are going to have Medicare beneficiary ID and there are other pockets within Federal Government that also have IDs too. We are kind of in a mixed ecosystem right now where there are those IDs that are available. It is not necessarily clear how often the Medicare beneficiary ID right now is used to support patient matching for Medicare beneficiaries. That would be kind of an interesting area of national experiment where policy interventions are already taking place. Congress mandated that the Social Security Numbers be changed out. And now that data existed for some period of time. How are health care organizations making use or not of the availability of those identifiers?

That was a long-winded answer to a short answer of general sentiment that I have heard is patient identifier would be helpful, voluntary or mandatory mixed opinions and still likely to be in a probabilistic world even with one if one were to exist.

Rich Landen: Thanks Steve.

I see four hands up. Let us start with Nick Coussoule.

Nick Coussoule: Good morning, Steve. Thanks again for joining us today. I appreciate your feedback. I have an almost step-back kind of question. If I am looking at – I am asking what the administration's goals and objectives. You talked about metrics and benchmarks for progress. There are always process metrics that you understand how you make progress. But I am also trying to think of the outcome metrics. If we ask the administration three years from now or at the end of the first term, potentially eight years from now, for a second term without weighing into the political side of that, are there particular high-level outcomes that they are looking at and looking for that is helping to drive your work, but that also could inform us to help drive our work and activities?

Steve Posnack: I am going to give you this from my – Steve's personal take on how I approach this kind of step back question. I like to refer to this as interoperability people can feel. Looking at it across a number of different dimensions through that kind of lens in that regard. Put ourselves in the patient or caregiver mode. Is the health care experience or digital health, e-Health health care experience easier for me? Is it easier for me to access my health information? Am I observing my care coordination happening in a more efficient manner when I go to a specialist doctor, et cetera? Do they know about me? Do they have those updates? That is gets to some of the 360 feedback loops that we have talked about. There is a whole slew of experiences from a patient caregiver perspective first that we are looking at. Are there improvements being made? Maybe that touches on some of that metrics and progress discussion that Rich and I were just having.

And then if you look at it from the clinical perspective, do health care providers feel more empowered? Do they feel like they have better access to more information that makes them better at doing their job? That is a lot of what I look at from just emotional feel of interoperability. Can I easily request? And I know these are somewhat qualitative because it is on the emotional side of things. Can they easily request access to patient information if they do not already have it available to them or is it built into an automated workflow process? It is just there.

We see that in some cases with respect to opioid mandates as a specific example. Where there has been heightened provider frustration there has not been that automation to have the check of controlled substance use to that prescription monitoring program fed back into the EHR in this case directly to the health care provider. They do not have to log into a separate system and do all this stuff and the like. Those are things that providers feel a difference in.

Similarly, for the care coordination, I know that a number of health IT developers have built in integrated functions where they will use the roster that is currently built for patients going to be seen the next day. They will do those queries out for the nationwide networks to get that data back in.

CMS is actually piloting something called the Data at the Point of Care where for Medicare beneficiaries, if you go to a Medicare provider, they can submit that patient roster to CMS. CMS will respond back with the claims information from any other doctor that Medicare beneficiary has seen. That may fill in some of the information gaps that that new primary care, that new specialist does not have.

Those things are – getting back to my earlier retort, it is like when we get here, we want to be able to do those things. We are starting to get to those places, but they are not scaled nationwide yet. I think as we look especially from a Federal Government office and a national coordinator's office perspective, we do not want these to be pockets of success that are just in particular areas, a metropolitan dynamic or some other type of localized success.

We want to see the scale nationwide and everyone has similar benefits of the digital infrastructure. Those are a lot of the different dimensions that we would look forward for what success looks like in the future, certainly sprinkled in the equity and other dimensions that I highlighted as well, making sure that health IT use continues and algorithms start to get rolled out more and more that that is not creating new inequities or other challenges that we are going to have to put on the list of things to solve when we can deal with them upfront and have more proactive conversations about it.

Nick Coussoule: That is very helpful. I appreciate the distinction between – it is one thing to say I can measure it so I have 32 and I get to 33 and 34 is better, but also to be able to frame it in terms that we can understand on a more humanistic level that helps then drive the activity. It is encouraging to hear that as well. Thank you.

Steve Posnack: Absolutely. Just a note to react to your point there, I think all of us recognize that there are intermediate or incremental metrics and outcome stages that we have to deal with and use as a best proxy for how we see progress. A lot of it is volume. I do not know that – if we take e-prescribing, which is a great. I was going to wedge e-prescribing into Rich's history. e-prescribing is one of those

steppingstones to get towards broader scalability and awareness. NCVHS has certainly had a role in e-prescribing standards too.

I do not if more e-prescriptions volume-wise is a good thing or a bad thing. It just is. We do know that more is happening electronically and equally sometimes when we look at success, it may be that – and this is a very crude metric of success rate, and I know all of us talk about fax machines and how much we load them. We could ultimately say we do not want anyone faxing. Maybe the measure of paper-based transactions versus electronic transactions and the proportion of those like we want to see paper go down as much as possible. We want to see electronic go up as much as possible. But that does not mean that all of the electronic transactions are highly efficient and satisfying to the user. They could just be another frustrating version of the workflow that they have. It is just not paper anymore. Those a lot of under the covers or layers that you want to peel back to look at to say have we digitized a paper process. I do not know that declaring success on that is an immediate type thing.

Rich Landen: Next question. My co-chair, Denise Love.

Denise Love: I think Jim was before me. Do you want to go, Jim?

Jim Cimino: Okay. Thank you. Jim Cimino, University of Alabama at Birmingham. With regard to the question of data quality from electronic health records, of course we have this big urgency to get data, use it for research. But all the efforts that we do and we call them phenotyping where we try to figure out what is wrong with the patient based on 20 questions instead of just going to the record saying does this patient have severe COVID. Yes or no. Instead, we have to look at structured controlled data to infer things and maybe we are right 95 percent of time, which is good enough for machine learning.

Do you have thoughts about how we can improve the quality and quantity of data and electronic health records to support not just research, but also better patient care, better decision support? While at the same time we have this big effort under foot underway to decrease documentation burden. Any thoughts about how we reconcile those two needs?

Steve Posnack: That is a great question, Jim. This is one where – you can tell I am taking pause – consider my options here of how I want to start my phrasing. This is a multi-dimensional problem and there are tradeoffs like you were indicating that are associated with pushing in one direction or the other and having a full understanding of where the juice to be worked is squeezed in terms of how data is getting captured and collected and where in the stream or in the cycle that is being done.

I think there is a lot of work that we can do with the clinical community to get their take on how to improve this because they are ultimately the ones from our perspective that are going to bear the largest either burden or success as we are successful in changing some of these practices.

It also comes down to, as you all know too, an institution-by-institution kind of customization, different work practices, different work styles, and the layers of information needs that people have at a particular time.

I do not have – unfortunately, like I was bringing to you all too – reflecting in the evening. What would be great to bring to NCVHS? The level of data quality and how it is used.

But also, I think, to your point is how can you pinpoint the information that people need at a particular time immediately. We often hear as we have increased electronic health information exchange, folks are in awash of data, and they are not able to sort through the key points that they want. Some of that is not necessarily data quality issues. It is just I cannot rifle through all of these CCDAs, consolidated documents, that I have received from these national networks. What are ways that can help me process some of this data?

This gets back to my earlier remark to Nick. There is a transactional aspect. We are happy data is moving. But that happiness dissipates quickly sometimes. We are like, yes, the data moved. I know Jamie Ferguson and I have had long conversations about this. The data moved. It got into a mailbox. But then nobody checked the mailbox. What is the implication of sorting through some of those workflows and how data is actually used and put into practice and where health IT can play a role there? I know it is kind of a quasi-unsatisfying answer to your question. But this is truly an area I think you highlighted that is a lot of work to – it remains to be done.

Denise Love: Thank you. I feel my head is spinning. I am sure your day-to-day feels the same way. I am going to be a little contrarian just because I am kind of old school. I feel like right now we are at a point of two ecosystems. We do not have a data ecosystem. We probably have multiple. I will reduce it to two. I am kind of jealous and protective of the one ecosystem, which is our administrative population health data systems be they vital records, but we also have health care data systems like all payer claims, et cetera, a whole host of those. I want to say that they have taken decades to mature and establish. I am sort of worried about them.

These are data mostly that are collected locally. Data quality is set and enforced locally. And they roll up into myriad of streams as we know. How do you see the transition so that we do not – because it is not going to come from the electronic health record. That serves a point-of-care purpose. But when we are putting it together system wide, how do we preserve those data flows and yet modernize? I am struggling a little bit to see how that transition will work without breaking these I think precious data flows.

One example I used yesterday is opioids and mortality. Well, the deaths were a lagging indicator. But some of the states through their all-payer claims were seeing horrendous practicing patterns system-wide where there were locus' in the rural areas of certain practitioners providing prescriptions at 12 times the rate of some others. How do we preserve the data flows yet merge and converge and make it more timely and modernized? What laws need to – does HIPAA need to change? What is going to make it happen? You are the visionary.

Steve Posnack: -- call it visionary, but I appreciate that. I am here to give some vision perhaps as far as I can see. You are right. This is a multiple ecosystem dynamic. I do not know if there are layers stacked on top of each other and we are trying to figure out how you go vertically through those layers. As much as we would like to see sweeping change, I think all of us around the grid here in our experience know that in most cases it happens incrementally. As much as the head spinning may happen for me too in the office, a lot of the fun part of the work that we do and I would say was the intellectually stimulating and mission rewarding was doing a bit of data detective work that we did early on during the pandemic as well as somewhat fresh in my mind. If there was a particular data need, finding out where the actual

source was or where the hops were happening, looking at electronic lab result reporting and why certain days were missing or not from those data streams.

And equally, as you mentioned, the vital and health records and where certain information is being recorded and who the particular jurisdiction that may have the most direct oversight. Is it a state-related policy that is informing something or is it something that is coming out of a federal level? Is it something that CDC does or is it something that could be changed through CMS?

There is a mix of progress areas that we can make certainly from the high-level statement. Regulations that stay the same for too long often get overtaken by industry or changes and they need to get updated. That is a good thing. I think that is part of just a regulatory process is that if you had static rules for too long then they are not right size anymore for the industry looks because the industry keeps changing as we know.

If we look at the incremental change that we are trying to see, understanding where I think the best places or the industry is ready from a maturity perspective to change – again, I am getting less on the tech side and more on the policy and culture side of – we know just to give real specific standards example – Health Level 7 Version 2 transactions are the lingua franca of public health transactions. To expect everyone to change unless there is going to be some type of huge government investment is not a reasonable or practical expectation. Then how do you work with folks to identify areas that may not have been put on V2 and that they want to step into the electronic transaction world to say we think we can move to a better set of exchange modalities and what is available to us and how do we move everybody together.

I think looking at the points of the ecosystem that are ready to change first is one thing that we can do and that helps build success and build momentum for the bigger scale issues that we have to bring along. Maybe this is contrarian too. Or the point that they are at is perfectly fine and it is satisfying exactly what is necessary and the level of systemic investment has not yet reached a point where they have to move forward so long as the job is getting done and the data is necessary is kind of getting transacted.

That is probably where I guess I would stop. I am happy to have more dialogue there. It is a super important question that I did not give fair justice to.

Denise Love: I just think as the two committees, there is probably a lot of overlap to work through that transition and work through it carefully so that we do not compromise our health statistics infrastructure, but we can modernize it carefully. That is, I guess, the bottom line is we do not just leap without knowing what the implications are. I think the two committees should work together and maybe work out a roadmap there.

Rich Landen: Vickie Mays.

Vickie Mays: Good morning. Vickie Mays, University of California, Los Angeles. I am a member of the Full Committee and also Privacy, Confidentiality, and Security and I do not have a conflict. I am sorry I had to do that, Steve.

Rebecca Hines: Thanks for reading yourself in, Vickie. Duly noted.

Vickie Mays: Thank you. Steve, I loved your presentation. I want to store it at something you kind of threw in near the end because it is a big issue for me and that is talking about machine learning and then at another point you talked about equity. This issue of machine learning to me in the health care sectors is really one of the public trust issues. I guess it was about three weeks ago the Office of Human Protection – Protection for Human Subject Research actually had us come in and I was one of the presenters to think about what is one of the ethical issues that occur as a result of some of these algorithms particularly in terms of care and whether or not the IRB has a role. An IRB really – we really struggled with this.

But the bigger issue to me where we began to talk about in that discussion is whether or not there are standards for the use of algorithms in the health care sector that have to be subjected to things like some kind of metric around bias specific to certain populations.

I guess I am wondering where you all are in that and what your thinking is.

Steve Posnack: Absolutely. This is a fascinating area, as you highlighted, and one of those where often the usual saying goes – the cliché saying with a lot of colleagues here. The policy always follows the technology. That law is always lagging behind. In this case, we are trying to get ahead, like you mentioned, Vickie, of this is a new area, lots of investment from venture capital just all the way down to trying to make specific changes in the healthcare ecosystem. While it shows a lot of great promise, there are also a lot of these issues that are part of ELSI is an acronym like the ethical, legal and social implications. What does it mean if we start to bring in other data sources that have not traditionally been part of the health care treatment scenario like social determinants of health and how are we going to approach the data governance perspective overall?

Where we are today is I would say recognition that this is on the burgeoning issues list of policy trailing technology and starting to have more dialogue with industry stakeholders to get input and to figure out like you mentioned. Do we need to work toward qualitative guidelines at this point to say for those of you out there in the field, these are some of the areas that once you get past these lines, it starts to get really fuzzy, and you should know that you are getting into that fuzzy territory? And then equally, looking at understanding, again, I think, to one of my earlier points, just what data is being used, where it is coming from, and what some of those ethical considerations that maybe implicated. And just even highlighting that is a little bit of a decision flow to say if you stick within this set of data, these are the types of implications that you may be considering.

But if you start to broaden or one of the interesting scenarios that came up was that getting social determinants of health data from other non-health care sources and having those brought into the health ecosystem too so not even necessarily collecting them directly from the patient, but kind of extracting them out of publicly available data sources and the like. That turns things on the side a little bit. We need to figure out what that is going to mean. We are really at the early stages of identifying where we need to have dialogue about some particular issues.

This would be a great opportunity either offline or as part of committee-to-committee discussion. It is definitely one of those forefront issues. We very much welcome additional input on this.

Vickie Mays: I am going to suggest that you think about the strange partner, not the industry, but the government's own activities in terms of ethics so things like working with OHRP, things like how in the grant area, you could actually require as human subjects some discussion of anyone who is engaging in research in the health care sector on machine learning that they have considered what the downstream impact can be in terms of realization of some of these things.

Steve Posnack: Yes. Now, you are cooking.

Rich Landen: I am not seeing any other hands raised. I will put out a last call in the meantime. Steve, one more question. In your response to Denise Love, you said one of the questions that you look at is how to move everybody together.

One of the things that we have been hearing in the Standards Subcommittee, not only back in our Predictability Roadmap, your roundtables and the listening session last week, is that the one size fits all. That is a principle upon which HIPAA was predicated and that was by design, by recommendation from industry. What we are hearing is that no longer works.

For example, or what I am saying is under the HIPAA transaction standards, there is only one transaction or one standard for a given transaction and one version and one version only to any one point in time. When there is cutover, everybody with the exception of small health plans, converges to the new version on the same date.

What we have been hearing is that is not working for industry. My question is is ONC hearing the same. What we are hearing is probably a future environment where multiple standards or one or two options for any given transaction and multiple versions should be supported simultaneously.

Steve Posnack: Are you sure it is not time for me to go? I am kidding. It is a great question. For those of you that remember the colleague on the advisory committee circuit Wes Rishel, he had coined a term or he used a term – I do not know if he coined it in particular, not to give to much to his credit. Wes always said and it stuck in my mind, which he referred to as bilateral asynchronous cutover, a term I am sure you may enjoy. It is a good ritualism, as I like to call it.

We have experienced that across the time within our own rules just in terms of transitioning. You could call it like light switch policy. One day you turn on the light switch and the next day everybody is on this new thing.

I think we experience in other industries, as we look at it. I am sure everyone is probably on a different version of Wi-Fi in their current work from home situation right now. We are not all on the same version of Wi-Fi.

As we have seen industry's maturity or maturation in terms of if there are incremental updates to standard versions and they feel like it is effective for them to enable communication with the broadest group of partners to support multiple standards and that is cost effective because I think some of this is

business drivers as well. They want to move forward because certainly new standards get developed to support new business use cases and new business needs. If you want to engage with partners to take advantage of those new capacities and those new standards then you want to move forward and do that. And then sometimes you feel constrained or feel held back by needing to meet the regulatory level, which may not be again the policy – technology.

I think we are going to confront that with respect to FHIR adoption because we have just put in my world. We currently adopted a version of FHIR as a single standard Release 4 and Release 5 is coming out in the near future. We will have to confront this from a regulatory perspective as to is it sufficient, is it going to be satisfactory. Will the industry be able to tolerate and still support the level of interoperability that people are looking for in supporting multiple versions of FHIR or does that create too much chaos and confusion in industry and push people or keep people in or out of the market.

I do not have a single answer for you, but I would definitely say support for multiple standards has definitely increased in conversational volume at least from my perspective over my time here. I think it requires due diligence and, in some cases, support to consider that, provided that it is going to keep everybody moving in the same direction so whether or not that fits. I do not the administration has exercised as well. But if there are incremental changes that the industry can tolerate and support and, in some cases, there are networks.

e-prescribing may be a good example in that case, which I know you all have jurisdiction over. The difference between a script version … the script version … plus one may not be all that significant, but the rule says what the rules says. That is an area where the industry would be right in saying we can tolerate both versions.

Rich Landen: Thanks. For the sake of those listening in, I want to make it very clear that this multi-version support is something we have been hearing from industry. That is not saying that the Standards Subcommittee has made any decision about whether that is the right way or the wrong way or somewhere in between. Just be very clear.

Nick Coussoule: Rich, just to add on one piece to that because oftentimes we will use the term industry. It is such a broad term, and it encompasses so many different things from very large either provider systems or payer – single dot kind of practices and other things. Sometimes that creates a complexity because when we use that term, and it sounds almost like it is singular when it is frankly not close to being singular. I think that is some of the complexity Steve was talking about a minute ago.

Rich Landen: Thanks Nick.

Tammy Banks.

Tammy Banks: I am again taking Denise's track and looking at you as a visionary giving guidance as we ponder some of these big questions because I really appreciate the ONC and CMS interoperability rule, the timeliness that it came out and was adopted. I also appreciate the digital framework that is being created. And within any change, obviously, there are so many – it is such a huge impact standard no matter what industry it is used in because it is multi-purpose.

Just some of the thoughts that – and I am going to use industry in the broad stakeholder perspective is there are finite resources. Where do you put resources? And also, there is a current governance structure that we are used to in standard development processes, moving things forward, whether it be one version or multiple standards to meet a use case. What do you see and again this is purely a visionary question, not leading anybody's thinking anything – you see the impact on HIPAA and the related regulations as it relates to the new type of interoperability and digital framework? Where do you see us going to get to that, not just administrative and clinical convergence, but actually interoperability convergence?

Steve Posnack: Yes. Absolutely and in two minutes. One other point on the multi-version - had the benefit of having my brain finally fire synapse there. The other thing that is worthwhile to consider is who needs to do the multi-version support. Is it the clearinghouse that needs to do it or Tammy, your point in terms of time and resource investments? Is it all the health care providers? Can they be on three or four different versions that work for them and then someone else handles the complexity? Where the complexity is handled, I think, is really important in terms of multi-version support.

Along those lines, a lot of people like to knock HIPAA and the privacy rule, in particular. I think the security rule has aged quite well. It was designed to be scalable and flexible. There is always guidance that can be provided.

There are definitely some pockets of the privacy rule. I know our colleagues at OCR had put a proposed rule about asking for adjustments and making some adjustments. Again, the ecosystem changes and where there are opportunities within current authorities to address those changes as a regulator, my regulator hat on, those are things that we should be willing to look at and take feedback from industry on.

Now, if folks want non-covered entities to be covered and behave in certain ways then at times that requires statutory action. You may remember, we worked on a non-covered entity's report that got published many years ago that is a Report to Congress. That is an ecosystem where health data fill in the misunderstood category. Health data is going in many different places. Equally, health data starts outside of the HIPAA paradigm and floats around in many different ways.

In a broader sense, as we always go back to, HIPAA is about who, not what. That is from a very colloquial way of starting of your covered entities and business associates. And then if you are outside that paradigm then the rule set changes dramatically, depending on if you are in California or you are not in California and all those variations that exist.

I think there are definitely opportunities where there could be improvements from an interoperability perspective, from a patient experience perspective. One of the things just from updated as not like my personal take, but as what we heard more of is that we have enabled through health IT adoption and this is like you follow along this stepwise pathway of when we get here so that page in my notebook. We got health IT adoption.

We have clarified HIPAA rules and access to laboratory data and all sorts of things that enable patients to get access to their information on their own accord. People have deployed portals. And now there are

third-party apps that allow us to get access to our information. And now, people are actually doing that, perhaps not at the rates that we would like yet. But they are seeing things that are wrong.

You can look at the patient experience for requesting a correction or amendment through their health information. It is one thing that is being pursued in the HL7 standards development organization for how to improve that process, how to make that work.

I think as we look towards certain areas, we would be like no brainer. When people get more and more access to health information, they are going to be in a good position to say actually I do not have this allergy. I do not know how this information got in here or there is some other thing that got crossed up or the patient matching – they go all the way back to the beginning. Two data sets got merged together.

The quickest – that happened to my mom on paper. The easiest thing for her when she told me that story is they literally took the two file folders, and they were like is this you. No. All right. It went in the other person's folder. Doing that electronically is a lot more complicated in this case. There are some things when you move digitally that get a little bit more challenging than with the paper analog.

Certainly, I think the department is open. I know my colleagues at OCR are always open to feedback about changes that may be necessary to the rules and that is obviously implied their proposed rule that went out.

As the industry evolves, I am always of the mind and – on the ONC side is making the regulations work for industry. We are not here to come up with just obscure rules that are difficult to understand and difficult to work. We are doing a lot of that on the information blocking exceptions, to make sure that people understand where their compliance obligations are and issuing FAQs and keeping that regulatory engine going. That is just part of the process. That is not a bug. That is a feature of – as we started to say, it is a feature of engagement and actively working with the industry on the regulatory paradigm.

Rich Landen: Steve, thank you so much. We are at the end of our time and I know you have a major commitment.

Steve Posnack. I do not want my folks to get nervous.

Rich Landen: We appreciate it. We look forward to continuing our conversations with ONC and HITAC and we do appreciate all the information that you have challenged us with this morning. Thanks much.

Steve Posnack: Thanks very much, everybody. Take care.

Rich Landen: Nick, Rebecca, I think we are ready to move into Denise's section on Convergence 2.0 and the listening session. Is there anything that either of you need to say before we do that? All right. Denise.

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Denise Love: Okay. It is just before break. I am sure everybody is just ready to move quickly.

Rich went through this this morning. Our former or initial workplan was built around the Predictability Roadmap, which really focused on some compliance use of standards and operating rules and process and regulatory improvements as well as the acknowledgment of the ICAD or the administrative and clinical data convergence and interoperability. This is just the foundation of the standards work, but we recognized that much has changed. As we develop our workplan going forward, we needed to know what has changed and how much.

The Subcommittee – to find out how much has changed and what should be our priorities, we acknowledged that our workplan needed to be built around an understanding of the ecosystem as it stands today. The Phase 1 of the standards work is and has been to assess the current health data standards landscape. We will hear about the listening sessions that was composed of both written comments, request for a comment, and a daylong hearing. I think there were 30 organizations that submitted comments and many individuals.

The Subcommittee will be analyzing the listening session information that you will hear about here in a little bit, identify issues and opportunities, and solutions and develop that workplan for Phase 2 based on both the Predictability Roadmap work that you saw on slide 1 and the listening session input that we are gathering right now. In Phase 2, we will refine these recommendations, consult with the Full Committee and industry to develop standards, regulatory enforcement recommendations, highlight convergence opportunities that we just talked about with ONC and HITAC, and identify other opportunities related to HHS priorities.

Additional topics came up in our discussions with the Subcommittee. We do not know exactly how they are going to fit in until we analyze the listening session. We clearly are hearing a lot about FHIR and APIs and interoperability.

We do have our eyes on all payer claims databases and their standard common data layout as they work with Department of Justice and HHS and Treasury on consistency of reporting for ERISA plans. But there is also the exchange of social risk data that is sort of outside of the typical HIPAA transaction.

We will be looking at conformance and enforcement improvement opportunities and exceptions and alternatives and health data flows again. We are hearing a lot more and more beyond the HIPAA and HITAC. Social structural determinants, public health, pandemic, patient consumer-driven data.

I just went through those slides to kind of level set where we have been with some of the Predictability Roadmap and interoperability. But today's focus – we want to highlight some of the findings from our listening session and request for comments.

Again, we have excellent input. And what I will tee up right now are just highlights from the panel's sessions. But the input that we have gotten – and I will go through each panel, and we will have the moderators update some of the high-level takeaways from each of the panel sessions.

Just for those of you not on the Standards Committee, we did issue a request for comments, released in June 2021 with four questions. There are my 30-plus letters received to date and they are still coming in. I think we have received a few more.

We asked them in the RFC how can data sharing be improved. I will not read the whole question. They are there for you. And what are the barriers? Are there any standards or use cases available that should be considered by HHS and NCVHS? We really wanted to understand how other industries have implemented, tested, and certified standards for data and exchange that might be considered for health care. What short-term, mid-term, and long-term opportunities or solutions do you believe should be priorities in the next five to ten years? The link on this slide is a link to the written comments if somebody is so interested if they have not done so already.

I was impressed with the quality and depth of these comments. It was a lot to wade through. And we still will be talking about this in the Standards Subcommittee in the weeks to come.

The themes. There were so many. These do not capture all. But without going through each one, there were some overlaps here with I think PCS, the Privacy, Confidentiality Subcommittee, and some opportunities to maybe as a committee talk about where that overlap is.

Public health and vital records came up. Social risk data. Support for the workflow. Just as we have talked in the last hour or so, many of these comments came through in the letters and in the listening session itself. Mobile apps, patient matching, you name it. Testing and return on investment for standards. That is a hot topic, and we will probably talk about that later.

What I will do is turn it over to each of the panel moderators to give their high-level takeaways and then we will come back and talk about where we go from here. The first panel, Panel 1, Jamie Ferguson. Jamie, I will just turn it over to you to give the takeaways.

Jamie Ferguson: Thank you. The focus of this panel was on coordination of standards across entire sectors of the economy and successful processes for standards adoption and implementation both in health care and success factors from other sectors.

We heard how US standardization works under the National Technology Transfer and Advancement Act and OMB guidance. We heard how coordination can be successful through standards collaboratives, panels, and workshops that bring together the public and private sectors in a neutral forum. This is not to develop standards and not to develop policy, but to determine how standards can support an evolving policy framework.

We heard some examples from other sectors of the economy such as how standards coordination has worked for dietary supplements, for unmanned aircraft systems, nuclear energy, but also an example from the past of the – actually, from earlier in ONC's history, the Health IT Standards Panel, which was active from about 2005 to 2010. Actually, that panel created a lot of the standards frameworks that are still used for most of the medical records exchange in the country today.

We heard that standards coordination requires dedicated resources and obviously standards development does too, but this was about coordination of standards that requires resources such as tools and meetings and staffing to ensure stakeholder participation. That stakeholder participation then is supported by measures and reports on the collaboration itself.

We heard that collaborations have to start with clear objectives and measures of success that then can be reported on throughout their life. Then we can identify standards issues and create roadmaps to solve the issues.

In health care, we have obviously some standards conformity assessments of systems such as ONC's EHR certification program or the FDA medical device program. But we do not have a lot of conformity assessment of information or data standards. We heard about the national framework of certification and conformity assessment. We had some discussion about the need for capability to assess conformity before attempting to enforce compliance particularly on the information and data standards.

We heard from FDA as well as the health standards collaborative about health care standards coordination outside of the HIPAA context.

We had a fairly extensive discussion about how standards frameworks can adapt the changing technology and can successfully manage transitions of standards on a timely basis.

We heard how that may require a different legislative framework. The FDA was an example that we talked about how they have an ability to recognize standards rather than adopting standards in regulation or by reference.

And then that actually came back in the closing discussion after all the panels where it was noted that this committee has a history of making recommendations to the Secretary, the need for legislative changes to further its work and make its recommendations work, which the Secretary then can request a pursuant to OMB Circular A-19. That was a very interesting part of the discussion, not just about the standards adoption process, but also about the specific HIPAA transactions as well. I think that is the summary for Panel 1.

Denise Love: Thank you, Jamie. I wanted to just reiterate that in addition to the request for comments, the 30 letters or more and 200 pages of comments that came through, we had the daylong listening session on August 25. I think I did not say that date where there were four panels. This is augmenting the RFC written comments.

I will turn it over now next to Tammy, who had the largest panel of the day and probably the most complicated. I will let you unravel that, Tammy.

Tammy Banks: Thank you. Good morning, everyone. I am pleased to report out on Panel 2 titled information exchange and HIPAA: present-day challenges and future opportunities. The panel was comprised of standard leaders and subject matter experts dedicated to driving standard work and bringing forward use cases focused on administrative burden reduction. Panelists included representatives from CMS, the National Standards Group, AMA, HL7, Da Vinci, Cambia, Cooperative Exchange, and WEDI. These presenters provided additional content on gaps in or opportunities for improving the adoption, implementation, and use of standards to accommodate the changing health information ecosystem that complements the plethora of thoughtful responses we received from the health care industry through the request for comments on this topic.

After the session, I was asked to report on two to three key takeaways from the session. As you can see, three takeaways turned into ten, which still does not give justice to the content-filled hour and a half. Keep in mind. We are still digesting the conversation and the responses to the RFC.

However, at this point, I would like to share initial review of the listening session. One point, not in priority order, is that there really needs to be greater coordination and collaboration between the SDOs to successfully drive interoperability. We heard of the good work of the Da Vinci project and X12 who were closely collaborating to ensure the administrative metadata utilized in the Da Vinci HL7 FHIR emerging standards, which includes the PA, is consistent with X12s as well as collaboration that was occurring between HL7 and NCPDP. Pairing emerging with existing standards and metadata will really allow us to leverage the technology investments that have already been made. We were very pleased to hear that collaboration and would like to see increased coordination between existing and emerging standards. This also includes the need for ongoing measurement of benefits and outcomes of these efforts to inform future opportunities.

We also discussed gaps in current X12 standards that included prior authorization and clinical data exchange, real-time pharmacy benefit transactions, and good faith estimates to the advanced explanation of benefits, which the industry and presenters listed as high priorities to meet the current regulatory requirements.

The conversation reconfirmed the need to test standards before adoption to ensure they meet the identified use cases, but also to ensure that the standards can be widely adopted across all stakeholders regardless of size or IT staffing.

There was significant discussion on return on – methodology and the challenges in collecting of monetary and non-monetary ROI to support emerging and revised standards. The conversation included an ask for HHS to consider publicizing requirements for ROI data needs and/or standard format that contains what should be included when attempting to compile this information to support future standards.

HHS was encouraged to support pilot standards – mentioned was the HIPAA standards and also the current HL7 FHIR exception for PA or other exceptions that are moved forward in the future.

The extended pace of the current standard adoption process was questioned. An increase in communication on the status of NCVHS recommendation as it relates to HHS priorities. ROI is mentioned before, and other requirements would be appreciated. This communication would assist health care stakeholders in their allocation of resources to meet national priorities within their roadmaps.

All entities that exchange standards must be held accountable to HIPAA transaction code set requirements through the extension of HIPAA to other entities such as practice management systems and other vendors. This would be similar to the extension that we find in HITECH to raise compliance accountability and allow administrative efficiencies to be realized.

Without all players being accountable to the implementation of standards and exchange of information, the value and savings from the widespread use of these standards is not being realized.

Two versions or models of standards could co-exist in use at the same time because system changes take time and data is pulled from different sources. For example, a different version of standards 5010, 8010 of X12 or HL7 and X12 standards to support a defined use case.

To tie these highlights together, partnership collaboration and increased communication is needed between SDOs, HHS and basically all stakeholders in the industry to meet the changing interoperability landscape.

Just like silos and data exchange will not work any longer, silos in the standard development will not be effective in bringing the vision of interoperability we have for post-pandemic America.

In follow up, I encourage you to become familiar with the standardization of information for burden reduction and post-pandemic America. You heard Rich talk a bit. It is basically known as Convergence 2.0 Project as we will take this information and consider how to turn it into actual recommendations for specific federal agencies, states, localities, and industry groups to collaborate and support of convergent goals.

We appreciate all your feedback and are enjoying our time reviewing all of it and also, we appreciate your support as we work through next steps. This is a large project and we really believe there is going to be some good opportunities as we work through your feedback.

Again, I just want to say thank you for the opportunity to share this preliminary report.

Denise Love: Thank you, Tammy. Thank you for referring to the scoping document. I think that was included in the eAgenda book, but also it is on the link online. It is a work in progress. But it is a little overwhelming when we think about all that needs to be done. Thank you for circling back to that.

Now, we will go to the next panel for Jim Cimino on the semantic harmonization panel of August 25 listening session.

Jim Cimino: Thank you. We were interested in methods for semantic interoperability, which we define as the ability of computer systems to exchange data with unambiguous shared meaning to extend it to the idea of semantic harmonization whereby parties that are exchanging information have a common understanding of the information so that the process of combining multiple sources of representation of data into a form where the items share meaning at a formal imputable level.

Of course, you can achieve semantic harmonization by simply all agreeing on one terminology that we all use for everything and that would be an implicit harmonization. But of course, we are not doing that.

We were interested in a number of different perspectives on what we might be doing with respect to semantic harmonization efforts to improve semantic interoperability. Do not get too hung up on the distinction because I will just flip all the cards and tell you it turns it does not matter that much.

Our representatives we had to listen to were from Kaiser Permanente, from the Office of the National Coordinator for Health IT, the National Library of Medicine, HL7, the American Medical Association, and SNOMED International. This slide and the next slide kind of summarizes the common themes that we

heard from the different speakers. Some of these points were made only by one speaker but seem to be sort of universally implied by one or more of the others. But some of these were also – these points were made by multiple speakers.

First is that functional interoperability, that is, the ability to really exchange data so that you can use it in a functional way, for instance, to be able to graph all the lab tests across multiple institutions on the same graph or use medication data for prescription writing or decision support is still lacking. But we are closing in on the data models, getting the data models the same. And once we do that then we would expect that functional interoperability would be achievable.

The consensus is that current exchange standards may be sufficient for semantic – to support semantic interoperability. We are talking about things like HL7 and FHIR and other standards as well. People did not seem bothered by the state of exchange standards.

There were no efforts to formally model the semantics or ontologies for harmonization. The idea is while some terminologies like LOINC and RxNorm and to a certain extent SNOMED, model the meanings of their term in formal ways, for instance, LOINC has a formal terminology for the things that are measured by tests and for the specimens and that kind of thing. It is not done for the purposes of harmonization. It is really just internal efforts.

The idea – most people said just use the same code – when we are doing drugs, just send RxNorm around. When we are doing labs, just use LOINC. That is how you solve the interoperability issue.

We heard from several folks that there is no need for new terminology. SNOMED, ICT-10-CM, CPT, LOINC, et cetera pretty well covered most of what we need and that maybe we can use natural language processing, LP, for the rest of the things that are not covered by those. That was an open question, but people are hopeful that that would work.

The consensus of the group was that manually curated terminology seemed to be the way to go. That is, adding things when they are needed. People will say this terminology is missing X. The people curating it, managing it, add X to the terminology and move forward.

The exchange with automated mappings where available. If we had mapping tables that we could create to send – say procedure codes that we use locally to CPT or what have you that we should use mapping tables; otherwise, exact text matching maybe sufficient for that and those crosswalks also are a way to go.

No one asked NCVHS to do anything other than support them and support what they are doing, support the status quo. Nobody said we really need deeper modeling of terminologies to achieve semantic harmonization in support of semantic interoperability. Please do that. Nobody said that.

There was no opinion that deeper modeling is needed. Just that brute force – what I call brute force methods, that is, manual curation, crosswalk text processing, lots of brute force methods will be sufficient. This was a listening session and that is what we heard. I am not sure we all agree that that is true, but that is what we heard from the listening session. I will stop there.

Denise Love: Thank you, Jim. I expect we will weave some of these comments from our panels into our discussion going forward. I do not know if that is good news that they did not tell us to do something or bad news. I am not sure how that translates.

The two Denise's, Denise Chrysler and Denise Love, co-moderated Panel 4. The purpose of this panel was to highlight insights of the exchange of public health, vital statistics, social service data as a part of a national standards strategy. We heard from our own Vickie Mays on the latest research, LaShawn McIver from CMS, Janet Hamilton from the Council of State and Territorial Epidemiologists and also the co-chair of the ONC Public Health Data Standards Taskforce, Shawna Webster from NAPHSIS, the National Association of Public Health Statistics and Information Systems and Vital Statistics, and Evelyn Gallego, Gravity Project.

The intent was to focus on some of the administrative and vital record systems that originate in payer and provider systems, which makes industry of course a key partner into collecting some of the data. We talked about standards are important, but we need a national coordinated system that incorporates workforce training, enforcement, validation, imputation, and disaggregation frameworks and purposeful uses.

Denise, before I go into the slide, do you have anything that you would like to add that I missed as far as the panel and the purpose, or do you want to circle back at the end to see what I missed? Either way.

Denise Chrysler: Let me circle at the end.

Denise Love: As you see here, we heard that both social and structural determinants of social risk data are needed to address social risk versus social need. One of the things that came out was your zip code may influence as much as your health and outcomes as genetics.

Collection and use of social service data is and will require interagency and cross-sector coordination because we need more uniform collection and appropriate access and use of the social risk data.

Data sources for administrative and vital records data originate in provider and payer systems, making industry key partners. We were really pleased to hear what the Gravity Project is doing in capturing social determinant data and putting that into the USCDI for the electronic health records. We are seeing industry taking this seriously and really looking for solutions.

We heard that a national coordinated system, I mentioned this earlier, that does not just address standards, but looks at the whole spectrum of use and how we use these data when we get them.

We heard that we need sustainable funding for the states on modernization, not just one-time infusions. We talked about revised reimbursement arrangements for public health.

We heard that SSA, Social Security Administration, will be distributing the death files in three years and some concerns about how those are priced, how that is governed and what HHS' role will be to look out for the public health infrastructure at the state level.

As usual, with anything on data, we heard about variation in access laws, collection laws across states. And the discussion really pointed to there needs to be some federal action. People are open to that. There are outdated laws that kind of embed those variations.

We suggested or in the discussion suggested master data collection law perhaps or some sort of federal mandate, recognizing states do vary in their own laws. But there has to be some more consistency and uniformity.

As we link more data sets, which is happening and will continue to happen, there is going to be more discovery concerns and protection guidance needed.

Denise, I know I missed some things. I will let you clean up.

Denise Chrysler: When it comes to data sharing as I think you already said, the other Denise, this panel really illustrated the challenge and the intersection between standards and privacy, confidentiality, and security and a lot of this does have to do with the variation in collection and access laws. Our panelists did speak to what extent standardization already exists. But still there is a lot of variation in what is permitted to be collected and what can be disseminated to community leaders so they can use it to improve the health of their communities.

And then it gets more complicated then when we talk about the social risk factors and the Gravity Project addressed that somewhat. If health care providers are collecting social risk factors and that would come under our usual standards for if they are collecting it from the patient or other sources that they are entitled to access. But then when we talk about directly accessing that data say TANF for WIC data or data from homelessness, management information systems then our challenge is just multiplied because of the variation in state laws and the variation. Some of these data sources are governed by federal laws, but variation between laws that apply to each different type of data or data source. It is our ongoing challenge and just brought home by this panel of –-

It seems to be the challenge I hear over and over again is how do we be able to achieve interoperability and deal with all of this variation because of so much especially in the public health context being governed at the state and local level.

Denise Love: Thank you, Denise. I really think that we heard from NAPHSIS especially is some engagement with NCVHS with the vital record system folks to watch how the future unfolds and insert some HHS leadership as some of the dissemination policies and laws change especially around mortality data. Thank you, Denise.

All of this is available to you. The Predictability Roadmap. If you forgot or if you are new to the committee, some HITECH suggestions on our convergence project.

As Tammy said, the project scoping document is online on this link and a recording of the panel discussion is also available on these links. You can go back and listen to the comments from that day-long hearing.

Where do we go from here? I am amazed at the Subcommittee on Standards and the diversity and the depth of experience just is incredible and every call – I learn from them. We will be engaging some more to finalize this analysis of input from the letters. We have mapped them into themes, and we will be meeting biweekly if not more through subgroups if we have to to go through each of the letters, each of the panels, and identify common themes, unique themes, and map them into our scoping document and workplan. And then we may have to identify which federal agency or state parties own some of the activities so recommendations that we find. We will be wading through that in detail. They are not final yet. I know that Lorraine is working on a pretty detailed spreadsheet and the committee has started looking at some of the initial topics. Again, we will be refining our workplan and bringing it back to the community and review our findings with CMS, ONC, HITAC, and others.

That is just our charge. Rich went over that this morning. I am not going to go over that.

I am going to turn it over to Rich and see what I have missed or if I missed anything and take it from here. We have the discussion coming forward.

Rich Landen: I think that was a great synopsis, Denise. Both Denise's, thank you and thanks to the panel moderators. Very informative session. A lot of work. Broad scope.

One of the things I want to comment on before we open it up for general Q&A and discussion among the members of the committee is that everything we heard is input from industry and that is critical. We will need to, I think, drill down and follow up with some of the commenters and panelists on some aspects.

But I want to emphasize that it is not – the public input is necessary, but it is really the subcommittee. As Denise mentioned, we have some really good people on there with a really broad set of skills and some different people with different deep expertise in different areas.

We will be analyzing. We will be deliberating. We will be consulting more. But it is not a process of saying we had six letters – to go left and three letters wanting us to go right. It is not a majority rule in that sense. But it is taking the input from the industry and then thinking about that through the lens of a larger and more long-term vision for what some of us call the health and wellness data ecosystem. Others call it industry. But it is figuring out how we solve problems, solve the current problems and position the country via recommendations to the Secretary, how we position the country for the road ahead and walking down a path that is as Steve Posnack described, takes us consistently forward in a measurable way where there is good value for the costs and effort of implementing.

I think the panel really provided a lot of good information and insight to the members of the Subcommittee. And it is going to be a challenge but a very rewarding challenge as the Subcommittee works through the themes and the topics and really gets down to saying who is doing what and what realms and how does this all fit together and what we come up with eventually is recommendations and a report.

Denise, unless there is something else that I missed, let us see who has questions or if other members of the Subcommittee would like to comment.

Wu Xu: I wanted to thank the Subcommittee on Standards. You have organized a wonderful hearing session. I do enjoy the participants and hearing all the panelists and discussion.

I have one comment on your next steps, number five. With the review findings from your work, I suggest adding CDC in there. You have CMS. Then the same thing on Rich's slide, your Phase 2 talk about the convergent for whatever your review with ONC. I suggest adding CDC in that bullet as well, because the convergent – we are including public health systems there. We need really bringing CDC in.

There is another thought about the social risk data sharing or connection or convergent. At least that is in human services. Human services agencies are in HHS. And also, in a lot of states either in their HHS or in a separate department of human services. Should we begin to bring those agencies in based on what data we need to share with them first? That is the part I was thinking of the data sharing standards and all the governance issues and privacy concerns. Just a thought.

Denise Love: I agree. My brain is trying to figure out how to bring them in. That can be a discussion going forward.

Wu Xu: For the opioid crisis work, we do work with SAMHSA. They are involved a lot on data governance sharing of who can see the data. That is one we worked closely. Then at the state level. Another way is actually we have another data sharing with children. Usually, they have a service database targeting children and disadvantaged families. I think we need for social risk data, we need also to prioritize working with agencies. This could occur at the federal level and also at the state level, local level like for aging services.

Denise Love: Thank you.

Rich Landen: Nick.

Nick Coussoule: Thanks, Rich. Just one comment. I think it is important – when we look through just a multitude of different areas and topics and feedback and potential action items, one thing I want to make sure we consider is what else is going on in the Federal Government as well as what is on their roadmap for the appropriate agencies to make sure that, one, it will help enlighten us to at least some of the current priorities are because that is where it becomes visible to those of us who are not in the agencies themselves, but also to try to make sure that we are going to create leverages as best we can with the things we believe as a committee and subcommittee are important along with what they have already said are important because it is either in their current activities or on the roadmap. Just to be cognizant where we can create leverage points. It does not mean that we are going to mimic that, but at least we can identify and make sure we create leverages where possible.

Rich Landen: Thanks, Nick. Good point. It leads me – I need to acknowledge the role of the staff to the Subcommittee, Lorraine Doo of CMS and Lorraine has done a ton of work along with Rebecca Hines and others in not only preparing for the listening session, but particularly in helping us track and digest the comments and keep us functionally focused as we walk through all the different themes.

In addition, and specific to Nick's – the comments that Nick just made, Lorraine keeps us very much apprised of activities in other sections of the Federal Government, specifically within CMS and HHS, but

also elsewhere and including helping us keep up with all the executive orders that impact on the area of the deliberation.

Vickie Mays.

Vickie Mays: Thanks. It is almost overwhelming. I am like Denise when Denise tells us about how her head is just about to burst. But it is like the richness of the information that you got was incredible.

I am really going to be a data nerd here and make a suggestion, which may not actually be feasible. But you really should consider whether there are resources for the committee to actually have either a qualitative specialist go through all those comments and pull all the things out or – again, I do not what the skill level is of the people who are around whether or not you can actually use machine learning, which we talked about, to help you. You have a really rich, but big pile of data. I just do not think the usual sitting and trying to summarize. But I think given that you want this to go to the Secretary in some format, amore formalized analysis if there are resources to do it, I would suggest that you all talk about and see if you can make a request.

And the other thing is – and this starts to get into the PCS, which is thinking about how to have some – the Federal Government gets in trouble for telling states what to do or the Federal Government can probably tell states what to do in terms of health data. In terms of this issue of the differences in confidentiality and privacy laws, coming up with some idea of what is the basic minimum, and that basic minimum is pretty important in terms of some of the cybersecurity stuff, the hacks. All of that might be actually feasible but that is where, I think, the two subcommittees will need to work together or have a committee of each group to try and work on that.

There is a report that I did a long time ago about the collection of data on race ethnicity and primary language. And what we talk about there was the difficulty of the differences in these rules by state. This is a very long problem that maybe because of cybersecurity we might be able to sneak in some kind of minimum standard that should exist around the data in terms of its privacy rules.

Denise Love: If I may, I was struck just in the discussion with NAPHSIS and how there was some openness to some sort of federal guidance solution to this very problem. I would love to probe that a little more and see where that sweet spot is, given that states are going to do what they are going to do. But I think they are looking for some federal solution here because states have such difficulty updating their standards locally. It is a big haul for staff and frontline workers. Anyway, there is a lot there and I agree.

Vickie Mays: But the timing may be critical because CDC just gave the $200 million out to the various jurisdictions to do updates and what have you. The question is is there any room in what they are asking them to use that money for to have this be one of those things.

Denise Love: Thank you, Vickie, and thank you presenting at the panel.

Rich Landen: Vickie, along the lines with your comment about the resources for the analytics, one of the things that we are exploring is a new possible availability of some software that will actually do what you are suggesting in kind of a machine learning type review of the written materials that we have gotten.

That is just something we are looking into. It is not a done deal yet. The thought is that great minds think alike. Thank you.

Tammy Banks: I am actually going to steal, Jim, one of our comments. Just to echo what Vickie said, we got such thoughtful really actually visionary comments that came through on those requests for comments and just really encourage those of you who are submitting these comments because they are really important to the thought process of where we go from here to try and create a summary page, make sure your thoughts do not get lost within the text because we try and read every word. But, again, because of the importance of these comments, I just want to give that suggestion to make sure your voice is heard and does not get lost in the narrative. I hope that is appropriate, Rich.

Rich Landen: You are spot on, Tammy. There are some levers that stood out more from others that really in a very pithy manner summarized the main thoughts and other letters. You had to read two or three times and figure out what the real key concerns were. Your comment is very much appreciated.

Vickie Mays: There was just one thing that bothered me that I heard from people who I thought they should kind of know better was this notion about OMB directives in the standards for race and ethnicity data. I want to make sure that standards understand that there is no prohibition about how far down the data can be collected. The tension is the way you have to report it up. The State of California does disaggregate data collection because we have to serve a diverse population. And when people see those five categories, they think OMB had something to do with it.

The important issue for standards to understand is that it is not OMB, but it is whoever the data receiver is like CDC or NIH or whoever decides they only want those five things. It is really important to start putting onus where onus needs to go around how we can have those data standards because OMB does not prohibit it. It is really time and cost. That is what has to be addressed is it is not a prohibition, but how we can use technology and what Steve was saying about how you can pull things from other sources and still not be violating someone's right to control their data.

Denise Love: Thank you.

Denise.

Denise Chrysler: Vickie just made a really crucial point, so I just want to join her in it. At least in my review with this area of law, my understanding – state collection, for example. States may need to report up to federal agencies, using the five racial classifications and the two federal ethnic – five racial classifications to ethnic federal classifications. However, that does not mean they cannot drill down to more specific groups by race or ethnicity. It is just the idea of being able then to roll back up into your broad categories so that you can make sure you can compare your data to other states or for reporting purposes.

Vickie Mays: Exactly. I think the issue is whoever says when you report up that they only give you the five. It is like why not give you all the disaggregated data and let the agency determine best – for privacy reasons to release it or not. We see this particularly of Native Hawaiians, Pacific Islanders. There are times we need to know it and there are times we cannot release it because it is too small. But that does

not mean then that somebody like CDC who is trying to determine directives and stuff. They have it internally to use in their guidance. They just cannot release it publicly to use.

I think we have to be really careful about these statements that people are making and who they are blaming. But it is like we have to rethink what the feds get and those reporting up what they use because then protected entities here are such that they can really have it all and make decisions for health planning. What they can release and share for others is a little different. There is protection of health and there is protection of data. Those two things may work differently.

Rich Landen: Good points. Other questions? I do not see any. Let me just – next steps are the Subcommittee will be working on this project for a year. We will of course update the Full Committee regularly as a couple of conversations have indicated. There will be ongoing interactions with the Privacy, Security, and Confidentiality Subcommittee and it would be a good process.

Ultimately, we will bring forward to the Full Committee our recommendations for a report out. I am assuming although it is a potential. I am jumping the gun here with assumption. Assuming there will be some recommendations made and those of course will be presented to the Full Committee for discussion and hopefully blessing.

No specific timeframe. Our work agenda of the Subcommittee in the near future will be to flesh out that process and develop a timeframe. I would think that at our next Full Committee, we will have an update that will have some more specifics with timeframe and deliverables.

Denise, anything you would like to add?

Denise Love: No. I think we have covered it and you will be hearing more about it over the next few months.

Rich Landen: As always, those of you who are not members of the Subcommittee on Standards are more than welcome to participate if you have a particular interest in any of these threads or themes. By all means, just let Rebecca or Denise or I, know and we will make sure you get the notices of when we are meeting and the agendas.

With that, thank you all very much. I will turn it back to Nick.

Nick Coussoule: Thank you, Rich. I think we will find the committee members are sometimes short of time, but never short of opinions or insights. That is always welcome.

Rebecca, can we move to public comment?

Public Comment

Rebecca Hines: Sure. I think that is fine. Thank you for bringing up the slide. For all of you listening in, this is now the public comment period. If you would like to make a verbal comment on Zoom, click raise your hand to have your audio unmuted or just put a note in the Q&A so that our Zoom team can get you an open line. If you are in on the phone, press *9. And of course, you can always send a comment by

email to the address there, NCVHSmail@CDC.gov. I see we have one. Greg, do you want to take it away? We have one person so far in the Q&A. Heather McComas, please. Heather McComas is in the Q&A. Can you elevate her to an open line?

Heather McComas: Hi there, everyone. I am Heather McComas from the American Medical Association. Thanks so much for the opportunity to comment today and also during the listening session last month in August on behalf of physicians and the patients that they serve.

As we heard this morning from the Subcommittee kind of recounting the listening session, it was a really much needed opportunity for different stakeholders to provide their perspectives on what is and is not working correctly in the current interoperability and standards health care landscape.

A clear message emerged from the listening session. The time is now to address unmet business needs in our industry. The AMA could not agree more. America's physicians and patients deserve technological solutions that reduce administrative burdens and support the delivery of high-quality, efficient care.

There was overwhelming consensus during the listening session in the hundreds of pages of written comments received from many different organizations that the Subcommittee should follow several fundamental principles as it considers solutions to standards and interoperability challenges to support the delivery of high-quality efficient care.

First of all, we must avoid disrupting systems and processes that are currently working in the health care system. Said another way, do not break what is working with existing transaction standards and operating rules.

Similarly, foundational terminologies and code sets will continue to play a major role in supporting patient care, meeting business needs, and health information interoperability. As Jim indicated earlier this morning, neither panel participants nor public comments identified or indicated that existing terminologies or code sets are impeding semantic harmonization.

Any changes in transaction standards and operating rules must be rigorously tested and show a return on investment before being recommended for adoption. ROI is not solely about money, but also time, opportunity costs, and improving the quality and efficiency of patient care.

As we heard from Steve Posnack earlier this morning, electronic transactions may not be efficient for the end users, and we really need to figure them out before we recommend them for adoption. Importantly, small and under-resourced physician practices must also realize an ROI. Hundreds of thousands of physicians work in facilities much smaller than highly esteemed facilities like Kaiser or Mayo and their needs must be considered as well.

As we heard during the listening session from the CMS Division of National Standards, any recommendations for changes in transaction standards and operating rule regulations must be supported with data in the public record, illustrating successful testing and return on investment. And, finally, to ensure the success of any recommendations, it is critical to include and carefully consider feedback from the right stakeholder throughout the process.

Again, as Steve noted earlier this morning, the end user clinicians who use these technologies are the ones who are either going to suffer or realize the benefits of them. It is really important to get the clinician perspective in all these decisions.

Considering these consensus principles, the AMA urges the Subcommittee to prioritize the following critical unmet business needs for patients and physicians. NCVHS should recommend transaction standards to support data exchange between providers and payers of all types for medical services and prescription drug prior authorizations. NCVHS should recommend adoption of the transaction standards for real-time prescription benefit technology that integrates with all electronic health record systems and provides accurate information for all drug plans and patients.

NCVHS should study, evaluate, and recommend a transaction standard and/or operating rule that addresses the good faith estimate and advance explanation of benefits requirements of the No Surprises Act.

Finally, NCVHS should recommend standardizing rules of data submissions to reduce the burden on physicians and streamlining compliance with disparate payer billing rules and requirements.

The AMA greatly appreciates the opportunity to provide verbal comment and intends to follow up with a more detailed comment letter to the Full Committee.

We commend NCVHS for undertaking this ambitious and critically needed work and stand ready to further assist in this effort. Thanks so much.

Rebecca Hines: Thank you, Heather. Any other public attendees would like to make a comment to the Full Committee?

Greg Richards: No one so far.

Rebecca Hines: Given that Heather was successful, I think the silence will suggest that we can bring the public comment period to an end. If somebody was trying to make a comment and was technologically challenged, please email me. We will give you an opportunity after the lunch break here on the East Coast.

Nick, are we ready to adjourn temporarily for lunch?

Nick Coussoule: Yes. Thank you, Rebecca. We are a little bit ahead of schedule, which is unusual, but welcomed because we have a busy afternoon. Right now, it is about 12:40. Why don't we adjourn until 1:30 so we can get started a few minutes early?

Rebecca Hines: I do not know that our 1:45 person will be available at 1:30. If you want to do something else at 1:30 --

Nick Coussoule: That is what I was going to suggest. Why don't we come back as a committee at 1:30? If Sharon is able to start early, that would be great. If she is not then I would suggest that we start with the

PCS follow up because we have some, I think, people timing restrictions later on in the afternoon. If we can get started with that at 1:30 that should allow us to make up a little time for this afternoon.

With that said, we are formally adjourned until 1:30. Thank you all for the great work this morning. Really good stuff. We will look forward to talking to you all in a little bit.

(Lunch Break)

Rebecca Hines: Nick, do we want to go ahead and start off our final stretch of the two-day meeting?

Nick Coussoule: I believe we do. We have a couple topics carried over from yesterday that we'd like to get to first. I know we have Sharon Arnold coming in in about 15 minutes, but it gives us a little bit of time to review and continue the discussion we were having with the PCS group in regards to the feedback from their prior meeting from a year ago and potential topics, so I guess I would like to turn it over to Melissa and Jacki to kind of continue that discussion with the subcommittee, or I should say, with the full committee.

Melissa Goldstein: Thanks, Nick. I am going to pull up a few slides. It's the same slide deck that I showed yesterday, but it's just really to focus the discussion on some potential topics where I thought the discussion coalesced a little bit yesterday: the idea of vaccine status passports, exploring the idea, perhaps standards, guidelines, for that type of information sharing. The ideas of long-term maintenance and use of data, the lifecycle of public health data collected in an emergency. What are we going to do with all of this data?

The topic of all of the waivers. We heard some public comment about this yesterday afternoon. The notices of enforcement discretion, the waivers granted for various specific purposes. Evaluation timeline. And more about the waivers, data collection and vital records. I know we focused on this a little bit. Are we getting the data? Are states and localities actually sharing the data? Are they hesitant to do so? If so, what incentives and/or barriers, how could we facilitate that?

Standards for the detail on what data should be shared. We had some of that discussion before the break. Who does the sharing? Who does the minimization? At what level does that happen?

And essentially these are just the topics that I thought we'd talk about, and then finally, if we do include a transmittal letter to the Secretary focusing on the hearing that happened, summarizing it from a year ago, what else might we include in that letter? What other types of things should we focus on at HHS now? Perhaps the idea of linkages of data, gaps where we could help, where other people are doing work, emerging ideas.

These are essentially the topics that we were talking about yesterday, and I really love your ideas, Jacki. Anything else you would like to focus on or raise for the group?

Jacki Monson: No, I think that sounds good.

Melissa Goldstein: Thanks. Questions, comments? Further ideas for us? Unfortunately, I'm not sure if Maya is actually here. Does anyone have anything they would like to follow up on from yesterday afternoon? Any new ideas? You can even tell us what you had for lunch.

Nick Coussoule: I think part of what we probably need to think about is the committee generally does better with what I'll call longitudinal things, rather than short-term things. So we need to think through some of these topics to understand if we can engage in both our ability to convene as well as have a long-term impact. That's the only, if you will, guidance or at least plug I would make is to be considerate of if there's something that needs sort of a public response in a very short time period, it's really not what we're structured for. So to make sure that we sort of take the long view on those topics to figure out what we want to focus the subcommittee and then the full committee's work on.

Melissa Goldstein: That is a good point. We're not particularly geared toward functioning quickly in emergencies.

Nick Coussoule: We're not an operating committee, right? So as an advisory committee, our job is to advise, and the process generally takes a little while. So definitely need to be a bit of a long view.

Melissa Goldstein: Thank you. That's very helpful. Are there any of the topics that we were thinking of that you think are more suited to long view? Analysis, recommendations.

Denise Love: Mine may not be well thought-through, and I'm sorry, but I go back to the data stewardship theme, because I think it's a domain where several things would fit under that, the sharing of data, the linkage, stewardship of combined datasets. And in public health emergency, what are some of the considerations or lessons learned. So I'm thinking of data stewardship report that we did some years back, it was helpful for those times, but maybe the principles are the same, but maybe they need to be refreshed or updated for data custodians who have found themselves in a fire swamp of politics and who's reporting and whose numbers? There are just a lot of things that fit under that rubric. So I just throw that out as a possibility.

Melissa Goldstein: Thanks, that is a good point. Several of the things we've been talking about have data stewardship penumbras, I might say.

Wu Xu: My comments also follow up with Denise data stewardship but in policy. For emergency management, at least in the States, we do have a law to say during that time, the government relationship, but now to have a detailed talk about the data relationship. In your slides, you mention emergency collected data, how long you keep, and who can access it. These are real issues happened locally. I know the real case, because the policy debate inconsistency or unclear, slow down the process for response. So I think from emergency data management, data-sharing policy perspective, there are some long-term needs and impact on there. So I really appreciate the PCS working on this topic.

Denise Love: Can I add one more thing that Wu jogged me on? Part of this data stewardship in an emergency thing might have some lessons learned from the Olympics in 2002 Utah post-9/11. And I remember kind of a SWAT team of all the agencies and the governor's office got together before the Olympics. We didn't know if there'd be anthrax or bioterrorism or anything else. But they put in place a decision-making process, interagency decision-making process and protocol, ahead of time, so as data

came in, it wouldn't be one person making the this is the truth and the source, that it would be a decision-making process and what datapoints and how they were going to make it.

I just thought this was interesting, because it may have had to shut down the Olympics, and one agency -- say, the health statistics or the biosensors, they saw a reading, were they going to shut down the Olympics? So what was the process, but those are the type of things that I think data stewards would benefit from, is having some guidelines of what should be put in place ahead of an emergency and how those decisions are made.

That jogged me from a thing in my past.

Melissa Goldstein: That is interesting, Denise. That makes me think of crisis standards of care. That it would be essentially data crisis standards of care. Thanks, that's a good example.

Rich Landen: You asked a question about what else might be included with the transmittal of the report, and thinking that the session is already a year old, the world has not stood still. So when we do the report I'd suggest that we call out anything that we know has changed from whatever status it had at the time that we held the session. So what's different now than in the report? And then I'd say based on our analysis of the report, maybe a list of national priorities to pursue, and then finally, of the priorities we identify, which we, NCVHS and PCS, will be pursuing, and which we can suggest the Secretary assign or monitor from others.

Melissa Goldstein: Thanks, Rich. That is a nice structure. That's a nice outline, thank you.

Valerie.

Valerie Watzlaf: I was also going to mention about the data stewardship part, and I think we had -- there were two, Chicago testimony on the lead exposure, and then the other one from the Maine Department of Health. So I think those could be good case examples that we could refer back to, and then look at some of the gaps as well. And then don't forget the part, I think the public trust could also fall under the whole data stewardship theme as well.

Melissa Goldstein: I agree. Thanks.

Vickie.

Vickie Mays: Thank you. I was just going to talk about the public trust and talk about building a bridge of public trust, because in an emergency, what we see is that people not sharing, not wanting to do things, often has to do with a distrust. So the public trust piece should be something that's worked on all the time, and then it has some kind of communication plan that then when the crisis part hits, and they have to go find this whatever we're going to give, a book or something, about data stewardship, that they know to do messaging that makes sure that they share with people what the data protections are.

One of the things I think for us in terms of thinking about data stewardship, is that I don't think that we're bringing enough people to the table, and this is building on what Denise is saying. When there's an emergency, there's a very unusual group of people that start being in charge and making decisions.

So, it's Homeland Security, it is FEMA comes into town. And I hate to say it, it's like do what you need to do and apologize later, is what we see in terms of some thing, and people will say I didn't know that that was a rule, I didn't know that I had to get permission from this entity over there.

So I think what we really need for this as an emergency issue, is to remember the most critical people who come to the table and whose authority almost usurps almost everybody else. Homeland Security, FEMA, and even to think about the White House, in terms of the edicts that they issue as well.

Melissa Goldstein: Interesting. An analysis of the stewardship in terms of the players and the operational, how do we all work towards the same goal, remembering overarching principles.

Nick Coussoule: I just want to add onto that, because it is less about a criticism of the immediate actions that are taken, which I think most people would say I get it, go try to fix, deal with it and address -- but more about what kind of preconditions, things can we set up in advance, structurally, such that as it plays out we make sure we've got it covered. I think that's sort of what I hear Vickie talking about.

Vickie Mays: It is like waivers, for example. Do we say okay, you put a waiver in place, but it has this thing that follows it to see where the data goes, or that, yes, you can have these waivers, but you've got to report back once a week or something, to make sure there's no distrust or mistrust that you're creating. That's exactly what I was saying. What's different about this is that this is not just data stewardship, but it's data stewardship in an emergency, because there's a whole other layer that goes on. So I would almost want to call it out from the regular data stewardship to it's data stewardship under declarations of emergencies.

Melissa Goldstein: And like Denise was saying, an evaluation of the principles. The principles may be the same; they may apply differently during different contexts, and an exploration of that would be very interesting, I think.

I think we've used up our time, and we need to move onto another section. Nick, I will pass it back to you. Thank you for adding some time onto our discussion.

Nick Coussoule: Thank you, Melissa. I think we are now coming to a section where Sharon Arnold, so I will turn it over to you.

Health Equity Update & Committee Discussion

Sharon Arnold: Thank you very much. A pleasure to be back with you. I had promised to come back to you to talk about the ways that the committee might be helpful to the department around collection of data to support health equity. So I want to first talk a little bit about some of the activities that are going on around the department, and then propose a series of questions that we think that the committee could be helpful in addressing, and then maybe have some discussion.

I think it's obvious that achieving more equitable health outcomes relies on data, both demographic data to assess differences among groups, as well as data to understand the drivers of health inequities, such as social determinants of health. In both of these areas, we have some of the necessary data to start understanding and addressing the health disparities, but there are significant data gaps.

The importance of this work is emphasized by several recent executive orders issued by the Biden-Harris administration, including an executive order on ensuring an equitable pandemic response and recovery, ensuring a data-driven response to COVID-19, advancing racial equity and support for underserved communities through the federal government, advancing equity, justice, and opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders, preventing and combating discrimination on the basis of gender identity or sexual orientation, and organizing and mobilizing the United States government to provide a unified and effective response to combat COVID-19 and to provide U.S. leadership on global health and security.

First, there's an increasing awareness of the lack of routine data collection on sexual orientation and gender identity, and the importance of these measures for understanding health equity. Although OMB has long established guidance for collecting data on race and ethnicity, there is no OMB guidance for data collection on sexual orientation. As a result, many HHS data sources do not collect these data, and among those that do, there is significant variation in how they are collected.

Second, there's growing interest in assessing social determinants of health, but not much consensus on how to do this in a consistent way. Across HHS data sources, there is wide variation in the extent to which data on various social determinants of health dimensions are collected, and the questions and response categories used to collect each element.

There is a range of recent and ongoing activities across HHS that are working to address these challenges. I'm going to discuss a sample of these. There are many. And these include adding new questions to existing data collection; the development and testing of relevant new data collection methodologies, instruments, and standards; facilitating the use and exchange of data related to social determinants of health; analysis and public reporting of health inequities, including disparities by demographic group and association with social determinants of health; and many taskforces, committees, and working groups focusing on addressing one or more aspects of these challenges.

Some examples of new data collection related to sexual orientation and social determinants of health include the recent or upcoming addition of social determinants of health modules to BRFSS, PRAMS, U.S. Diabetes Surveillance System, the National EHR Survey, MEPS, NHIS, and HINS. IHS has recently added sexual orientation to their EHRs and trained staff to voluntarily collect this data. IHS also added social determinants of health mapped to ICD-10 Z codes to their EHRs.

CMS has finalized payment rules for data collection on race and ethnicity, preferred spoken language, health literacy, transportation, and social isolation, in all post-acute settings, and implementation of this data collection has been delayed due to COVID-19 public health emergency, but there is interest in kind of getting that going again.

There are examples of new data collection methodologies, instruments, and standards, which include a CMS-developed and implemented the Accountable Health Communities health-related social needs screening tool. The National Institute on Minority Health and Health Disparities added 19 new measurement protocols for social determinants of health to the PhenX Toolkit.

ONC is spending HL7 for social determinants of health standards development. HHS is involved with the Gravity project, which is a multi-stakeholder public collaborative creating consensus-driven data elements and use of existing systems like SNOMED to harmonize social risk data for electronic health information exchange. And the ONC's standards advisory now includes social determinants of health. ONC is expanding U.S. Core Data for Interoperability to include both sexual orientation and social determinants of health.

Some examples of efforts to facilitate use and exchange of data related to social determinants of health include AHRQ, which built a consolidated set of national standardized databases on valid and reliable small-area level social risk factors. ACF developed a toolkit to clarify confidentiality rules in an attempt to limit impediments to data sharing and to help address social risk factors, and ONC is developing social determinants of health information exchange and social referral toolkit.

Some examples of analysis and reporting of social determinants of health and health inequities include CDC and Office of Minority Health developed the Minority Health Social Vulnerability Index. AHRQ's annual National Healthcare Quality and Disparities Report presents quality of and access to healthcare as well as disparities related to race and ethnicity, income, and other social risk factors. And CMS Office of Minority Health has posted disparities and performance among Medicare Advantage plans by race, ethnicity, and gender and has developed an interactive tool mapping Medicare disparities using an equity summary score that can be stratified by race, ethnicity, dual enrollment status, age, or gender. And HRSA produces an annual health equity report including trends in health disparities and improvements in health equity.

Some examples of relevant taskforces, committees, and working groups include the COVID-19 Health Equity Taskforce, which is tasked with providing specific recommendations to the President for mitigating the health equities caused or exacerbated by COVID-19 and for preventing such inequities in the future.

The final report will address any ongoing health inequities faced by COVID-19 survivors that may merit a public health response. It will describe the factors that contributed to disparities in COVID-19 outcomes, and it will recommend actions to combat such disparities in future pandemic responses. There's also an interdepartmental health equity collaborative led by the HHS Office of Minority Health, which convenes a data workgroup to identify existing policies and practices for improving access to data and use of data in support of policy development.

This group has produced a compendium of federal datasets addressing health disparities, a free resource of publicly available data relevant to research and programs that aim to reduce health disparities. And the HHS LGBT Coordinating Committee includes efforts regarding data collection measurement. The executive order advancing equity, justice, and opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders established in HHS a President's advisory commission on Asian Americans, Native Hawaiians, and Pacific Islanders, whose mandate includes advising the President on policies and practices to improve research and equitable data disaggregation regarding these communities.

And there are many more informal groups within HHS focused on disparities and social determinants of health.

But amid this landscape of all these activities, there are some notable holes and some areas where we think the committee could be really helpful. Our potential ask for this committee is to focus on analysis and recommendations around the collection of sexual orientation and gender identity and social determinants of health data. We ask that you consider the following types of data: survey data, administrative data, and clinical data, with a question about whether these are the right kind of chunks of data, or if there are other definitions that we should consider.

We're interested in specific domains of sexual orientation and social determinants data that should be collected by data category, including prioritizing among domains, in the case that limited data can be collected. So, what are the most important datapoints that we should think about collecting systematically?

We're very interested in best practices for how these data should be collected, including guidance on specific data elements, data standards, the order of questions, and any other guidance regarding options or alternatives to improve our ability to improve equity.

Finally, we're very interested in recommendations about specific privacy considerations, both for the collection of sexual orientation and social determinants data in each setting, as well as specific privacy considerations for the potential use of sexual orientation and social determinants data, such as administrative use, for example, program enrollment, clinical use, and research purposes.

This is a lot, in terms of the scope of what we're particularly interested in, and I would welcome discussion, feedback, questions, with the committee, about whether this is something that the committee would be interested in taking on, and whether there's a specific focus within these questions that you would particularly be interested in.

I think this is a big bite to chew, so if this was of interest, I would be particularly interested in how to stage this information so that there could be at least some recommendations that are submitted in a shorter-term, six or eight months, with other questions addressed over a longer period of time. So what is a long-term agenda that might consider these topics?

I welcome any comments or suggestions. Nick, I'll turn it over to you.

Nick Coussoule: Thank you, Sharon. It's an exciting topic. Clearly of interest to the administration, of interest to many of us, as we hear lots of different efforts going on, which I think is just indicative of both the complexity and the challenge associated with it, as well as the relative immaturity of it in the process. So let me open it up to the committee members for questions, comments, concerns, for Sharon, or just general discussion amongst the committee. So please raise your hand and I'll try to do my best to call on the folks.

Vickie?

Vickie Mays: What an ask. There's part of me that's thrilled, and there's part of me that has chills. Let me offer some comments, because you presented it very smartly, which is buckets are very important. Part of why I think we're feeling so overwhelmed about things being done in so many different places is that the needs are different. So what's going to happen in the healthcare sector versus what we're going to do on a survey and what we have to worry about in terms of privacy, confidentiality and security is just very different.

So I think the issue of buckets really would help the administration in general to think about the issue, and to me, that's almost like a short-term kind of thing, to point out what are the issues in terms of the context in which data is being collected, and then what is -- we were just talking about this earlier -- the data stewardship then requirements in that context. So I think that's one.

The other is -- how do I say this? -- I'm not sure that, there's a bucket that hasn't been really talked about, and that's the research bucket. It's one thing to be a survey, because you might have certain rules, but research that's done by, say, funded entities, you have a whole other set of guardrails that can be put on that data. It's almost like that needs to be thought about, because that has protection in terms of IRBs, and that gives you a whole other set of things that you can do much more creatively than in terms of some of the other. So I say add that bucket. I would think a little bit more, because there's some other hands up, and then I have another suggestion.

Margaret Skurka: I enjoyed the presentation. I always am interested in collecting data on SDOH. But I want to do that without burden on the physician, because if it's a hospitalized patient, the physician has to then document homelessness, inadequate housing, inadequate food, extreme poverty, low income. There's all of those codes are available in I-10, but the coder can't code them for collection unless the physician documents them. So the coder is climbing all over the physicians to get the complications and comorbidities and the primary condition and all of that. So we just need to think outside the box on the collection of the data without physician burden.

Sharon Arnold: I think about priorities, given that we can't collect everything, we shouldn't be collecting everything, can we come up with a set of priority variables or items that are the most important and we agree are the most important for limited ability to collect?

Nick Coussoule: Just to weigh in on the discussion, I think it does raise an interesting question, because you talk a little bit about both the collection as well as the use, not just the privacy but the use cases. And then we had discussions even yesterday, in regard to data linkage. So where do you collect this data, and how do you make sure that it can be applied, either across datasets or across populations? So I think there's some interesting, complicated questions that are involved in that.

Margaret brought up a really good point. But then the question is okay, how do I then still obtain and make use of it to inform policymakers and the decision. So I'm just thinking out loud a little bit here of the tentacles how me might even address something like that.

Sharon Arnold: I was just going to add that obviously there's a tremendous amount of work going on across the department on this, but as you can tell from my presentation, I think the work isn't as well coordinated as it could be, and I think one of the benefits of this committee is the ability to convene and

bring people together and provide an external perspective. So I have been talking about surveying the work that's been going on in the department and trying to get my arms around it, you can see why that's been so difficult. There's just so much going on in so many different places, at different levels. but I'm hoping that these set of questions, I think, is maybe larger than you might be able to do in the short term, but they're certainly work that might apply to each of the standing subcommittees, and there might even be additional work that could be done. There's such a wealth of expertise here. So we're very much looking forward to your contributions.

Rich Landen: Apologies beforehand. As Nick said, this is kind of brainstorming, so there may be a few nuggets here, but there's certainly going to be a lot of loose ends and unfilled gaps. In listening to the conversation, I kind of get the sense that we're looking at it from a traditional look, and that is that the only data collection sources mentioned have either been providers, as in Margaret's comments, and providers and the relationship then with coders, or the folks administering the surveys.

What occurred to me as a half-baked idea is many of the answers need to come ultimately from the consumer or patient. A person is not always a patient. So maybe we should think more in terms of patient empowerment, and what occurred to me is something like Project Bluebook, where if we can identify the data that we're looking for SOGI and SDOH and the rest, much of that data ultimately has to come from the patients. Why not get it from the patient directly? That's not to say that the patient, that every patient, every consumer, would be willing to provide it, nor is it saying that every individual in the country would understand what we're asking and give accurate answers, but somewhere between getting it from the patient or getting it from the patient in conjunction with the provider or with a survey administrator would get us good quality data and would also go a long way toward minimizing provider burden.

The challenges, of course, are how do we do that and how do we then integrate it in our interoperable system with the appropriate patient permissions, privacy and security. But again, the concept is something like the Blueland(?) project, would serve as somewhat of a precedent for doing it. Blue sky thinking, out of the box, maybe.

Denise Love: This is going to be multi-faceted problem, as we all know. That's an obvious statement. But I think when I think of the data sources, different data sources will be sources of the needed information. It's not ever going to be in one data source. But I think a lot of the data, whether it comes from the patient themselves or industry, again, I go back to public health, states and providers are collecting these data right now, in various forms, on the front line, daily. They may not be doing it the same way, they may not be collecting the same thing, but they are collecting it, and I also think that we may need to, as an industry, or segments of industry, think about changes in regulations to accommodate some these data collection laws on the front line are written decades ago, and they need to be updated.

I also think HIPAA would accommodate better capture of these data. These are little fixes. That's what I'm saying. It's not going to be one magic wand, but I think of -- I've long begged for the 834 enrollment data to be a transaction where you can capture that data from the patient, not in emergency, but at the time of enrollment. But that's just one example of maybe a fix, just a little piece of the puzzle, and in

the HIPAA 837 -- Sharon, I agree with you, I think we have little pieces of that puzzle that we can bring to bear.

I don't think there's one grand solution, though. I think it's going to take a lot of different people working on it. If we can get on the same page and work at it from our various data sources, that would be helpful. I think I'm rambling now.

Nick Coussoule: It's an interesting question about -- are we talking about how we might frame up some research and work, or how do we solve the problem? Or a little bit of both.

Sharon Arnold: I think what I'm expecting is, this is kind of a long-term agenda, and there may be things that can be addressed more quickly, and things that will take longer. But I think this is a multiyear set of questions. But I think the committee is well positioned to opine on this.

Tammy Banks: Sharon, thank you for bringing this forward and the thoughtful ask, even though it's ginormous. You made some really good points of all the good work that's occurring just within the HHS, as well, as we know, there's other activity that's going on in the industry. Maybe forgetting about solutioning at this point, and identifying who those key stakeholders are who are driving these initiatives and getting them connected and identifying the points that Vickie made and Rich and others, on what questions need to be answered, and point out some of that expertise. Because then we get buy in, and hopefully we can get these groups to move in the same direction, versus identify use cases that may turn out to be running counter down the road. Recognizing, again, each of these use cases is unique and may have a different solution. But was just thinking that may be step one, before we take a look at the how, let's really identify what's being done and the what.

Sharon Arnold: I completely agree. I think that the committee's convening power and ability to bring people together will be extraordinarily helpful in addressing this series of questions.

Nick Coussoule: Great. Vickie. Just as a reminder for everybody, if you're not speaking, please put yourself on mute.

Vickie Mays: One of the issues is that things are mobbing not just within the federal government, so as Tammy was saying about the agencies and what have you, the who in terms of the outside partners. I can tell you that academic medical centers are working as a group. There's the SIREN project, there's a couple of others in which, we have a committee at UCLA that is across our ten campuses, about how we're going to align, for example, social determinants in all of the clinics and things that we have across the ten campuses. And some of that will be in the context of things that are very Californialike, in terms of we will have disaggregated data more so than some other groups. So there's a lot of -- we have more undocumented people we're worrying about. So there are certain things that we begin to prioritize that has a lot to do with our context.

The other thing that has been talked about is the issue of what is the data that needs to be behind a firewall? If a woman is the victim of domestic violence, is that behind a firewall? It's similar to the way we put HIV/AIDS data sometimes behind a firewall. So there's a thoughtfulness about to just the collection but also kind of the context in which you're collecting and then who it is that going to have access to it, and that's going to vary tremendously.

I think the task, Tammy, of getting different groups together will be just like, I don't know, I have a sense of talking heads. If you talk to the clinical group they want one thing, and talk to another group, they want another thing. This is why I think we're having a hard time coming together.

So it may be that an early issue is to identify what are the best practices depending upon who you are? Are you a small community practice? Are you a rural area? So there are certain things that I think we might need to do first in order to get people to come together to realize that they can be different and that we're going to have some differences in what we see as important to collect and how we use it.

And I just want to say about the burden issue. For example, we're not talking about physicians collecting the data, we're talking about if a person is homeless, once that box gets checked, they get sent to social services, and social services really starts to fill out yet another kind of inventory that is based on not the healthcare need but the social needs. And that the social needs, so that we don't medicalize social determinants of health, that that then gets sent as a social need. So we're trying to staff up different aspects of our institution, and the different data collections would go with the needs, so that the whole burden is not in the healthcare visit.

Nick Coussoule: Thank you, Vickie. I didn't know if you were going to respond to that, Sharon.

Sharon Arnold: I think that certainly we want to understand kind of what is going on in the community, because if we're going to propose kind of federal regulations or have kind of guidance coming out of federal agencies, we want to make sure that we're consistent with what is going on, or if we're not consistent, there's a good reason, and certainly we know that there is going to be different data that's collected by different groups and for different purposes.

But at the very least, we should be thinking about are there common data elements that are necessary across all kinds of different settings and cases and we want the data to be kind of usable and transferable in different settings. So I think this is a huge ask, I know.

Nick Coussoule: If it were easy, it would already be done, right?

Sharon Arnold: That is right.

Nick Coussoule: Other comments, questions, from the committee members? Wu?

Wu Xu: Thanks for this ask, and it's very exciting. So you also, Sharon, you also mentioned what the committee can deliver six to eight months, short term. So I was thinking social determinants has a lot of elements of content. Maybe we can just focus on, as the first deliverables or test case, we focus on the sexual orientation. So the gender identities, focus on that issue, kind of the standard and privacy, all the -- just as maybe the first deliverables can be narrowed down the scope. Then we need to have -- this is multiyear project -- we need to have it phased out how to work it. That's my thought.

Nick Coussoule: Thank you, Wu. Other comments or questions from members?

Let me take one step back. I think this is a pretty exciting ask. I think it's an interesting topic. I do think it is something that the committee, it's lots of components of this that are in the committee's

wheelhouse, as you said, Sharon, as far as our ability to convene, our ability to bring together lots of different parties to talk about complex topics that are very much within the detail of the work that we do.

I guess I'd ask a little bit from a committee standpoint, do we have people that would be interested in working on this in the committee? If you can just raise your hand or say something like that, I think it seems clear to me that we'd have some interest in doing part of this.

So, yeah, I think maybe what I'll suggest, Sharon, is that we take it kind of offline into consideration through the executive committee and others to talk about how we might frame this up and how we might tackle it, and then we can have another discussion maybe at a soon-to-come executive committee meeting or something, say here's how we think we would attack this and what the scope and approach might look like, and then see if we were able to come up with something that worked for everybody.

Sharon Arnold: That sounds terrific. I really appreciate your interest and look forward to hearing your ideas.

Nick Coussoule: Thank you, and we appreciate you bringing it forward. We are an advisory committee and we're trying to make sure we're meeting the needs of the groups that we're trying to provide advice to. So it's always helpful to get priorities and challenges that are real that we can tackle. So thank you for bringing it and having the open discussion with us.

Sharon Arnold: Thank you.

Nick Coussoule: Thank you, Sharon. Okay, if we move on to the next topic, we've got sort of two remaining action items. Why don't we take up the ICD-11 letter next, and then we can follow up with the workplan and anything that's lingering that we need to cover.

NCVHS Workplan & Remaining Follow Up on Action Items

Rebecca Hines: Okay, so some of you are aware that the emails have been flying fast and furious since last -- since we convened, or adjourned, yesterday. So I'm going to pull up the latest version that Rich Landen sent at the lunch break, and it's the clean version. If you're wondering what changed, the email had a track change version, and then Rich added track changes on top of that.

Rich Landen: Rebecca, sorry to interrupt, but it turns out what I commented on and what I marked up was not the latest version. So I'd suggest we start with your latest version, because the edits in there have transcended my comments.

Rebecca Hines: Beautiful. So we're in that beautiful version control land. All right. So I will make sure I close the wrong ones here. I believe I have the correct version, day 2 p.m. All right, that's where we are. Day 2, afternoon.

So thanks for that, Rich. I think we should go down paragraph by paragraph, because there's been significant change from what was sent in the e-agenda book. So go ahead and read the first paragraph.

I do not believe we had any changes in it, actually, but let's just take a second, and if you don't have a question, could you lower your raised hand?

Rich?

Rich Landen: Is it possible you could show the markup version?

Rebecca Hines: I sure can. Okay. So what I didn't do is there are some paragraph things that happened once we cleaned it. So this is what the clean version looks like. What's not track changed is that footnote number 1 is new.

Margaret Skurka: Just a comment. Vickie, we put the footnote in, but I know you may want to have checked it. It was the one about the cost, I believe.

Rebecca Hines: Is that the one -- it is AHIMA, so it should be fine.

Vickie Mays: I saw it in more than a couple of places. So that's why I thought it was okay. I wasn't able to get to the original CMS thing, but I saw reputable groups discussing it.

Rebecca Hines: So this paragraph here was Vickie's addition late this morning, the red one, per yesterday's discussion.

Vickie Mays: I thought that that was to go somewhere else.

Rebecca Hines: Right, we were not sure where to put it, and I think the question is if we were to put it in the 10 research questions, it wouldn't stand out in the letter.

Vickie Mays: Okay, because I took it as I was writing a research question. So I thought that would go there. So what you're asking instead is you want something to make sure that this is highlighted, that social determinants.

Rebecca Hines: In response to what you said yesterday, that was what we thought you were saying. If that's not what you were saying, then no. We were trying to be responsive.

Vickie Mays: No, no, I was being responsive to the email that said a research question. So I think it may be that we're just kind of -- okay, let me -- can you send this one so I can make sure which one I have and let me look at --

Rebecca Hines: You have this. This was sent around 12:45 Eastern. So that would be 9:45.

Vickie Mays: Okay. I thought that wasn't the right one. Let me go in and pull that up. Why don't we go ahead and then let me come back.

Rebecca Hines: So nothing changed here. Oh, sorry, Tammy.

Tammy Banks: That's all right. I was kind of talking to Vickie's point, and I don't know if we wanted to copy that and take a look at what the support was for recommendation 1, because I know we're trying

to add urgency, and a couple of those pieces, tying it to equity, I think we may have done it, but that would probably be a better place to put it.

Rebecca Hines: What would be a better place to put it, Tammy?

Tammy Banks: After the recommendation 1, and where we put the rationale for recommendation 1 and see if it makes sense there.

Rebecca Hines: So you're suggesting that would go --

Tammy Banks: Let's see what the rationale is and see where it makes sense in that section.

Vickie Mays: Rebecca, can you also turn on the comments? Because there were comments about things people put in.

Rebecca Hines: They are not in what Val and Margaret sent.

Valerie Watzlaf: We just added your comments, Vickie, but I do have them, but I think we included everything that you had there. But I didn't see that you had a place for where you wanted that particular addition.

Vickie Mays: For example, I commented on Rich's use of your predecessor, and I just said I didn't think we needed it.

Valerie Watzlaf: We took it out.

Vickie Mays: Okay, sorry, I didn't see. Okay, got it.

Rebecca Hines: Rich wisely suggested we look at the red line. I was trying to jump, but we're not there. So you can see your comments here.

Rich Landen: As far as the selection that we're talking about now, I agree with both Vickie, and she said it should be in the research questions, but also to emphasize it, I think Tammy's put it good that it could be a new point 6 in the rationale for recommendation number 1. And I think that would serve to cover our bases there without getting overly wordy.

Valerie Watzlaf: Then we have to tweak the wording, because now it's not parallel with 3 is assess the quality, develop, provide, okay, investigate.

Vickie Mays: I think we did, we were thinking either here or under number 8 in the research question.

Rebecca Hines: There is no reason it can't go on both.

Rich Landen: We can put it in both, because it's literally a key question. And then when we're done with that, Rebecca, I've got a comment earlier.

Rebecca Hines: So do you want this -- here, I'm going to stick a page break. So you want it as a same -- do you want a sub-bullet or just include it as part of the paragraph?

Valerie Watzlaf: I think because here we do give a little more detail, so I think that's okay.

Rebecca Hines: Okay, so I'm going to go back up to the first page and I'm going to delete it.

Rich Landen: Vickie, are you -- did you read where it was inserted and are you, does that meet your objectives?

Vickie Mays: Yes, but I had a question, because there's two parts to it. Where is it, Rebecca? Can you go to it? Okay, so there are two parts, I want to make sure both parts should be here. If you notice, 1 is about the research on the actual codes and making sure they're adequate, but then this other thing is -- and I think it was, was it Margaret yesterday that said we have them, but people aren't using them. So I wanted to make sure that what people agreed that this issue of either through communication, because I think you should make sure that you're in agreement with mandate.

So I said there's also a need to determine through communication, coordination, or mandate how these codes can be effectively utilized and integrated. So I don't want us to overlook that word. We can get a lot of emails about the word mandate being there. So I want to make sure I called it out to see what you're most comfortable with there.

Rich Landen: In that light, maybe I'd suggest adding the word training. Through communication, coordination, training, and yeah, I share the question about mandates. I'm not sure how that fits in in the context of this number 6.

Vickie Mays: Well, it is almost like we have the codes. We just had a conversation about how important these codes are. But people aren't using them and they're not using them sometimes because it takes time, they don't know how, and I think we're trying to solve this problem and the question is what if this was mandated? Would it be solved? But again, as I said, I don't want this to slip by you. That's a big thing.

Nick Coussoule: The only thing I might add to that is that's a little bit of the how to do it when we implement as opposed to making sure we do the research to identify the issues and challenges appropriately. So that's where I'm struggling a little bit. The first part of it I absolutely get. The second part is more of a figure out how we're going to implement this as opposed to make sure we do the research to understand the challenges when we go to implement as opposed to exactly how we do an implementation.

Rebecca Hines: So it sounds like the second sentence might be more global to say there is a need to identify -- to research how these codes can be effectively utilized. Is that what you're saying, Nick?

Vickie Mays: He's saying implementation, that it's almost like here is the basic research, and I think the question, Nick, is are there things we need to know to understand why people aren't using them, and then how, what to use in order to --

Nick Coussoule: I think if we look at number 4, just a couple above, I think we cover a little bit of that. So this is basically saying how do we, what are the use cases for EHRs and how it can be supported.

Rebecca Hines: I hate to ask this, but we just heard from Steve Posnack this morning, I mean, are we long-term thinking like they would be added to the USCDI?

Nick Coussoule: Again, that is a solution, not necessarily a research of ideas of how we go about it, right?

Rich Landen: And like Nick, part of me is concerned at this level, why are we singling out this particular data, this category of codes, for special consideration as opposed to other categories?

Rebecca Hines: Because it is a priority for everybody right now. It's top priority all around.

Vickie Mays: We have an executive mandate to actually deal with this. So this is kind of very timely now.

Valerie Watzlaf: But mandate is such a negative word. I don't want to wordsmith. It can stay in or it can go out, but it's really a --

Rebecca Hines: What if we cut out this language here and just left it, again, stop solutioning, cut that out. There is also a need to determine how these codes can be effectively utilized and integrated into the EHR.

Rich Landen: And maybe we cite the executive.

Tammy Banks: If you strike it, then what is the difference between just highlighting social determinants as an example of what kind of data should be integrated in the electronic EHR in number 4. I think you're trying to emphasize the diversity, health equity, as a priority. So I think leaving it makes more sense. But I don't like the word mandate. I would use incentive or penalties. Because these are so important. This is not just ICD-11 codes. This is to meet a national priority.

Lorraine Doo: Nick or Rich, can I ask a question? I might be a little bit confused, but in the USCDI, in version 2, there are -- they did approve certain social determinant codes already. I don't know if you're asking about ICD-11 codes, but they did approve certain social determinant codes, social determinant factors, already. But that's for EHRs or for -- well, actually, no, because they'll be applicable to a number of things. But those are already added for version 2.

Vickie Mays: I can tell you that there are articles and research that's starting to come out about they're not adequate, and I shared one article that said, well, why this one and not that one?

Lorraine Doo: Right, but there is a process for submitting that's going on now.

Tammy Banks: And I don't mean to put words in your mouth, Vickie, but just because this is a national priority and these codes are not being collected, the question is should it come from the medical provider? Should it come from another data source? Should it come from community service organizations? That's the question I think you're thinking should be researched in this initial research, right?

Rebecca Hines: And Denise Love reminds us, for those who are insured, could it be asked upon enrollment? There's 1,000 ways to do it probably. The question is what do we want to emphasize in this high level description to HHS so that they'll get some follow-through. That's really what you're looking for is follow-through on this initial suggestion or recommendations. I would just remember that's what you're trying to accomplish with this particular language.

You can go down to the research questions and attachment A and then we can do that, but I think for the body of the letter, just remember you're trying to make this compelling so that someone will say, you know, let's put this in the action box rather than in the let's reply and have a nice day box.

Tammy Banks: Just a point, these are in, where it is now, these are in order of importance as well, these six.

Vickie Mays: I am going to say that the communication, coordination, training, or mandates or whatever, I think may be a different concept that needs to be someplace else and that -- I don't want to lose it, because that's the urgency, but if this is to be equity here, then it would be there is also a need to determine how these codes, in order to support health equity, can be effectively utilized and integrated into the EHR.

Rebecca Hines: So why don't we have that in the research attachment A and maybe take that part, this part out right here, or --

Vickie Mays: No, that's not what I'm saying. I'm saying take out what you have highlighted in yellow and leave here -- just park it somewhere and say here there is also a need in support of health equity to determine how these codes -- no, that's not what I said. There's also a need to determine how these codes in support of achieving health equity can be effectively utilized and integrated into the EHR.

Tammy Banks: Can we also add collected? Can be collected and effectively utilized and integrated. Does there need to be incentives? Does there need to be -- who is the primary source, depending on use. Again, we don't need to answer any of those, but there are a lot of questions here.

Rebecca Hines: Very good. So just while we're on this topic, let's go down to the attachment. So this is where it is right now.

Okay, I can go back. Do you want to -- what was the word here? Can be collected and effectively utilized. So now the detail is here in the list of research questions. Is that what you all were thinking? And then the question is do you want to leave the word mandate there?

Tammy Banks: I would put incentives or penalties instead of mandates, if you're going to keep it. I'd sure rather see incentives.

Rich Landen: It just seems to me that that's getting way ahead of the game. We're telling them what to do with the research that we believe they're going to find.

Rebecca Hines: So would we reword this to say this could inform how these codes -- in other words, sort of --

Denise Love: Right, I would leave out incentives or mandates.

Nick Coussoule: I would almost suggest that -- because the thought is it should investigate that the social determinants adequately capture the most important risk factors needed across the diversity of the population in order to achieve the goals of health equity, including how they can be collected and effectively utilized. I think that gets the point without telling them what to do.

Jamie Ferguson: I was going to suggest simplifying that last sentence to say there's also a need to determine how these codes can be collected and effectively utilized, period.

Rebecca Hines: Okay, so Nick and Jamie, does this now capture what you just said?

Tammy Banks: Can we go with effectively collected and utilized? Just so it modifies both.

Rebecca Hines: You ready to lose this little bit now?

Tammy Banks: Are you happy, Vickie? You looked sad there for a minute.

Vickie Mays: I was. I don't like losing those, but it's consensus time.

Rebecca Hines: Let me go back and fix that. I need to go up here and fix --

Rich Landen: It be collected and utilized, period.

Nick Coussoule: You need to take another look at the other language. It didn't say that down in the bottom. I think we just said collected and utilized.

Speaker: Because it's not just integrated in EHR. It's going to be in a lot of different systems.

Nick Coussoule: Just collected and utilized. I think we stopped it there.

Speaker: Get rid of the EHR in this instance. That's only one source engine.

Nick Coussoule: Rich?

Rich Landen: Yeah, if you go back up to the -- I don't know if it's the second or now third paragraph, the letter, okay. Beginning with the purpose of this letter, the end. I'm sorry, next paragraph. The department's delayed action, that last sentence there, we put this forward now to avert significant avoidable transition cost and burden to the U.S. healthcare system, including public health, like those experienced in the most -- I found that three-time repetition of ICD a little bit awkward, and I suggest that we just delete the word most. Yes, that deletion of ICD is correct, and then go back two words and delete most. So that would read like those experienced in the recent transition from ICD-9 to 10.

Tammy Banks: Can we put a comma between transition and cost in the second line? Right there, yeah.

Rich Landen: Actually, I was referring to transition cost. And then when we get there, I have another comment down right above the conclusions, but I think we're in the process of walking through from here on, still, aren't we?

Rebecca Hines: Are we okay with therefore? I think it's good, but just --

Nick Coussoule: I just point out that we deleted entirely that third recommendation that was in yesterday's draft.

Rebecca Hines: Okay, so again, there is no changes to the description of ICD-11. No changes to the why. We just added a few things here. Somebody added as well as identify other potential benefits.

Here's our new paragraph. You ready to move? Somebody tell me where you're at.

Speaker: I think we're good with that paragraph in blue. Twelve months or less is good.

Rebecca Hines: I'm going to suggest we put original so as not to confuse the reader.

Oh, we changed the last bullet point on the rationale for rec 2. That's a nice addition.

Vickie Mays: I just thought that throwing this in for COVID helped with the urgency.

Rebecca Hines: It does, Vickie. Thank you.

Nick Coussoule: Ready to move? Okay, in this paragraph, NCVHS considered a third recommendation, when I reread that, now that we've removed the actual third recommendation, I kind of got lost about, well, what are we talking about with blanket access.

Rebecca Hines: Yeah, I thought you were fixing that, yeah?

Rich Landen: What I am suggesting is new language -- where did I put it? What I was suggesting is to close the loop. Remember, our original letter had a third recommendation talking specifically about copyright and license agreements. So what I'm suggesting here is replacement language for that paragraph and, Rebecca, if you can type it in, then we can discuss it.

In its initial recommendations on ICD-11, NCVHS had included a third recommendation regarding copyright and license agreements, period. We are removing that recommendation because the WHO has now published its license agreement -- and this is where the footnote would go -- which we believe addresses the committee's concern, period. End of edit.

That would be footnote 8, after agreement.

Vickie Mays: So Rich, I want to make sure I understand, because in order to know what the problem was, they need to go back and read it. So is that the intent that you want to make -- because it seems very simple to make sure we're just saying we're removing that rec, because now it's published, da-da-da. Which we believe addresses the committee's concern about copyright or about access. Can't we just tell them right there what our concern was?

Rich Landen: Sure.

Rebecca Hines: I don't think it's going to resonate to say we're removing what it is as we're not including that in this. It's like there is no recommendation regarding copyright and license because it's been dealt with.

Rich Landen: Okay, so we are not including that recommendation in this update.

Melissa Goldstein: This is a letter to the Secretary, right? And it's a different Secretary and it's a -- so this Secretary presumably never read the first letter. Probably doesn't know anything about the first letter.

Speaker: It's attached.

Melissa Goldstein: Right, but it strikes me as a little odd to talk about something that you are removing from a letter that he never got and requiring him to go to the previous letter and consider an issue that's no longer an issue.

Rich Landen: The alternative to that is if we don't address it, then it creates ambiguity; does the third recommendation from the first letter still stand? Or does it not?

Melissa Goldstein: What you present that it does not stand if it's not in the letter that you're getting today?

Nick Coussoule: Well, I think you're guessing. If it's silent, then you're guessing. If we are explicit, then at least it indicates that it's not there.

Melissa Goldstein: Legally that's not how it works. If it's not there, it's not there. And the man was an attorney general. So I just want to point out that it strikes me as odd. You guys can go with it if you'd like to go with it, but if I got this letter as a former attorney general, I would think that it's quite odd.

Rebecca Hines: The only thing that I still am not 100 percent -- I understand the license agreement, whether it covers everything. I mean, if you're a third party software. So if by not mentioning it, are we agreeing that it's totally an issue that doesn't need to be researched or considered in the research?

Rich Landen: I think that is a great point. I don't think we want to put ourselves in the position of trying to interpret that license agreement. It's just that our initial concern is nothing existed, and now we've got this license agreement, we've got input from Donna Pickett and others that we seem to think it's okay, but maybe it's, as Denise brings out, maybe we should add that to the research questions. Look at the license agreement and does it meet the country's needs?

Denise Love: I would assume that the research would incorporate that, and so whether we put it in this paragraph or insert it into a research component, I just don't want to be assuming that because WHO says it's free that it truly will be free.

Nick Coussoule: Yeah, and to Melissa's point, we are asking them to do two things, right? We're asking them to do some research and we're asking them to set up a communication plan. I think probably the best place to put this, if we're not going to include it as a third item, would be as a bullet point in the

research and say confirm or evaluate whether the licensing agreement would meet the needs without creating undue burden or something like that. I think you then accomplish both of those things, which is explicit two things we're asking them to do, but a reference to that needs a confirmation in regards to the details behind the license agreement.

Melissa Goldstein: For right now, you could code something in the next five minutes. It's free.

Vickie Mays: No, it's available. I've learned this, that things that are on the web can be available but the attorneys have dinged me sometimes by taking something off the web and it still -- remember, licensing and copyright will differ by countries. So even though WHO says one thing, the United States needs to make sure that its agreement with the software people who set up some of our systems that this is actually -- we're not in any way intruding.

Speaker: It does say that, though. If you have a computer, you can, that's all you need, you can use it.

Nick Coussoule: But can you embed it in a commercially available product which you're selling for profit?

Rebecca Hines: Nick, can you repeat what you said so eloquently?

Valerie Watzlaf: Could I just mention something? You believe that research could be done around that, around the licensing agreement? That would be research around it?

Melissa Goldstein: If there are going to be modifications, they are going to need to look at that see if there's an impact, right? Or if there needs to be more negotiation with WHO or it meets its needs. What about secondary uses? Is it covered in there? Is there not, again --

Rebecca Hines: Nick, do you have the language, can you just say it again? You nailed it about three minutes ago, and I never got a chance to capture it.

Nick Coussoule: So the third bullet would be to evaluate the licensing agreements to ensure availability without -- availability to the healthcare ecosystem without undue financial burden. Something like that. That's the thinking process. Probably just leave it at that level. There's way more detail that's going to need to be reviewed.

Rich Landen: I would suggest we take out accessibility and take out healthcare and substitute for the U.S. users.

Nick Coussoule: I think that is a good point, Rich.

Rebecca Hines: Rich, can you help me out here? Evaluate the ICD-11 licensing agreement to ensure availability.

Rich Landen: And usability for U.S. users.

Nick Coussoule: Yeah, because it wouldn't be just the healthcare system. It's software providers, et cetera.

Rebecca Hines: Sorry, Val, what were you saying?

Valerie Watzlaf: Do you want to put the footnote for the agreement there?

Rebecca Hines: Sure. It's actually still in my paste. There it is. You got to love software when it actually works.

Rich Landen: Nick, did you -- I think you said undue cost burden, was undue a critical thought? I'm ambivalent.

Nick Coussoule: Yeah, I mean it's a question of whether it's trivial or zero or significant, right? So I'm not sure the best way to frame that. If it costs a dollar, it's no big deal. If it costs a million dollars, it's obviously a big deal. Ideally, we'd like zero.

Tammy Banks: Currently it's zero the way written. So maybe we want to keep it without cost burden.

Nick Coussoule: Yeah, I think that's fine, Tammy. I'm good with that, too. Let researchers worry about it.

Rebecca Hines: Where were we, where we took that? Here we go. So are we going to take this all out completely?

Nick Coussoule: Yes, that would go away.

Tammy Banks: Melissa, are you happy? You're not smiling.

Melissa Goldstein: I am happy. Just for the record, I would never touch copyright, but I would know that I would need to get a lawyer who knows what to do with it.

(Laughter)

Rebecca Hines: I am going to stick a page break here just so you can read the conclusion in its entirety on one page, a temporary page break.

Nick Coussoule: One suggestion, Rebecca, do you want to take a moment to sort of accept all the changes and then just walk through it quickly so everybody can take a look?

Rebecca Hines: Absolutely. I just want to make sure that now all these edits are made, this is still acceptable conclusion language.

Okay, so I would suggest everybody take a four-minute bio break. I will clean this up and bring it back up.

Nick Coussoule: Perfect. Sounds like a plan. We'll adjourn for four minutes.

(Break)

Melissa Goldstein: I will make a motion to approve the ICD-11 letter as is, with -- what's the language that if there's minor changes that it's acceptable, as well? Content remains the same.

Vickie Mays: Second.

Rebecca Hines: So Vickie seconded it.

Melissa Goldstein: So time to get out your raised hand button, folks.

Okay, so I count 10, 11, 12, 13, 14 hands up. We have unanimous approval of the letter. Thank you, all. I will send it around so you can just see your handiwork, and if you catch any grammatical errors or typos, please send them along.

Nick Coussoule: Thank you. I know this is sometimes a bit of an arduous process. It's just difficult to get to with so many people and participants and opinions. So I thank everybody for the diligence of going through this.

Margaret Skurka: I'm so thankful that we don't ever say anything about clinical modification. Oh. We don't want that.

Nick Coussoule: Okay, we have one more topic on our agenda before we call it a day here, and that's just to kind of briefly go through our workplan. Rebecca, can you bring that up and we can hopefully get confirmation from the different committees, subcommittees, that the workplan is accurate or anything we need to add to it, and then I can wrap up.

Rebecca Hines: Do you all have this in your agenda book? I am not sure what page. It's hard; if I make it small to have it all on one page, it might be a little hard, but let's try this. So Nick, first row, I think we can put a fork in it. It was approved.

Nick Coussoule: Okay, and the second row, I guess I would ask primarily Rich and Denise.

Rebecca Hines: It looks directionally correct.

Nick Coussoule: I think we can get an update after at the next subcommittee meeting and then adjust it then, but I think we did the things we're expecting to do here.

I think three is similar.

Rich Landen: We have received no incoming requests. TBD is still an operative word.

Nick Coussoule: Then I guess Jacki or Melissa, obviously we did that portion, and then the question is going to be where does, from a timing perspective, where does the next step lie, because it's in the third quarter bucket, more a sequencing perspective or timing perspective here.

Tammy Banks: Is the question whether we would move -- I'm hopping back and forth between the agenda book -- whether we would move prepare and approve letter to the HHS Secretary to phase 4 or not? Is that the to beyond --

Nick Coussoule: It's more of a lining up with -- if you scroll up, the column heading is actually Q3 and Q4 this year. So I think the phases are right. I think just the sequencing is -- is this going to happen in the fourth quarter or is it going to happen next year? That's really the question.

Rebecca Hines: Well, we can't approve it in the fourth quarter, because we're not meeting in the fourth quarter.

Nick Coussoule: So we probably just need to adjust that topic to be in the next bucket along with the phase 4. So there would be a phase 3 continuation of preparing the letter and a phase 4 is the prepare the report.

Rebecca Hines: So Nick and Melissa, are you saying that there would be at the January full committee meeting a discussion and vote? Or is that too far?

Melissa Goldstein: Let's see, draft recommendations. I think that's reasonable to work towards, right?

Rebecca Hines: This is a working document. So if you decide it's not right, you can change it next week.

Nick Coussoule: Without being too nitpicky, I'd probably rearrange those two bullets, because the first one is the discussion and vote on the letter, and then the second piece is the actual -- is a follow-up, report following the letter.

Melissa Goldstein: Are you looking at topic 6 or topic 5? I'm confused. Oh, 5, for the security project. Is Jacki on? I can't tell.

Jacki Monson: Yes, I'm on.

Melissa Goldstein: What are your thoughts for the security project?

Tammy Banks: I think it is fine how it's laid out, with swapping them around like Nick said. I would guess we're going to have a recommendation letter, but it probably -- if we're really diligent, may be ready for January.

Nick Coussoule: And phase 4 just gets into basically next year. It's just after this calendar year. So we are not trying to force a level of specificity, just trying to get at sequencing.

Rebecca Hines: All right, and now, Melissa, we're at the data collection and use during public health emergencies, row 6. And there's nothing in next quarter. So do you want to sketch something out to put here?

Melissa Goldstein: Do you generally, for quarter 2 it said draft recommendations, which we haven't done. Do you typically retroactively move those?

Rebecca Hines: We certainly, yes, this will be dated as of September 10. So if we want to move this, we can move it.

Melissa Goldstein: I would move the first bullet, maybe both of those bullets actually, to quarter 4, or quarter 3, right?

Rebecca Hines: All right, the page numbers keep swapping, very confusing. All right, so for October-November-December, quarter 4, we have draft recommendations from last September 2020 hearing and share with the executive subcommittee some time in the next three months. Does that work?

Margaret Skurka: Do we want to call it draft transmittal letter instead of recommendations, or does that matter?

Rebecca Hines: This is our collective workplan.

Margaret Skurka: This is for us to know what we're talking about. Okay. Let's call it transmittal letter.

Rebecca Hines: Okay, and so then it sounds like for January the idea would be actually to actually bring it right to -- bring forward for -- and vote. Okay. Very nice. I think we're good for row 7, Nick, yeah?

Aha. This has been changed quite a -- this is the ask we just got.

Nick Coussoule: Yeah, why don't we reframe that? I'll talk about it a little bit when we close and we'll add another line item for next time, because it's a work effort. We're going to have to even define the work effort. So I don't want to try to make something up too much right here.

Rich Landen: One of my questions on that is next year's budget, if we're going to -- as we talked about earlier, if we're going to do a convenings or convenings on that, is that going to impact the number of convenings available for the standards subcommittee?

Rebecca Hines: Excellent question.

Rich Landen: Or does the ask come with funding for convenings?

Tammy Banks: Would this be an existing group, or will this be an ad hoc workgroup, because the topic is kind of --

Nick Coussoule: To be honest with you, I am thinking through that, Tammy, trying to figure out the best way to accomplish it without putting a permanent structure that wouldn't be productive. So let me noodle through that one a little bit, and then we'll talk about it as a group, and then -- so just one of our takeaways, right? So I'll just cover that now. It's probably an appropriate time.

So obviously Sharon made an ask, a pretty big one. I believe it's a topic that we have a lot of interest in, and I think would be well in our wheelhouse to address. It's definitely a structural question and not a temporal question. So exactly how we organize around that, who participates, how we structure in our group, I gotta think through that one a little bit. And so I think what I'll do is I'll put together a model or two and we'll review it at the executive committee meeting and then share it with the committee members and try to gauge an interest, et cetera.

So like I said, this is a little bit new. It's a little different than kind of the things that we've undertaken before. So I'd like a little bit of time to noodle through that, and then get all of your input with a straw man, if you will.

Tammy Banks: Nick, just a question. Not for you to have to answer, because I know you're still noodling it. But with the new administration, is there any appetite to reconvene the population health subcommittee? Because we do have the expertise on this panel. Anyway, I didn't know if that was even an option for you to think about, and if so, what the process is.

Nick Coussoule: There's lots of options. I'm just trying to think through the best way to handle it with the least amount of overhead and the short-term and long-term. But I do think, and I think most of the members here would agree, it's a pretty exciting topic. I think we have lots of expertise as well as interest. So I do think it's something we'll want to undertake. We just have to figure out how to make sure we can do it within what our capacity to get it done is and the priorities of what we're working on.

Vickie Mays: I just want to raise one issue in your noodling, and that is which comes first? And it's like I think it's really important to find out the resources, because I think for us to make decisions, they are going to be made in -- can we not do other things, do we have the ability to do an issue, whether or not we're going to be able to do hearings. So it may be that there needs to be that conversation.

Nick Coussoule: I think that is all very fair conversation, Vickie. That's why I said I just kind of -- it's just tossed out. I hadn't had a chance to think through it in any degree. I wanted to make sure we had enough interest and excitement and wanted to have Sharon be able to communicate it to everybody, and then we'll start talking about how we might tackle it and what it means in total for the committee.

Tammy Banks: We love giving you more pressure, Nick. So that's why we keep bringing this up. We could do it in December, right?

Nick Coussoule: See, what you don't realize is I took a picture on my phone of everybody who raised their hand before for volunteers. No, it's an exciting topic. So I'm hopeful that we can attack in a way that makes sense given our structure and capacity and resources.

Vickie Mays: We have to ask whether his phone has enough protection about our data, our pictures.

(Laughter)

Nick Coussoule: Okay, excellent. Really good. So let me try to bring us home here. First, a few different things. One, I want to make sure I thank everybody that's participated in this as well. Thank you to the members for your time and expertise as well. Thank you very much to our staff, Rebecca, Lorraine, Rachel, Maya, et cetera, all the folks that help us do this work, Geneva. I know I'll miss people if I do this, but I want to make sure they realize it takes a lot to put these things on, a lot of stuff that happens behind the scenes as well. Our AV folks did a great job as always, setting up for us and letting us run this way. So thank you, as well.

I also want to thank our outside participants. We had some really, really good topics of discussion, both yesterday morning with folks talking about some of our data linkages, et cetera, and some of the new

work happening in our work there as well, as this morning with Steve, his input there. So we've had a really productive couple of days. We finished two work products, which is a momentous occasion in any given full committee meeting, both the return of the report to Congress, as well as the ICD letter. So I think we should all be very proud that we've accomplished a lot I think, and hopefully we'll have some good activity coming out of those actions.

We do have a follow-up, which we just talked about, as far as the ask which we were just talking about, Sharon's ask of us. Again, I will try to put together a straw man, not by myself, but we'll work on that. We'll work on the executive committee and then make sure we get everybody involved in that discussion. So it will not be done in a cabal, if you will. Not the way I work personally.

Our next meeting is scheduled for January 24 and 25. I believe it's on the calendar already, hopefully, and so we will do that. We're scheduling three meetings in the next fiscal year. Hopefully, we are fingers crossed, that we might do one of them in person later on in the year. I know that's sort of our straw man going in plan, where we'd love to be able to physically all get together, but obviously the facts on the ground will tell us that as well as anything else.

I think we've all been dealing with those challenges for a good while and until things get to a place where we're all comfortable and it all works, we'll keep doing this. Good news is we are productive here, but the better news is I'm hopeful that we can get together in person before the next calendar year is out.

With that, Rebecca, am I missing anything? Rebecca always catches me when I miss things.

Rebecca Hines: Not that I'm aware of.

Nick Coussoule: Okay. Well, again, thank you, committee members and thank you to our audience for listening and hopefully we've been able to provide some good information and insight into what we're doing, and with that, we will formally adjourn, and I will look forward to seeing you all soon.

Rebecca Hines: Take care, everybody.

(Whereupon the meeting was adjourned at 3:30 p.m.)