National Committee on Vital and Health Statistics
Meeting of the Full Committee

Transcript

March 31, 2021 10:30 a.m. – 5:45 p.m. ET

Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Nicholas L. Coussoule	**Horizon BlueCross BlueShield 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 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	Individual	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**
Micky Tripathi	ONC	National Coordinator for Health IT
Evelyn Gallego	EMI Advisors	Chief Executive Officer
Sarah DeSilvey	EMI Advisors	Clinical Informatics Director
Bob Dieterle	EMI Advisors	Technical Director
Kin-Wah Fung	NIH/NLM	Scientist

Call to Order/Roll Call

Rebecca Hines: Good morning, everyone, and welcome to members of the public, committee members, and staff. It is so good to see you. I hope everyone is staying safe and well. This is the spring meeting of the National Committee on Vital and Health Statistics. My name is Rebecca Hines and I serve as executive secretary and designated federal officer for the committee. Typically, the committee meets in person at the HHS Humphrey Building. Starting last March, the committee continued to carry forward its work virtually as most of the country and the world have been doing. Today and tomorrow, we are continuing the work of the committee from November's virtual meeting.

Since the November meeting, there have been changes to update you on. First, Frank Pasquale, who was chair of the Subcommittee on Privacy, Confidentiality, and Security resigned so he could attend to a new work opportunity. We are delighted to report that Melissa Goldstein and Jacki Monson have agreed to serve as co-chairs of the subcommittee. In addition, Denise Love has stepped up to serve as co-chair of the Subcommittee on Standards together with Rich Landen. Alix Goss' term ended, and Denise was willing to take on the role. We are grateful to all three women, Melissa, Jacki, and Denise, for giving generously of your time. Serving as a subcommittee co-chair is a substantial lift. I can attest from where I sit. We should note today is the last day of Women's History Month and it is wonderful to celebrate our new women leaders here on the committee.

Let us go to roll call starting with our chair, Nick.

Nick Coussoule: Good morning, everybody. My name is Nick Coussoule. I am a senior vice president at Enterprise Business and Technology Solutions at Horizon Blue Cross Blue Shield of New Jersey. I am chair of the Full Committee and I have no conflicts.

Rebecca Hines: Great. I am going to go in alpha order by first name. Debra Strickland.

Debra Strickland: Great. Thank you. My name is Debra Strickland. I am a member of the Full Committee and member of the Standards Subcommittee. I have no conflicts.

Rebecca Hines: Denise Chrysler.

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

Rebecca Hines: Denise Love.

Denise Love: Hi. I am Denise Love. I am retired and public health data consultant. I serve on the Full Committee and co-chair of the Standards Subcommittee and no conflicts.

Rebecca Hines: Jacki.

Jacki Monson: Good morning. Jacki Monson. I serve as Vice President at Sutter Health and on the committee, I am the co-chair of the Privacy, Security, and Confidentiality, member of the Full Committee and I have no conflicts.

Rebecca Hines: Jamie.

Jamie Ferguson: Good morning. I am Jamie Ferguson. I am Vice President of Health IT Strategy and Policy at Kaiser Permanente. I am a member of the Full Committee and the Subcommittee on Standards and I have no conflicts.

Rebecca Hines: Jim.

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

Rebecca Hines: Margaret.

Margaret Skurka: Hi. I am Margaret Skurka. I am a retired professor from Indiana University, now Professor Emeritus. I own a consulting company in suburban Chicago. I am a member of the Full Committee. I am a member of the Subcommittee on Standards, Review Committee, and I have no conflicts.

Rebecca Hines: Melissa.

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

Rebecca Hines: Rich.

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

Rebecca Hines: Tammy.

Tammy Banks: Good morning. I am a member of the Full Committee. I serve on the Subcommittee on Standards and I also have no conflicts. Thank you.

Rebecca Hines: Valerie.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf and I work for the University of Pittsburg as the Vice Chair of Education and Associate Professor in the Department of Health Information Management. I am a member of the Full Committee and I also serve on the Subcommittee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Vickie. You are on mute, Vickie, or something is not working. We will read her into the record until we get that worked out.

Wu.

Wu Xu: My name is Wu Xu. I am a retired public health informatics director and adjunct faculty for the University of Utah. I am the member of the Full Committee. I have no conflicts.

Rebecca Hines: Great. Let us move over to staff, beginning with Sharon Arnold.

Sharon Arnold: Hi. This is Sharon Arnold. I am the Associate Deputy Assistant Secretary for Science and Data Policy in HHS. I have no conflicts.

Rebecca Hines: Maya Bernstein, would you like to say good morning?

Maya Bernstein: Good morning everyone and greetings from New Mexico, where I am at the moment. I am the senior advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation. I work for Sharon, who just introduced herself. I am the lead staff to Sharon as executive director of the committee and also staff to the Privacy, Confidentiality, and Security Subcommittee.

Rebecca Hines: Great. Thank you, Maya. And Lorraine Doo.

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

Rebecca Hines: Great. Thank you, Lorraine. I have heard from Rachel Seeger, who is here today. She is lead staff also for the Subcommittee on Privacy, Confidentiality, and Security and together with Maya's backup. We also have Mariette Squire and Geneva Cashaw, which you all know, offer tremendous support behind the scenes.

Is there anyone else who would like to say good morning?

Kianna Morris: Good morning, Rebecca. This is Kianna Morris. Hello everyone. I serve as the Acting Director for the Office of Planning, Budget, and Legislation within NCHS and the administrative advisor to the committee. Glad to be here. Thanks.

Rebecca Hines: Thank you, Kianna.

Anyone else?

Vickie Mays: Rebecca, can you hear me now?

Rebecca Hines: Yes.

Vickie Mays: Good morning, everyone. Sorry for the technical difficulty there. Vickie Mays, University of California, Los Angeles. I am a professor in the Departments of Psychology and Health Policy and Management in the School of Public Health. I am a member of the Full Committee. I am a member of the Privacy, Confidentiality, and Security Committee and the Review Committee for Standards.

Rebecca Hines: And you have –

Vickie Mays: I have no conflicts.

Rebecca Hines: Thank you, Dr. Mays.

One final note for the members of the public, the agenda includes time for public comment both today and tomorrow. Today's public comment period is scheduled for 5:30 p.m. Eastern. Typically, if you are a regular to our meetings, we adhere to the agenda although tomorrow scheduled for 4:45, it is possible

that could shift earlier or later depending on how things proceed with the agenda tomorrow afternoon so just letting you know that for awareness.

With that, Nick, over to you. Put up the agenda please.

Welcome Remarks/Agenda Review

Nick Coussoule: Good morning, everybody and all the members and staff and the participants. Thanks for coming today. First, just a couple of opening comments before I walk through the agenda. One is I want to thank everybody on the committee and staff. There has been a lot of work happening over the last 12 months and some rather challenging circumstances, as we all know.

I do want to thank all the committee members and staff and others that have helped us try to make progress on the initiatives that we have through all the challenges that you are all going through as well locally. It is unfortunate that we have not been able to do more of these in person. There is a lot of value in us building both the relationships and talking to each other offline as well as talking to our audience members and folks that come in and talk to us online. I am hopeful that we will be able to do that soon although predicting that is – I leave that to the prognosticators and not me, but I look forward to the time where we can meet in person again.

I am also very excited, as Rebecca indicated, to have subcommittee leadership in place both in Standards as well as NPS and thank the members as did Rebecca for their commitment and willingness to share more of their time and expertise to those efforts. That is going to be really helpful as we continue forward.

Let me walk through the agenda now. First, we are going to have an ASPE update. Sharon is going to provide that for us. And then we will spend roughly an hour, a little over an hour, going over our Report to Congress. More details and the status of that as we get to that topic.

We will take a break for lunch and then we will have two different sessions. The first section of the afternoon for the Subcommittee on Standards. The first one, we will talk a little bit about the priorities and alignment of work, but we have a special guest, Micky Tripathi, who is the national coordinator, new national coordinator for Health IT at ONC, will be our special guest there and will talk to us for a while about his – what he is seeing in priorities for the administration.

Then the second section of that, we will talk about the potential future project, a proposed project from the Standards Subcommittee where Rich Landen and Denise Love are co-chairs, who will head that up as well.

We will take a break and then we have some really good external speakers coming in late this afternoon. We will get an update on the Gravity Project from Evelyn Gallego. And then we will have a discussion on ICD-11/10 continuation. Margaret will provide a report for us and then Kin-Wah Fung will give us an update as well for that.

And then we will finish off the afternoon with a Standards discussion that Jamie Ferguson will lead in regard to semantic harmonization and classifications as some of the challenges and opportunities inherent there. We will have public comment, as Rebecca indicated, scheduled for 5:30 Eastern Time. And then we will hopefully adjourn shortly thereafter. That is our schedule for today.

For tomorrow, do you want to walk through that briefly, Rebecca?

Rebecca Hines: Sure, Nick, happy to. Tomorrow we are going to focus on the Subcommittee on Privacy, Confidentiality and Security, primarily focusing on a new proposed project that they are going to share with the Full Committee for discussion, as well as any other follow-up work that may be happening. And then we are delighted. We are going to have Dr. Daniel Jernigan from CDC, discussing all of the work underway under the Data Modernization Initiative known as DMI.

And then in the afternoon, two of our members, Vickie Mays and Denise Love, have organized a fantastic expert panel at the suggestion of ASPE on data collection of race/ethnicity data, especially focusing on where things are now with the pandemic. The details on those experts on the PDF agenda and the most up-to-date version is on the website. For those in the audience if you would like to see the lineup for tomorrow at 1 p.m. Eastern, it is there on the website.

And then, as I mentioned in my opening comments, the afternoon, we are going to play by ear. We may need some more time to discuss the Report to Congress or not. And there is time to look at our workplan, given how the discussions unfold over the next two days and then we will finish up with public comment when that falls. It might be before 4:45 so just a heads up.

Also, the other thing to mention is that public comments can be emailed. I forgot to say that. If for whatever reason you do not want to speak, I can read them into the record and they go to NCVHSmail@cdc.gov. That is NCVHSmail@cdc.gov. Feel free to send comments that way as well.

With that, Nick, do you want to get us back to introducing our first presentation?

Nick Coussoule: I will and now we welcome Sharon Arnold. Sharon, I will leave it with you. Thank you.

ASPE Update

Sharon Arnold: Thank you very much, Nick. Let me say this has been an extraordinarily busy time at HHS. There is a lot going on. The vast majority of the department's workforce continues to telework due to the pandemic. We do not have a sense as to when we will be back into the office full time. But we are fortunate to be able to operate relatively seamlessly remotely.

Since our last meeting in November, we have welcomed a new administration and have been working to transition in new personnel and envision new priorities for the department. As you may have seen, Secretary Xavier Becerra was confirmed on March 18. Rebecca Haffajee was named as acting assistant secretary for Planning and Evaluation and principal deputy assistant secretary for Planning and Evaluation on March 8.

Dr. Rachel Levine was confirmed on March 24 as the new assistant secretary for health, who made history of the first ever transgender person in a senate-confirmed office. Additional appointments are Vivek Murthy as surgeon general, Rochelle Walensky as director of the CDC, Micky Tripathi, who we will hear from later, as the national coordinator for Health Information Technology. Loyce Pace is the director of the Office of Global Affairs. Marvin Figueroa is the director of the Office of Intergovernmental and External Affairs, Sean McCluskie, as chief of staff, and nominees have been sent to the Senate for the deputy secretary, assistant secretary for legislation, assistant secretary for preparedness and response, and the CMS administrator.

Rebecca Hines: Sharon, can you speak up just a bit? Something happened with your audio.

Sharon Arnold: On January 21st, the Biden Administration released a National Strategy for the COVID-19 Response and Pandemic Preparedness. The National Strategy was accompanied by three executive orders to ensure an equitable, data-driven, unified, and effective response to the pandemic. The first executive order related to organizing and mobilizing the United States Government to provide a unified and effective response to combat COVID-19 and to provide United States leadership on global health. It also creates the position of COVID-19 Coordinator to the President.

The second is to ensure data-driven response to COVID-19 and future high consequence public health threats. This executive order instructs the heads of all executive agencies in coordination with COVID-19 response coordinator to facilitate gathering, sharing, and publication of COVID-19 data with appropriate protections for confidentiality, privacy, law enforcement, and national security. Most importantly, it is not only focused on the current pandemic, but really encourages HHS to think about and prepare for any future pandemic.

And the third executive order is ensuring an equitable pandemic response and recovery. Again, it is tasked with developing recommendations, addressing data shortfalls exposed by the pandemic, particularly challenges with data with respect to underserved populations. We have data – vaccine distribution is well underway. We have reached and exceeded the President's goal of 100 million vaccines administered in his first 100 days in office. We have a new goal of 200 million shots in 100 days. We are hopeful that we will meet and exceed that goal as well.

CDC has developed a smartphone-based tool called V-safe that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID vaccine. Using V-safe, you can quickly tell CDC about any side effects after receiving the vaccine and receive information tailored to your experience. CDC is using this information to develop and share information about vaccine side effects.

As part of the administration's ongoing efforts to promote health equity in response to the pandemic, HHS recently announced a $150 million investment to increase monoclonal antibody therapeutic treatments for patients in vulnerable communities across the country.

On March 29, Dr. Walensky issued a warning about a possible fourth surge of the coronavirus. Following the statement, President Biden urged governors and mayors to restore mask mandates, given that many communities have repealed or loosened mandates recently.

Other major news is the American Rescue Plan of 2021 became law on March 11. This $1.9 trillion economic stimulus bill affects a wide range of areas. It includes provisions to expand unemployment benefits, provide direct payments to household and authorize various spending measures for COVID-19 pandemic response. The American Rescue Plan is going to be central in playing a role in addressing health care disparities.

On March 23, we celebrated the 11-year anniversary of the passage of the Affordable Care Act. On February 14, President Biden declared a state of emergency in the State of Texas as a result of emergency conditions, resulting from a severe winter storm.

On March 26, the Office for Civil Rights as of March 26 has settled 18 enforcement actions under the HIPAA Right of Access Initiative, which supports individual rights to timely access of the health care records in a reasonable cost under the HIPAA Privacy Rule. OCR issued a notice of proposed rule making

on December 10, announcing proposed changes to the HIPAA privacy rule to support individual's engagement in their care, remove barriers to coordinated care, and reduce regulatory burden.

ONC in partnership with PCOR recently announced a synthetic health data challenge inviting researchers and developers to test tools, algorithms, and disease modeling approaches on synthetic data sets.

In addition to the executive orders related to the pandemic response, the Biden Administration has also signed orders to advance racial equity and support for underserved communities, to restore trust in government through scientific integrity and evidence-based policymaking, to strengthen Medicaid and the Affordable Care Act, to develop a sustainable public health supply chain, and to protect public health and the environment. HHS is busy working on these orders, the COVID orders and the new priorities of the administration. A lot going on.

ASPE is currently implementing a critical aspect of the Cures Act, which was signed into law in December of 2016, which requires the secretary to issue a certificate of confidentiality to protect research records from legal processes such as subpoenas or court orders. We have been working on this. We continue to work on this. We hope that we will be able to announce activities soon.

We continue to work on the implementation of the Foundations for Evidence-Based Policymaking Act. We are working on Title 1 deliverables, which relate to the evaluation agenda. There are also Title 2 and Title 3 activities. Title 2 is the section of the evidence act on open data. And Title 3 is the reauthorization of CIPSEA or the Confidential Information Protection and Statistical Efficiency Act. We are still waiting for final guidance from OMB on those last sections. But in the meantime, we have forged ahead with activities on both of those fronts.

That is my summary at this point. I am happy to take a couple of questions if anybody has questions.

Nick Coussoule: Sharon, this is Nick. Thank you very much. It is good to hear that there is not much going on your end either as there is in the rest of our – certainly, a plate full that we are excited to hear about as we go forward. Certainly, the new and updated priorities and focus areas of the administration. Thank you very much for sharing that.

I have one somewhat pointed question and then I will open it up obviously for the other committee members. You mentioned the V-safe to reporting side effects for vaccine implementation. What kind of take up and feedback have we gotten for that so far? Do we know? Is there enough information to be able to share at that point? More of a curiosity than anything else.

Sharon Arnold: I actually do not know. I do not know if any of the staff on the call knows, but I can find out and get back to you on that.

Nick Coussoule: More of a curiosity than anything else. Thank you.

Other committee members, questions, comments?

Maya Bernstein: We will try to find an answer to that question, Nick. I am not sure what it is.

Rebecca Hines: Members, please hit the raise hand function if you would like to ask a question.

Vickie Mays: As usual, Sharon, thanks for a very informative set of comments about what is going on. Again, like Nick, not too busy there.

The President has very quickly accelerated a lot of orders around the equity agenda. I am wondering if you can share with us the space that you think that puts the committee in terms of one of the most important things being data. In preparation for the panel, it was just clear how many of the offices, which in HHS were interested in listening in. I have a sense people are paying attention.

Sharon Arnold: People are definitely paying attention. I will say that one of our first activities is really landscape assessment of what kind of data we are collecting under what circumstances and whether that data is harmonized or not and whether we have the ability to get to harmonized definitions across multiple data sources. In some cases, especially program data, we may be constrained. But I think if there is going to be a huge effort to expand the kinds of data we collect and make sure that we can harmonize across data systems. That will be a huge effort where we are undergoing fact finding now. I could see us welcoming input from the committee on that.

Vickie Mays: Will it be also with states or is the goal just across – if we just did even across federal systems, that is great. But is there any sense that we want to try and have better sharing and linkages and harmonization with state data?

Sharon Arnold: I think right now we are going to start with HHS. That is where we have authority and control. I think that HHS links with a lot of data. We collect a lot of data. We may spread out a little bit with data that we collect. But I think first step will look within and where we have the authority to make the changes and the ability.

Vickie Mays: Thank you.

Rebecca Hines: Melissa Goldstein.

Melissa Goldstein: Hi Sharon. Thank you so much for the comprehensive summary. There is a lot, but we really appreciate it. Thank you again.

My question is about the certificates of confidentiality that you mentioned that you are continuing to work on it. Any idea about a timeframe particularly for protection of the research data. This is what I am concerned about, which of course was ongoing before we got hit with the pandemic and I know that it is continuing. But I am just wondering about the timeframe.

Sharon Arnold: I do not have a timeframe at this point. I think we have been exploring this for the last year. I know that the pandemic makes this even more important. It has taken attention away from our ability to really dig in on this. I am going to turn to Maya Bernstein, who is actually our lead staff on this and see if she has a better sense.

Maya Bernstein: I think we did get away from it during the pandemic. What we are starting with is the most core part of – they cover all federally-funded research. That is inside the department and also across the whole Federal Government where the secretary has more authority to tell other departments what to do. It is not clear what we can say to the Department of Energy about their research, for example. That part is complicated.

If you are interested, you can find a pretty comprehensive write-up on the NIH website because they were the first out with a solution for all their grants and of course the biggest grant maker in the Federal Government.

FDA and CDC have also done some significant work there. We have now partnered with our Office of Grants Policy and the lead there is telling us it should be reasonably quick to get a policy together for HHS grants. Contracts. Some offices do research work by contract, which is a little more complicated. That might take a little longer. We are hoping to have the whole department done this calendar year. It is not clear whether we can move on the same track to start working with other federal agencies. There is, in fact, a further part, which is that on a discretionary basis. The secretary is allowed to grant certificates of confidentiality to non-federally funded research. Imagine Robert Wood Johnson or Facebook or Google. It is a long process, but we are starting with HHS grants and contracts and then moving out toward the Federal Government. I expect to have some solid pieces this year and then the more complicated pieces maybe next year after that.

Melissa Goldstein: Thank you. Thank you both. That was very helpful.

Nick Coussoule: Any other questions from committee members? I do not see any hands raised. Sharon, thank you again and Maya for your input. We very much appreciate that.

NCVHS 2021 Report to Congress

Nick Coussoule: We will move on to our next topic then, which is the 2021 Report to Congress, previously referred to as the 14th Report to Congress. I am going to walk you through a presentation deck that is going to talk about what we are trying to accomplish and how we are going to do it today. We do not have the report, I think, in a place where we are going to likely end up voting or finalizing it today, but hopefully we can make some good progress.

Let me walk you through the deck. Again, it will help explain a little bit about the background for those of us who may not be quite as familiar. A little bit of an update and then talk about a little bit about what we are going to try to accomplish today.

We did send out the most current draft to the members. We do not intend to necessarily bring that up on the screen, but it will become more obvious as we go forward.

Again, just for everybody's background again. NCVHS' role is we are a public advisory committee to HHS on health data, statistics, privacy, and national health information policy. We assist and advise the department. Particularly what is relevant here, the Administration Simplification provisions of the Health Insurance Portability and Accountability Act, aka, HIPAA and inform decision making about data policy by HHS, states, local governments, and the private sector. And some of that – convening authority. And also, to monitor the nation's health data needs and current approaches to meeting those needs, i.e., identify – for example, identify emerging health data issues, including methodologies and technologies of information systems, databases, and networking to meet those needs. This is really just some of the definition of what NCVHS' role as part of this.

We have a couple of pretty specific responsibilities that are in the topic today, which have responsibilities for advising the Secretary and the Congress on the status of the implementation of Part C of Title XI of the Social Security Act. That is very specifically the Administrative Simplification provisions of that act and to also assist and advise the secretary in complying with the requirements imposed

under Part C of Title XI of the Social Security Act -- the Administrative Simplification provisions. And then ideally, to study issues related to the adoption of data standards for patient medical record information and the electronic exchange of such information, and report to the Secretary recommendations and potential legislative proposals for such standards and electronic exchange.

Again, that gets into a little bit of our role and more specifically to the role of the topic we are talking about now, which is the Report to Congress. The primary purpose of this role is to update on the implementation of the Administrative Simplification Provisions of HIPAA. Pretty clear. Again, HIPAA requires the secretary to adopt standards to support electronic exchange of information – information exchange for an efficient, effective health care system, including standards for security and privacy to protect individually identifiable health information. Again, to try to make the system work a little better to try to make it more electronic and consistent while at the same time making sure that security and privacy are in fact protected.

Report to Congress will address the following topics to the extent that the committee determines appropriate. Again, this is really right out of the language – that the extent to which persons required to comply with Part C of the Act are cooperating in implementing the standards so to what degree is it being implemented. To the extent to which such entities are meeting the security standards adopted and the types of penalties. Again, where it is not being met or where there are problems or challenges to what is happening there.

Three, whether the federal and state governments are receiving information of sufficient quality to meet their responsibilities so is the feedback to the state and federal government sufficient to allow them to also help in this process. Problems that exist with respect to implementation of such parts so challenges that are arising in the ecosystem that may need to be addressed or potentially be addressed to the group. And the extent to which timetables under such part are being met. Initially, there were clearly some timeframes, implementation timeframes, et cetera, that were part of the different rules that – our Report to Congress is supposed to address those challenges and report back on a regular basis.

This is the 14th Report from NCVHS since it was enacted again. We have changed the title to instead of saying the actual 14th report to say the year that we are issuing the report. That typically is the way we have done it in the past now. It covers the two prior calendar years and reporting period. We think it will make it a little bit simpler to make sure you can recognize what year this is referring to as opposed to just a numeric number, which is not as meaningful over time.

And then the proposed format of this year's report is that we will have an executive summary. We will have four sections in the main body. I will walk through those in a minute. Then we will have a number of appendices that basically provides some background and contextual information including a synopsis of the committee's work again which leads into some of the things that we have tried to do to reflect and improve upon this act as well.

What we are going to try to do today is a couple of things. One, I will just say where we are. First is we received lots of edits and comments on draft report provided by our members. I want to thank lots of the membership that have spent the time going through the draft reports in detail. This is a very iterative process. Frankly, it is made more difficult by us not being physical proximate, so we have to do a lot of these things via the wire, which is oftentimes difficult when you are trying to have 18 people edit a document. But I really want to thank the time and effort put in by the membership. It has become

apparent today in the work product in some of the questions that are coming up that we are -- I think the questions are becoming generally a little less substantive, at least in the first few sections and more about how we frame it – we have lots of good input from the subcommittees directly through their work as well as through individual members reading through the details.

We are going to walk through the overall structure and framing of the document, again, the different sections. We will spend some time hopefully getting in agreement on the high-level framing and topics with a focus on Section IV of the document, which is the one that is most influx, if you will, at this point in time. And then hopefully, we will then spend whatever time we can going through in detail the language and suggestions provided by the members focusing on the first three sections of the report. Again, we sent out an updated draft. It is really not for public consumption yet. But we did set it up for the members and we will hopefully have some time to work through some detailed comments on the first few sections as time allows us in our work efforts today and our schedule today.

The outline of the report is that there is an introduction and report overview. That is the first section of the report, as you will see. That covers a number of pages.

We go through, secondly, the evolving context for health information policy. That is really about what has changed over the last couple of years that would hopefully provide some context and insight to the actual status of the Administrative Simplification provisions and implementations within HIPAA.

Then we will provide the third section, which is progress and status of HIPAA implementation. There are two different – we have broken it up into two different areas. One is the transaction and medical code set standards and then secondly, the Privacy, Security, and Breach Notification questions. If you think of that from a work perspective, the bulk of the first bucket is really driven through the work of the Standards Subcommittee. The bulk of the second bucket is driven through the PCS Subcommittee. As you all know, very rarely do these things fit neatly into one bucket or the other. There is a lot of work effort across all the different subcommittees and members to try to get to work product and status that makes sense.

And then the fourth section is – as I said, the second section is somewhat of a look back as to what has changed and what the impact is. The third one is where we are all and a little bit of what has happened specifically relevant to those two different components. And the third section is more of a look ahead to some of the challenges that the committee sees relevant to the status of the HIPAA implementation over the next couple of years and then some potential NCVHS focus areas that we will likely target as a committee.

When we look at the evolving context for the Health Information Policy, this is the five major trends that we have identified through the committee in health information over the last couple of years. Specifically, the new technologies, platforms, and models for managing health information with varying degrees of maturity and implementation have emerged to meet pressing information needs.

Secondly, patient roles in accessing and using the health data have expanded and evolved. Let me read through these first and then we will ask for commenting questions from the other Subcommittee members.

Third, the convergence of clinical and administrative data standards is gaining momentum and the challenges associated with that.

Fourth, the pandemic, as we all know, has exposed some pretty significant weaknesses and challenges in the public heath information infrastructure with lots of work already to try to address some of those with significant, more longer-term implications.

And then fifth, the health information privacy and security challenges have proliferated. I think that is going to be a theme we will see that will likely not to change for a very long time but is particularly relevant in some of the information that you will see in the report.

First of all, questions and comments regarding to the trends as we looked at the context of health information policy from the members. If you will raise your hand in the chat, we can try to make sure we are disciplined – I am not in the chat so raise your hand and we will make sure we call upon you appropriately.

Rebecca Hines: Nick, do you want to keep the slides up for this discussion period or have them temporarily off?

Nick Coussoule: For right now, let us leave this slide up, but would love members' feedback on the particular topics. Again, we have been through a number of iterations of this. We will get into a little more of the details later on, but I just want to make sure we are generally in sync or if we believe there are things that need to be added or potentially even reframed at this level.

Rebecca Hines: Rich.

Rich Landen: Thanks. I am really happy with the organization and formatting and approach. I think it looks good and will concisely convey a lot of work by a lot of people over a lot of years. But specifically, I want to mention number three on the screen right now, convergence of clinical and administrative. We started out looking at that as the HIPAA transaction and operating rule standards relative to the standards being adopted by ONC under promoting interoperability. But our conversation based on industry input and other things has widened that. When we talk about clinical and administrative data standards, we are not as narrow as we used to be. We will be getting into some of the other aspects of what the bullets mention as public health data reporting, lessons learned from the pandemic and looking more at an ecosystem rather than narrowly at the federal regulations under HIPAA and ARRA HITECH. Thanks.

Nick Coussoule: Thank you, Rich.

Other comments, questions? Okay. Let us move onto the next slide then please.

If we get into the third section of the report, which gets into the progress and status, we have initially a section that covers the transaction and medical code set standards. This just walks you through a little bit of the sequencing and background and their transaction background, implementation status through 2020, which is more of the metrics, a transaction initiatives and actions that have happened over the last couple of years, code sets and related terminology and vocabulary actions and initiatives over the last couple of years and then other related simplification initiatives and actions for 2019 and 2020.

Any general comments about those categories first? Again, I will ask members to please raise your hands.

Seeing none then let us move on to the next slide, which is the organization of the second component here, which is more in regard to the Privacy, Security, and Breach Notification sections. Again, the way that is organized is there are some proposed changes to the privacy rule that are discussed, guidance on HIPAA, guidance on the HIPAA and Health Information Exchanges, Disclosures for PHI. Again, we have seen a number of these things over the last 12 months – regards to HIPAA and COVID-19, breach notification updates, enforcement updates, and then Right of Access Enforcement Initiative.

Any general comments on this? Again, we will get more into the details. I will mention the language where we might have questions or concerns. Please raise your hand and we will make sure we do not miss anybody.

Seeing none raised, then we will go onto the next page. This is where we have Section 4, which is looking ahead component of the report where it is framed up into two different – we have made some significant changes here. Really, I would like to get feedback on the framing. Some of the detailed text we know will have to be adjusted based on this change of framing. We may not get into the detailed text obviously today depending on the timing. But we framed it up into two different components. The first one is the – some of the relevant – what I will call the relevant national health information challenges and opportunities. This is by no means supposed to reflect all of the challenges and opportunities that are out there. That would not be possible. In fact, we would be way outside the scope of what we are talking about in regard to the administrative simplification provisions of HIPAA. But it is supposed to represent feedback from the committee members of some of the particular challenges that we think are relevant to be successful and continuing improved implementation of the administrative simplification provisions. There re five of them here. I will read them, and we can get feedback at the end.

One is the lack of comprehensive, integrated, national health information standards. Two, the need for enhanced data sources to support payment reform and price transparency. Third is the lack of equitable information technology access across the last mile and we can ask for more detail on that, but it really means to be able to get into all the different components of this including small provider practices. Four, lack of a nationwide, digitized infrastructure to enable pandemic information sharing. Some of these, as you might imagine, not hinted, but talked about some the administration challenges and priorities already. And then continually increasing challenges to privacy, confidentiality, and security that I indicated before. I do not think this is really ever going to not be one of the ones we see. It is an ever-evolving challenge in regard to both our efforts at transparency, interoperability, and patient access to be at the same time making sure we have privacy, confidentiality, and security in regard to that data.

Comments generally about the framing, if you will, of this section and the specific challenges and opportunities that have been at least provided here as our --

Vickie Mays: Go through Number 4 and make sure that I understand exactly the who of this because in digitizing the infrastructure for health information, are we talking about the digitizing within the health care environment only? Are we talking about digitizing so that we have both health care and public health because in this epidemic, we had a lot of problems in public health literally being able to link with federal data, with provider data? In L.A. County, we are still struggling to be able to map some things and it is not because of the lack of the work. It is the lack of having an infrastructure in which that is easily done. I want to make sure the scope of this that it also should probably include public health. Is that the intent?

Nick Coussoule: I will actually ask other members to weigh in as well. Denise, please feel free to weigh in.

Denise Love: I am figuring out the hand thing.

Nick Coussoule: That is okay. This is really open for committee members to weigh in.

Denise Love: I think it does include public health in the nationwide infrastructure. I think COVID has emphasized that and we will hear a little bit about it tomorrow that private sector data is feeling some of those gaps. How do the two sectors work together to fill these information gaps and share data across sectors and systems?

Vickie Mays: I think in some way then it should be maybe clearer because it is kind of like we are talking national health information and often that is kind of seen as health care. I just want to make sure that that goes forth as that.

Rebecca Hines: Vickie, if you look at page 29 of the draft sent last evening, you will see the language and whether the title of this issue, this challenge needs reframing. You might want to look at that language and see whether it needs any tweaking, but certainly actually both public health and population health are in the first sentence underneath the description and what this challenge entails.

Vickie Mays: Then you need to include public health. Population health does not have to be public health so public health is very specific. I think that was kind of why I was raising it.

Rebecca Hines: When we move on to Melissa, could you maybe think about some rephrasing for that? Melissa?

Melissa Goldstein: I guess I just wanted to clarify perhaps for myself and I guess this is a question for you, Nick. These are just the titles of the various sections. There is obviously a lot of detail that we need to get into.

I would also want to point out and also ask the question for clarification. We, as a federal advisory committee to HHS, obviously have limitations in what our purview is. That could include limitations in this particular report, versus or vis-a-vie all of the other work that we do. In this section of the report, my understanding is that we are trying to frame in a broad way the areas where we have some purview, but we cannot do – we do not make recommendations to Congress. We make a Report to Congress and then we have a lot of other work that we do as a committee.

These five topic areas I think we would have variable things to do, things to say, and that is also covered in the report, but in a different section what we are planning to undertake as a committee in the near term.

Nick Coussoule: Two comments. First is in regard to this section in my mind is it is supposed to be providing a context for why the committee is going to focus on some things that we are going to focus on going forward. It is intended to provide what we believe are some of the challenges inherent in where we are at today in regard to the implementation of the administrative simplification provisions and what some of the challenges will be going forward with that. It is, again, not intended to be a comprehensive view, but is intended to say a little bit about why we are informing some of the

committee's work going forward, but it is not intended to be a particular recommendation as much as some of the challenges we view to inform our work.

The next section of the slide – in fact, let us just go there very briefly and then we will come back. Again, the idea was to look ahead. That is some contexts of things that we believe are pretty significant challenges in the ecosystem. Again, this is Nick's framing, and I would love everybody else's feedback, but some of the challenges we see. By the way, here are some of the things we believe that NCVHS is going to be focused on going forward that ideally will lead towards some potential advice and recommendations in regard to some of those challenges. These are some of the focus areas that we are looking at for what is going to go forward.

We will get back to this one in a minute, but again the idea of we will promote some convergence of clinical and administrative standards and hopefully focus on improving some of the – and creating some information and recommendations ideally to improve the cybersecurity posture, talking about ICD-11, which again I think it gets into that as well, potentially supporting modernization of public health data systems.

Again, these are ideally focused areas that had not intended to be we are going to make a recommendation on this one thing this way. But here are some of the big challenges and big nuts that we think are then to help inform NCHVS in our purview to – what areas we might tackle.

I would love comments on that, but if I could even go back to the previous page. Again, love the other members to comment on that as well. Melissa brings up great points.

Rebecca Hines: Reminder to members that the draft with all the track changes for this section starts on page 26. If you want to see what has changed since the last version to inform our discussion here this morning, it might be helpful to have that up or printed out.

Nick Coussoule: Depending on how much time we have, we will get into more of the details later. I wanted to make sure from the members' perspective, one, is that we all understand and agree on the framing. These are some of the challenges and opportunities. Again, there are lots of details and lots of words behind these, each of these, I think Vickie's point earlier, of making sure that, one, that we understand at a high level what these five points are and then obviously, two, that the data behind them and words will support that. We can wordsmith it. I do not mean that to be a diminutive sense. We can wordsmith to make sure they accurately represent the details and vice versa. We just frankly, again, as we were going through iterations of this that we made some changes to this section to reflect what I presented here. We want to make sure that the words do support that. We did not have frankly, enough time as we went through different framing questions here to be able to provide all the contexts here.

We know there needs to some more work there. But if the members could reflect the document that was sent out yesterday, the latest iteration of this and certainly that could hopefully inform our discussions going forward.

Rebecca Hines: I do think we have enough time to spend a few minutes to Vickie's point. I do not know, Vickie, you had anything specific. It would be great to come away today or by the end of the day tomorrow, with agreement on the wording of these five – here is what we are identifying under the committee's purview, and of course the next slide shows and here is the work we are going to do.

Vickie Mays: I think I was confused. I thought you wanted me to put language in the document. I am happy to think of ways in which to do the bullets or these five --

Rebecca Hines: These are the five topics in the document. And the first job is to get the topics obviously framed correctly.

Vickie Mays: I get it.

Rebecca Hines: If you think Number 4, for example, should have public health in the topic title then we need to do that.

Vickie Mays: I am trying to think of how to say it. Lack of a nationwide digital infrastructure to enable pandemic information across health care and public health.

Rebecca Hines: And just so you know, one member sent a comment saying, enable pandemic data – Wu, you sent a comment to enable pandemic – I think it was data collection and information sharing. Was that right?

Wu Xu: I do think currently, the wording pandemic information sharing will include collection, and also is broader than just health care and public health because when we redefined pandemic, it has involved more domains.

Rebecca Hines: That is why – the problem is digitized infrastructure is in the eyes of the beholder. Do we want to say, what are all the means that that encompasses?

Wu Xu: I think add collection will be – you try to fix the problem, have a standard data collection at the beginning. So it is good collection under sharing. But I wonder if you specify domain, how many domains we should be specifying with the pandemic impact either because a lot of social services are involved.

Denise Love: I cannot remember. Did we get in the write up under that topic - I think we get into some of those domains. I know community, public health, clinical, and health care. But should we state in the titling?

Rebecca Hines: That is the question for you all.

Nick Coussoule: I think that is a really good question, Denise, because part of what we are trying to reflect here is obviously we would love for people to read all the details of the report, but they have to understand the things that they are interested in from the framing. We want to make sure that at least – if somebody is reading through the table of contents, for lack of a better term, that they at least have some clear understanding of what is going to be there even though there is going to be a lot more details behind it. We do want to make sure the framing of the challenge, of the opportunity, if you will, is clear.

Vickie Mays: Nick, one of the issues, and this is what I am struggling with is that in the pandemic, probably if I had to say what would have helped us to move quite quickly, it would have been the ability to use data across sectors. For example, you will see when I do my presentation, we had to use built environment data because that was very critical in how infection spread.

The question is where we want to go of either saying this needs to be across other sectors. We have no authority in HUD, in all these other places that we needed the data from. But it really is what in the last disasters that we have had in terms of when there is a hurricane, all that stuff, we need housing data. People even have to go out and say is this person still alive in this house and all that kind of stuff.

And then later we learn about those structures in terms of what if something, a building collapses that it causes death. I do not know how far we want to take this, but if we really want to do well, it would be for our health care and public health data to be able to work across other sectors. But I do not know if we are jumping the gun here.

Nick Coussoule: We have to be sensitive to two things in my mind, Vickie. Again, obviously, I would love other committee members' feedback. Is this specifically reported on the administrative simplification provisions of HIPAA? There are going to be clearly things that the committee would like to explore and undertake that may not be relevant, but may not be directly relevant to the administrative simplification provisions and how those get advanced, but maybe other topics that we want to undertake.

This framing is, again, ideally, towards the things that we are concerned about in the ecosystem, more related to that. Otherwise, we run the risk of making this a very expansive report on topics that really do not fall under the administrative simplification provisions at HIPAA.

Again, it does not mean it is unimportant for the committee's perspective. Clearly, some of these are very broad. We have topics and issues. But I just want to make sure we do not get too wound up into that aspect of that. Because definitely in some of the areas we undertake, we will get way broader than this. But we do need to make sure it is framed up in a way that we understand and say, this is what we believe the problem and challenge is, not necessarily what we are going to do about that related to the HIPAA administrative simplification – we think are also relevant and go to take up through another work effort in one of our subcommittees, et cetera. Does that make sense?

Vickie Mays: Yes. I just do not know what to do.

Denise Love: This is Denise. I do not know how to raise my hand and I wrote Greg about this. Isn't this part of the convergence too, the convergence activities that brings these intersectional pieces together of community and public health and health care?

Rich Landen: I point out that Bullet 4, we talk about digitized infrastructure. But in Bullet A1 above, that is where we talk about the health information standards so the ability to collect data and ensure that it is interoperable. I worry a little bit about trying to expand the title on Number 4 – because we cover some of the subjects in 1. Maybe just looking at the title, I like the idea of adding something to cross-domain or cross-jurisdictional.

Nick Coussoule: That is a good point, Rich. Denise Chrysler, did you have something?

Denise Chrysler: Sorry. I keep putting my hand up and somebody does something that is relevant that I put my hand down. It has been up and down several times.

I believe we have already talked about it and I think it fits within Number 5 as always concerned about the effect of HIPAA either directly or by setting the bar with regard to privacy and the ability to share information with community leaders, with the public, informing the public, empowering the public,

making certain that government is transparent. But I think that comes within 5 and to the extent in a limited report, we address it would be there.

Nick Coussoule: Great. Thank you, Denise.

Tammy Banks: Really like the conversation and just want to make sure that in the infrastructure, that the lack of data requested and the definition of that data is included in infrastructure because that was really a big issue throughout the pandemic.

And then the second point is just for consistency. You have lack of comprehensive, need for enhanced. Maybe for the fifth bullet, you may want to put need to address the increasing challenges to privacy, confidentiality, and security.

Nick Coussoule: I actually made a note of that last night to myself to make sure that the field of tensing of framing was consistent, but that is great. Again, we will have opportunities for all the committee members to weigh in on the details behind these as we get – the framing that makes sense for us and then we will have some details behind it. We will obviously be iterating off of the content as well. I am not sure we will get to a lot of that today in this particular section, but we will certainly have time to make sure of that. It does not mean we cannot come back to the framing of the editing, if you will, but at least it will help us guide the comment part as well.

Rebecca Hines: Melissa, you have your hand up.

Melissa Goldstein: Yes, particularly with the section on the nationwide, digitized infrastructure and within health, within health care, within public health, within – we could call it the entire ecosystem, which I think is the phrase that we use sometimes in the report.

There is this fine line that we tread as a Federal Advisory Committee and again with regard to this particular report as being a Report to Congress versus our advisory capacity to the Secretary. This is something we have been working towards as this nationwide, digitized infrastructure. Vickie was absolutely right that it would have helped to be able to collect the – Vickie and others – the data across sectors.

I would also want to emphasize what Denise Chrysler just said about the fact that the more data that you collect and the more interconnected they are, the more increasing challenges we have in the privacy and security world, which is one of the issues that we are planning to take up in a security project, which we are talking about tomorrow and which is noted in the B slide that you showed, Nick.

I guess the thing is that we do have a current legal structure for reporting data and that legal structure has a federal rule and then there is a state and locality rule. I am not sure if we are thinking about a nationwide, digitized infrastructure whether that means it is required from everybody and that would require actually changing the legal infrastructure, which I am not sure whether we are actually contemplating or not or whether we are contemplating making that recommendation to Congress, which gets pretty far away from HIPPA and its limitations. I guess that is also where the balance is and how we much we expand Number 4, in particular, or contract it, what is required, what would be nice, what we want from a voluntary aspect from the local and states, which is how it works now. I guess those are the things that I am thinking about during this conversation. I would like for us to all keep in mind as well.

Nick Coussoule: Those are good points, Melissa. One of the challenges that we are in, again, is we are not trying to necessarily solve or even in some ways recommend the solution to some of these. We are really trying to frame it up. Some of them, I am sure, many of us have in our own heads what would be a solution to some of these or what we would recommend, but that is not really the purpose of this report. I think it is to try to frame it up as much as we can and then talk about the work we are going to do hopefully going forward. It will not work on solving all of these challenges – some of these are not relevant to what we are going to be doing. But I think – become important to be either inhibitors or enablers to some of the things that we would like to advance. I appreciate that feedback.

Anybody else? I see Melissa still has her hand up. I did not know if you wanted to follow up with that, Melissa.

Melissa Goldstein: I am just slow with the hand thing.

Rebecca Hines: I just want to point members to a couple of comments in this unusual situation of being on Zoom. We are able to see comments from members of the audience in the Q&A, which we would not normally be able to do, but feel free to look at those to inform the discussion. We do not need to respond to them, but certainly feel free to think about some of the questions that are put forward.

Nick Coussoule: It looks like we have a little bit of a Zoom glitch, depending on the version that the raise hand function may not always be working. We particularly targeted that for just a couple of people, but it did not really work. If you have questions and that is for some reason not working for you, if you can have your camera on and literally just put your hand up. I am watching all the members. Denise Love, please we would love to hear your comments.

Denise Love: I am testing the hand because I do not have a digital hand.

Nick Coussoule: Technology does get to be challenging. When you are in a room, it is a little bit easier to do this work.

Maya, you have some comments for us please.

Maya Bernstein: Just testing my hand like Denise.

Rebecca Hines: Nick, do you want to just review the last slide and then get into some details like we talked about?

Nick Coussoule: That is the intent. To the last slide or at least the last slide for this part of the presentation, which is some of the NCVHS' focus areas going ahead that we have got from the committee members. First is to promote the convergence of clinical, administrative, social service and public health data. I think to Rich's point earlier, the work effort here is potentially very broad. It will be important for us to be able to frame things up what I will call long-term structure kind of thing we want to undertake as well as more tactical deliverables to any of the projects we undertake. This is one topic.

Focus area secondly is to hopefully be able to improve the health care industry's cybersecurity posture. To monitor and advise on ICD-11 readiness and then supporting modernization of public health data systems. Again, those would be focus areas that the committee would try to undertake ideally to address some of the challenges and opportunities that we have just framed up.

With that said, I am not sure there is a whole lot of discussion in regards these particular focus areas. It will probably be more apparent in our workplan document. But we do want to make sure that in our report, we are highlighting areas that we believe are both in the committee's focus area as well as relevant to the advancement of the administrative simplification provisions or challenges therewith.

Rebecca Hines: I will just say to the members, after today and tomorrow, we should be able to get Section B tightened up and pretty close to final because we will know what it is we are going to be doing. This should be fairly straightforward to finish up relatively in short order. We do not need to worry about wordsmithing these because we will be able to do that after this week. I will call upon our wonderful subcommittee chairs to help orchestrate that and perhaps get some other members to help us just wrap up this part of the report.

Nick Coussoule: What I would like to do with the next chunk of our time that we have allocated so we have about 30 minutes left in here is to actually start walking through the details of the first few sections and some of the comments and questions that we have had so we can debate and try to get to resolution of some of those as a group. I think, Rebecca, we are prepared to bring up the actual portions of the report now.

Rebecca Hines: Sure. I am going to share my screen. Starting in Section 1, Nick, we did not get any comments, I do not believe.

Nick Coussoule: I think that one was fine. It goes down into Section 2. Again, our attention is to now walk-through areas we had comments to make sure that we are in sync about both what we are trying to communicate and how we are communicating to make sure that it has the right impact and has the right topic, subject, and impact.

Going down to the paragraph in the middle of the screen right now, one of the changes – read this out loud. But the question became – we had a framing of this and in time would transform and talked about changing that to transformed instead. Again, of course, is that a future looking or more of an already happened question? We would love feedback on that from any of the committee members.

Again, one of the things I would suggest is we obviously – hand raising makes it a little bit easier, but if you have a comment, just go ahead. And if we have multiple people then we will try to get more into sequencing from hand raising. It might be easier just to weigh in verbally and we will see how we can get from there.

Rich Landen: I have a question on the edit that deletes the word normal before adherence. To me, I think we need some sort of word. It does not have to be normal, but something that would constrain the adherence a bit because the way it reads now without that normal, it seems to be that the HIPAA privacy security is totally irrelevant. It is not. It is a loosening or a relaxation of enforcement as the sentence starts out. But I think we need to qualify that.

We should not simply say without any adherence at all to HIPAA privacy and security requirements. I will of course yield to those who know more about this than I do. I may be off base. But I do not think the intent certainly is to throw privacy out of the window. It is to reduce or relax it.

Nick Coussoule: Would the term strict make more sense, Rich? Again, I defer to some of our PCS members. In fact, they have more knowledge of the details of this.

Rich Landen: That is clearly in line with my intent. Yes.

Melissa Goldstein: I would actually defer to Rachel and Maya on this question. There are quite a few guidances that came out. We listed some of them earlier during the pandemic that I believe are – this is what I need to verify with Rachel and Maya are still in effect and not necessarily time limited in their own wording. I think one of the questions is how long will that relaxation continue and what happened with the relaxation? There are also questions that a community has raised about the necessity of so many guidances. Is it excessive or not? There is a lot behind that single word "normal", Rich, right? I think that is what you are getting at too.

We could say without the previous adherence because it was different before. We do not know where we are going next. I guess what is normal. Normal might be what we were doing before. We might have a new normal after this. I think that is the thing we are struggling with. It changed things very dramatically in the past year and a half. Depending on your personal opinions, that was good. It did not need to be so dramatic. Maybe it needed to go farther. A lot of people have a lot of different opinions about that. That is a lot of baggage that that one little word carries.

Nick Coussoule: Maya, did you have something? I thought I saw you put your hands up.

Maya Bernstein: We can describe what happened that the department took these measures to relax certain requirements. But I will say that it is controversial, as Melissa pointed out, in some communities. I do not want to put an evaluative or suggest that it was the right thing to do or not the right thing to do at this time that is particularly controversial. It may be something that at some time that even the committee may want to weigh in on.

I think a neutral way of describing that this happened could be better than putting any kind of gloss on whether we approve or do not approve of it. Better just to describe that this happened at the beginning of the pandemic and throughout the pandemic, and yes, some of these leniencies, I will call them, have been going on for now more than a year. There are some legitimate questions about whether that is really appropriate. At some point, it was supposed to be easier for covered entities to deal with all that they were dealing with in the pandemic because it goes on long enough.

There is a significant community of people who think that it is too long. By now, you should have figured out how to comply and reducing the rights of individuals. I think a neutral discussion of this until the committee wants to opine particularly or make recommendations about it would be appropriate.

Nick Coussoule: Let me even see if I can put a – difference on what you just said or try to reframe it, not reframe it, but rephrase it. We are not trying to provide a context that we think this was good or bad. We are more trying to say this is what happened. We talked about – I do not want to get too far into wordsmithing. We can let others do that. It says right now we expect that statutory adherence, but we will relax the rules. Is that what you were talking about, Maya? Is that what we are trying to get to?

Rebecca Hines: And Rachel also put a note in the chat that she can work with us to get this so that it reflects reality in a neutral way.

Nick Coussoule: Denise, I think you had something as well.

Denise Love: I think Rachel is on it. I was going to say instead of previously, pre-pandemic to get the previously. But I think Rachel probably can craft this better than I could.

Maya Bernstein: She suggested previously followed. You could say in the before times.

Nick Coussoule: But I think we are all in sync about what we are trying to get to. Rachel can help us with some of the wording and we can – excellent.

Down to the next section. By the way, one of the things we do not see is you do not necessarily see who made all of the changes, but you will see some of the comments added in from different folks. We are just trying to let you know where some of these things came from. Unfortunately, if we try to put every change to every detail in there, we have missed that. But we have tried to with the comments where we put for intentional purposes.

Rebecca Hines: The first comment here is a structural one. We will just be clear on how we refer to other – intra-report referral.

Nick Coussoule: Then the next section in the cross-cutting trends.

Rebecca Hines: This here is an important question that has been raised about the way we word this. In the past, I have tried to remove things like the committee believes, but sometimes there is a statement that needs to be – that there is a desire to include. We just need to reword it. Rich, I see your hand up.

Rich Landen: Actually, I have two comments on here. The first is the second sentence. NCVHS, with representation from – I struggle with that because it really was not representation. It is NCVHS based upon dialogue with or in conjunction with. Something like that.

Participant: It is both of our personal opinions as well as a lot of the things we gather through hearing testimony.

Rich Landen: Right. And I am thinking back to what we went through as the Standards Subcommittee and then the whole committee with the testimony around the operating rules. We got testimony, but we, as appointees, that liberated that testimony and came to our own conclusion. We, as NCVHS, are issuing judgment, but it is based on evidence that we have gathered.

My second comment is that last sentence, the one that is entirely struck through. I hear the concerns about saying “we believe”. But on the other hand, I think what this conversation today is about is what do we as a committee – what is our consensus about what we heard? Leaving the verb aside for a second, I would suggest that we do not delete the first part of that sentence. We leave it in there. The committee -- whatever the verb is – the strong national leadership is essential to meet these new opportunities and challenges, but then put a period and not mention forward looking, policy law, et cetera.

Rebecca Hines: Rich, is the committee – the word that we used on the last report finds or has found, something like that.

Rich Landen: -- concurs.

Rebecca Hines: That strong national leadership is essential to meet these opportunities and challenges and then you are saying put a period – that is your suggestion is to put a period here.

Rich Landen: Right.

Rebecca Hines: Melissa has her hand up.

Melissa Goldstein: On this, I would go back to my previous statement about the purpose of this particular report being a Report to Congress and primarily a report about HIPAA implementation over the reporting period. I think that sentence – and you can see in my comments in the margin actually. And you all will notice, everybody who has joined us today for the meeting as well, that I am a frequent commenter. I think once a teacher, always a teacher. That might be – I am not sure I should apologize to that, but a way of explanation.

I also do not know that we have done a poll to see if we all believe this. I think that the purpose of this report is very different than our recommendations to the secretary. The recommendations to the secretary we tried to find consensus. And if we do not have consensus then there is an ability for anyone who does not agree to give a different opinion. We are actually making recommendations as a committee. I do not think the role of this report is to make recommendations to Congress. I think that that last sentence in the paragraph treads too narrowly on the line there. First of all, I do not think factually we can say it that we generally find anything. What this is is a Report to Congress.

And second, I just think it is a better idea not to advocate in this particular report and to take out the sentence.

Rich Landen: I would push back on that for a couple of reasons. One is, as I mentioned, we are meeting as a Full Committee and this is our opportunity to find out whether or not we do let us use the term believe although we are not going to use that in the report I do not think. Let us see. Do we have consensus around this statement or do we not? If we do not get consensus, out it goes.

I also am very concerned about – let me phrase it differently. I do not see that it is such a narrow – bright line between talking about issues and what we have been learning and talking about what is part of the ecosystem. That is different than making recommendations. I would agree we do not make recommendations, but I would also say that we would fail in our duty if we do not describe the ecosystem and the challenges and opportunities that we have learned about in this report.

Melissa Goldstein: I guess my answer to that, Rich, would be to go to our staff who are the specialists and experts in the role of this committee, and that would require input from Sharon first of all, and then from Maya and Rachel and then to Rebecca as the --

Rebecca Hines: Melissa, as the designated federal officer, I can say looking at the charter, it does say advise HHS and Congress. And certainly, we have precedent in 13 previous reports to Congress to make statements like this. If we want to change our stance, we certainly – if that is the desire, there is no reason we cannot. But so you are aware, the charter does say advise HHS and Congress. I do not see this as out of purview from that standpoint.

Sharon Arnold: Rebecca, if I could interrupt. I think we have been in the process of seeking clarity from our general counsel on the scope of the committee and the extent to which it advised broader than the secretary. Let us pause on that and get back to the committee after we have had a chance to circle back with counsel sufficiently.

Rich Landen: Rebecca, I would make a different suggestion. I would say let us put in here what we have as a committee consensus. I just think it is a cart before the horse as to charge staff – something to

dictate the content. What I would say is this is a draft. Let us put in what we think and then if staff upon review of the language we have has an issue with that then of course we are going to deal with that.

Rebecca Hines: Unfortunately, I do not see a thumbs up voting button, which we had available last time, Greg. I do not know whether there is a way to just get a sense whether there is consensus or not on the statement.

Debra Strickland: This is Deb. I agree with it.

Nick Coussoule: We had a couple of other hands up – comment before we go too far. Vickie and I think Tammy both had their hands up. Vickie, first please.

Vickie Mays: Mine was just in terms of the FACA rules, it actually says – now, remember, you have two congressional appointees and there is a reason for that. And it actually does say that federal advisory committees may be established by Congress, the President, or an agency had to render independent advice or provide the federal government with policy recommendations. It really does say that that could be done. I agree. Sharon can ask. But I just also want you to remember that Congress does put us here for a reason.

Tammy Banks: I support the sentence wholeheartedly. I would actually go a little bit stronger and say the committee encourages strong national leadership to meet these new opportunities and challenges because we are going to need to have it in order to make these changes.

Nick Coussoule: Denise.

Denise Love: I agree with Tammy. I am wondering if we can wordsmith it. If you want to soften it, you could say the committee based on stakeholder input believes because that is what I hear from various stakeholders. They are looking for the NCVHS to set the tone or a leadership position on some of these very high level and difficult issues.

Debra Strickland: I just wanted to make sure that I was heard before that I do agree with this stand as well.

Nick Coussoule: Jamie, you were raising your hand.

Jamie Ferguson: I agree with the statement also. I like what Denise just said. But what I was also going to observe is that this is an area where we are developing recommendations to the secretary. We are developing recommendations around strong national leadership to meet these new opportunities and challenges. In a Report to Congress if we do not want to give advice to Congress, we could just observe that we are developing recommendations to the secretary that require a strong national leadership.

Nick Coussoule: One comment from my end and then I will ask a couple of others. A slightly different take. When we say that we encourage strong national leadership, I would actually frame it to say strong national engagement and leadership. And the reason for that is because we are not just asking Congress to do something or the secretary to do something. We are talking about this is going to require lots of different parties to be engaged in driving this from both the participant as well as the leadership perspective. I think if we did that, it might get away a little bit from that we are asking somebody to do something as opposed to saying that we believe this will require that level of engagement.

Melissa, you had your hand up. I am trying to make sure I am not missing somebody on the screen here too.

Melissa Goldstein: I would support the edit you made, but it was engagement and leadership, not leadership and engagement.

Nick Coussoule: That would be the order I would actually recommend.

Melissa Goldstein: I would also support – I believe it was Jamie – Jamie's phraseology as well. I could not support the way the sentence was already written. Depending on how you define the word consensus, I would not define that. And I do have to also note for the public that of course I am a law professor. I am sorry, but I cannot support that. But I do support the way that you phrased it and the way that I believe Jamie just chipped in also. Thank you, both.

Rebecca Hines: Melissa, is what is on the screen capturing that or is another edit needed to get there?

Melissa Goldstein: I think that that is fine because it is does not say Congress, we want you to do this. It says it could be a lot of different parties. It could be public-private partnerships. It could be the secretary, which we are – that is our primary charter and this document is a Report to Congress. It is a report. While Vickie, of course, is 100 percent correct that we have an advisory capacity. Our primary role in our charter is we are a FACA. As Sharon said, we have a legal designation that I am concerned that we follow. I like the way that it is —- the middle ground that you found, Nick, seems great to me.

Nick Coussoule: Tammy.

Tammy Banks: I was just wondering. Denise made a good point about the stakeholder input. Should that be included in this or do we want to stand with just the committee?

Rebecca Hines: It is above here. I think we do not need to say it twice in the same paragraph. I defer to members of course.

Nick Coussoule: Other comments? I want to make sure I am not missing anybody. I can see all the faces.

Tammy Banks: The word engagement also to me brings in the idea of input from others.

Rich Landen: Building on what Melissa said, I just want to make sure it is clear for ourselves and for those listening that when we talk about strong national engagement leadership that is definitely not the same as saying that we are interested in seeking any sort of federal mandate. What we are talking about is leadership.

Nick Coussoule: I think by saying engagement and leadership, my personal opinion is it broadens it into we are not asking one party to lead this. We are talking about there needs to be a lot of parties involved and leadership all around to help drive that. At least that is my personal take.

Valerie, I am not sure I saw you raising your hand.

Valerie Watzlaf: I just wanted to say that I also support the statement, particularly as it has been edited. I am in support.

Nick Coussoule: Other comments? Rich, your hand is still up. I do not know if you have more or you were just a hanging chad there.

Xu Wu: I support the current statement.

Nick Coussoule: Are we ready to move on to the next section?

Rebecca Hines: Is value-based care capitalized? That is the $64 question of the report.

Nick Coussoule: That is an interesting question. I have seen it both ways personally in lots of different contexts.

Rebecca Hines: Let us just pick one. We can either have staff pick it or you pick it. Somebody just says what you would like. No preference.

Rich Landen: Lower case.

Rebecca Hines: Lower case. All right. We will go with lower case.

And then there was a phrase entered right before that and respecting patient's privacy. How about this. Anybody not want that phrase added?

Nick Coussoule: I think that is a good add.

Rebecca Hines: I think the rest of these edits – let us see. There are little edits here. In the next sentence, we will lower case value-based care. And then we added a footnote that defines population health and public health because they are certainly not the same. I hope this footnote is adequate. If it is not, we do not need to do that right here. That would be an academic exercise. But if somebody has edits to the footnote, which defines the committee's use of population health and public health, this is what I came up with to deal with that.

Nick Coussoule: Any other comments with the edits in here? I think this becomes more readable and clearer.

Jamie Ferguson: I have a minor comment, and it is actually about the social determinants of health. I realize that I will probably be in a minority on this and that this term is broadly accepted. However, social factors do not determine health. They are not determinative and therefore I prefer to call them social factors, not social determinants of health so social factors affecting health or what many others prefer is just to call them essential human needs and not social determinants. I really would prefer if we could not promote the use of the word determinants.

Nick Coussoule: Other feedback? Rick, you still have your hand up.

Rich Landen: I am in agreement with Jamie. I also worry that social determinants of health and the acronym SDOH is a term of art. If we can incorporate Jamie's suggestion somehow with edits, even a footnote, because if we use something other than SDOH, I am not sure we will be understood by our readership and that would be a problem. Jamie makes a good point that these factors are not determinants of health. They are correlated with outcomes among a population and not necessarily an individual.

Jamie Ferguson: I would just say that where possible if we could use the term social factors or the term essential human needs, I would prefer that.

Nick Coussoule: Just from my perspective, I do not disagree with what Jamie is saying. I just want to make sure our audience is going to have the same understanding depending on who is involved and what level of detail with this. And although I do agree that we could probably argue the details of whether they are deterministic or not and Jamie is probably right. The question is is that more of an understandable phrase although not precise or do we change that. That is an open question although I do understand what Jamie is saying. I conceptually agree with that too -- what is the right framing to make it understood the same way.

SDOH has become very much a phrase in industry that has a certain understanding for a broad audience. And the question is if it is imprecise, that is a different set of challenges.

Denise Love: I think we can wordsmith it and get both in and I do not think we have to do it here, but you could say for the purposes of – explain what Jamie just qualified, which is great. And then just say, for the purposes of this report, we will use common terminology otherwise known as social determinants of health, recognizing its limitations or something like that, just to acknowledge because he is right in that. I agree with Rich that the horse has left the barn as far as terminology whether we like it or not and we want them to.

Nick Coussoule: I really like that idea of reflecting that detail in the footnote that that is a more commonly used phrased even though it may not be precise because I think it does get a broader audience to understand what we are talking about and something that they may have in the back of their head and we actually, I think, can also lead to say is why it is a challenge. If that could be done in a footnote, it lets us get our point across by still referencing it. I think that is a great idea.

Jamie.

Jamie Ferguson: I would just also point out that in talking to leaders of community organizations that are involved in addressing these social factors or essential human needs, their customers or patients, find that the term social determinants of health appears to be demeaning to them. It makes them feel less and that is another reason to avoid it.

Denise Love: It kind of displaced SES. Back in the old days, it was SES, social economic status, which was even more offensive.

Nick Coussoule: I think that is great feedback. Any other comments? It is an important point.

Denise Chrysler: I was trying to do my other screen to search because I know Robert Wood Johnson Foundation often recommends updated terminology. I could not find things immediately, but I would think that others have discussed this topic and what language works best. I know often we are talking about social, political, and economic considerations. But we are not going to be able to include long phrases, and we have these social determinants as sort of our catch all. But I know these conversations have been going on and there must succinct ways we can transition to improve terminology.

Nick Coussoule: Just a timing perspective, are we in general agreement that what we are trying to accomplish is a little more precise phrasing and not use the term SDOH as part of our report, but maybe

reference that as what some people are likely to think about the things that we are getting more precise with.

Thank you, Jamie. Great input.

Evaluates care, do you want to address that again?

Rebecca Hines: I think the answer from CMS is no. Our resident CMS expert says CMS does not capitalize it so I am happy to go with no.

Nick Coussoule: Okay. Just to clarify.

Last reporting period – the last two years saw. Any strong opinions of that one?

Melissa Goldstein: I just thought that last two years might confuse people depending on when they read it and depending on when it comes out and is published and submitted, so that if we clarify the reporting period and since we got it in the title, it is clear to everybody what we are talking about. I just thought it might be easier for people.

Nick Coussoule: I like that.

Any other comments there? Okay.

I think AI should be referenced that way, too. I think that makes sense.

Rebecca Hines: Melissa, on the API, do you want us to – is the footnote there – do we need to add a different footnote or something?

Melissa Goldstein: I think there just was not -- I thought that perhaps staffers – not everyone knows what it means. I thought it might be helpful. Maybe we are speaking to an audience where everybody does, but I was not sure here so I thought I would raise that question.

Rebecca Hines: Lorraine, can you help us make a footnote that addresses that a little more directly?

Lorraine Doo: Sure.

Nick Coussoule: I think your point is well taken, Melissa. Those of us who live in this world regularly probably are not thinking quite the same as folks who do not and making sure that it is clear. I think that would be a useful footnote if we could get somebody's assistance in doing that. Lorraine happily volunteered, I see.

Lorraine Doo: Always.

Nick Coussoule: Jamie's suggestion to separate out the HIE organizations and networks, given the definition of HIE it is typically – it is geographic and boundary bounded, but the networks are interoperable. I think that is a clarification. Any other comments there?

Last sentence there – I think Melissa's suggestion is a good one. How do we do that here? Just make a reference and then – or just make a note --

Rebecca Hines: Actually, this is referred to in the appendix so we could actually – appendix and then it is like – I forget which letter it is, but 1 – I will put 1X. There is a whole description of that in the appendix.

Melissa Goldstein: Great idea.

Rebecca Hines: And make sure that what is in the appendix is what is – the brief synopsis of that hearing is correct that if you want to make any edits to it in the next couple of weeks, please do.

Nick Coussoule: Any comments on that? Jamie's suggestion to guidance and regulation. Is devise the right word there?

Jamie Ferguson: Maybe published instead of devised, but I think devised is okay.

Nick Coussoule: There are probably others more familiar with the regulatory process than I to make sure it is accurately stated.

Rebecca Hines: On the next one, Jamie and Valerie, it looks like there is some commonality between your comments here.

Valerie Watzlaf: I was not sure if some of what I commented on was in the appendix or if this is out of the scope at all.

Rebecca Hines: I am just going to propose this and then please modify my statement. Jamie, it seems like what you said and what Valerie is saying in the note could together we could make a footnote that addresses the SDOH or the social factors affecting health data elements and data collection more head on a footnote.

Nick Coussoule: One question where we are also use the term SDOH here. Do we use that term here or do we adjust it based on the previous comment --

Jamie Ferguson: I would recommend putting in social factors here instead of SDOH, social factors data. And then, Rebecca, I would agree with putting that in a footnote. I would be happy to help draft that.

Denise Love: When you put in social factors, our new replacement or whatever that – I am assuming will carry out throughout the report, do we want to make a little tiny note saying aka also known as SDOH? I am just worried people will not --

Nick Coussoule: I think we can do a similar thing to what we did in the last one. I think that is appropriate. Again, it will provide some continuity that we are changing language and it is consistent the way we are changing it. I do not see a problem with that. Again, that is – more of a reference to what people generally understand.

Rich Landen: I would agree with that. I think if we just say social factors, we run a serious risk of people not really understanding that we are talking about the same concept as – SDOH – I like Denise's suggestion.

Denise Love: And I like Valerie's suggestion of the ethical collection and use of that. I am not sure it goes here though, but somewhere in the report. That is the good comment.

Rebecca Hines: It reminds me of social distancing because when it came out, I said we are not socially distancing, we are physically distancing. But it just got picked up and everybody calls it socially distancing when you can still socialize over the phone or over Zoom. Phrases get taken up and then you are done.

Nick Coussoule: I think it is important for us to be as clear as we can be, but also make sure it is understood by the biggest and broadest audience that we can have so that is where you get into a little bit of challenge of doing both of those things.

A little bit of comments in what I will call the internal chat, which is in regard to using SDOH or not – that it is in fact used by CDC and others as well.

Rebecca Hines: I really would encourage us to put together a footnote that goes into this. And then the question is are you all – now, what we have here are social factors affecting health, aka, SDOH. Is this what you – we need consensus. Is this okay?

Nick Coussoule: I am not sure I like aka framing.

Rebecca Hines: Right. We do need to come to some consensus on this.

Denise Love: Commonly referred to as SDOH.

Jamie Ferguson: Or footnote it.

Rebecca Hines: I think we will footnote it again like we did the last time.

Jamie Ferguson: Social factors affecting health and then a footnote, also known as SDOH.

Nick Coussoule: I agree with that.

Tammy Banks: I was just going to switch it. Since there has been so much work to put social determinants of health and make that a priority. Is there any way to compromise and go now include social determinants of health and other social factors? I understand the intent, but since we are talking about code sets here and the work of Gravity, getting more code sets and increasing that concept, I am just wondering if starting with SDOH and other social factors may accomplish both.

Jamie Ferguson: I don't agree to that because the SDOH work of Gravity is a subset of social factors, not the other way around. It is not and other social factors. It is just social factors that include the work known as SDOH. I said I was going to be a minority on this.

Tammy Banks: I just hate not having it in just because of the priority across the industry to increase awareness of an inclusion. I totally agree with your point, Jamie. I do not want to lose momentum. That is all.

Nick Coussoule: Just for the sake of time, why don't we – I think we understand the points we are trying to get to. Why don't we move on and we can revisit this after we maybe think about some things offline and maybe come back to it tomorrow. But I think we get the point.

Rich Landen: Just as a quick comment. I think this is a critical point. From an offering standpoint, the first time we use the term in the document, I think that is the place where we should do an explanation of why we are no longer calling this SDOH, and then let the editor come back to us with a proposal on how to handle it throughout the rest of the document. I agree with you, we should not spend any more time here now.

Rebecca Hines: I did not hear consensus on – and we do not have to have consensus. I hear a range of viewpoints on this. I do think we need to all weigh in as much as we need to. We do have time on the agenda tomorrow to continue with this.

Nick Coussoule: Chair discretion, let's move on to the next sentence for now.

Rebecca Hines: The sentence crosses pages here. This is just a minor edit, which affect IT support. I think that is fine.

Nick Coussoule: I think that is fine as well.

Jamie Ferguson: Sorry. I guess this is the part where I talk a lot. One more minor point on broadband access. Actually, broadband access specifically – broadband access currently is available, over 99 percent of the US population. I think what we are really talking about is affordable access with a focus on affordability rather than technical access. Certainly, the land-based systems frequently are more affordable than the high-speed satellite systems.

Nick Coussoule: I would agree. Access is a better word – affordable access rather than connectivity. That gets into the broader challenge.

Rebecca Hines: Is this okay? Affordable broadband telecommunications access. Is that all right?

Jamie Ferguson: Yes. That is fine. It could be affordable connectivity or affordable access. Either way. But so long as it says – the issue is affordability.

Denise Love: I am one of 1 percent in Idaho that we cannot get it.

Nick Coussoule: You could say affordable and available. It gets to both points. I would prefer actually personally the term connectivity than access there. Maybe I am in the minority. Input on this? Okay. Thank you, Jamie.

Rebecca Hines: Just a time check.

Nick Coussoule: Sorry. I just did not realize what time we were at. I think we are back where we are at time. We have lots of – very busy afternoon actually. Pretty exciting rest of the day. We will stop here. We will reconvene on this one in the morning and try to get some – also some feedback for how we hopefully think through and how we frame up the SDOH for the social factors question.

With that then I think we are on – officially going to be on break until 1:15 p.m. Eastern Time. It gives us about 40 minutes. Thank you to the committee members and staff and others for helping to do this. I did not ever want to be remiss of thanking our technical support folks for helping us put all this stuff together as well. Let me do that now before I forget before the end of the day tomorrow for all that

help. Please be back at 1:15 Eastern Time and we will reconvene with Subcommittee on Standards and one of our special guests, Micky Tripathi. Thank you, all.

Rebecca Hines: Denise Love, did you have a question?

Denise Love: During the break, should we reload an upgraded version of Zoom if we do not have the hand? Would that be a good use of time?

Greg Richards: If you are able to, yes. If you were not able to use the raise hand feature right now, it might be because you are on an old version. If you are able to update, now would be the time.

Denise Love: Thank you.

(Break)

Nick Coussoule: Welcome back, everybody. We will reconvene for the afternoon. We have a busy afternoon setup and productive. I will turn it over to Rich and Denise for the Subcommittee on Standards to both introduce the next section and our special guest. Rich.

Subcommittee on Standards Update

Rich Landen: Everything working. Thanks, Nick. We are going to spend most of the rest of the afternoon in areas related to the work being done by the Subcommittee on Standards and we will be looking at a lot of issues, sometimes same issues through different lenses so they may not appear at first glance to be those issues.

I want to set us up just by doing a quick overview and update. That is primarily for the newer members of the NCVHS, but also for those listening in. I will not spend too much time on that. But then go down and we will get into some other topics and then leading into a good conversation with the new national coordinator, Dr. Micky Tripathi, and hopefully we will get to him quickly because there is going to be a lot of good conversation in this opportunity.

The subcommittee charge and scope. We will not go into the details, but the subcommittee reports to the Full Committee. We are charged for different aspects of activity by several pieces of legislation. The three key ones are HIPAA, the Medicare Modernization Act, and the Affordable Care Act. We identify opportunities and issues in health data standards and bring those to the committee's attention.

We do outreach, liaison, and consultation with the industry and essentially it is all the stakeholders, not only those who are actors that have some sort of role and actually do something, but also those who are beneficiaries of the actions. The list is on the slide. I will not go through those.

We then bring back recommendations to the Full Committee. It is not narrowly about the electronic standards or terminology or vocabulary. It is a little wider issue. As we go forward during the day, you will understand some more about how the scope has been changing since 1996 when HIPAA was first enacted and the concept of administrative standards was pretty standalone, which it no longer is.

Then we make recommendations to the Full Committee on strategies to promote a continuing process for developing, adopting, implementing, and maintaining standards. We produce recommendations for

the Full Committee's Report to Congress, some of which you got a flavor for this morning and we will do more tomorrow.

And then we collaborate with other NCVHS subcommittees. Right now, that is Privacy, Confidentiality, and Security on cross-cutting issues, specifically out of recent history. The conversations we had with them on the ICAD report as it dealt not only ICAD report, but also our operating rules hearing when it dealt with specific issues around security under HIPAA.

And then we collaborate with other federal advisory committees on cross-cutting issues. An example of that we will talk about more with Micky Tripathi and the ONC's advisory committee, HITAC.

A lot of our work recently has been based on what is now about a four-year initiative that started off fairly small, but grew in a lot of different directions. We refer to that as the Predictability Roadmap. As this slide says, it has a whole lot of objectives about what we do to make recommendations to address business and technology changes in health care. Interoperability did not exist back at the time that HIPAA legislation was crafted.

Improve availability and access to updated versions of standards. Something we have heard often and loudly from the industry.

Are there ways to improve the standards updating and adopting processes? How can the regulatory processes be improved to enable better access to updated or new standards by industry? Reduction of administrative burdens. Some of the ways that standards happened 20 to 25 years ago is not necessarily the way they have to happen today or in the future. And then finally, addressing clinical and administrative data intersections.

The concept's takeaway here in terms of what constitutes the core of the roadmap thinking at this point and I will mention we have done several recommendations to the secretary over the last couple of years.

Some of the big things we are thinking about in this concept is smaller, more digestible bites for standards updates. Instead of doing all the standards at one point in time, let us do smaller bites more frequently.

Enabling a quicker response to changing business needs. The example there is value-based purchasing whether that is capitalized or not capitalized. Back when HIPAA was passed and the first set of standards were adopted, everything was fee for service. That is no longer the case. As the business needs of industry evolve, the standards and the regulatory process have to evolve in lock step with them if we are to successfully utilize standards to achieve the objectives of interoperability and burden reduction, cost effectiveness.

And then finally, two more points, one on the Predictability Roadmap is a setting a basis where innovation is encouraged, not discouraged by the framework for the regulatory and adoption processes.

Then the last point I would like to make is what came up in industry testimony is a lot more visibility around the enforcement process and the guidance to different industry constituents who can benefit from lessons learned by other constituents.

In the recent couple of years, here are the key highlights. We did a hearing and then made recommendations to the secretary on adopting updated NCPDP pharmacy standards. Specifically, that was the Version F6 and also then the Medicaid subrogation updates.

We did a hearing on adopting new operating rules from CAQH CORE relative to prior authorization and connectivity. In the end, we did not recommend that the secretary adopt those operating rules as under HIPAA. But we did recommend that the industry pilot the operating rules and do some more testing and proving and then a separate recommendation back to CAQH CORE to update the connectivity rule specifically for some of the security concerns that were in there.

As mentioned a couple of times, we worked with the ONC Health Advisory Committee, HITAC, and its taskforce on ICAD, the Intersection of Clinical and Administrative Data. We had one of the Standards Subcommittee co-chairs, Alix Goss, who was mentioned earlier who rotated off the NCVHS due to term limits. Alix co-chaired the taskforce. There were three other Subcommittee on Standards' members that were active participants on that taskforce. ICAD developed recommendation, published a report that was presented back to ICAD, accepted by HITAC, and then presented by HITAC to ONC.

We did a follow up letter on recommendations that NCVHS has previously submitted to the secretary on the Predictability Roadmap in which we were promoting opportunities to apply for testing exceptions. There is a whole set of regulations about exceptions to the HIPAA transaction requirements as you test new versions.

Also, talking about adopting of a standard for attachments. It used to be called claim attachments. It is a lot broader than that now. And then, as I mentioned, the publication of activities related to enforcement.

On ICAD, that is the taskforce of HITAC, the ONC FACA. The report envisioned what it called an ideal state for prior authorization and prior authorization was used and is exemplar to conceptualize the whole vision, I guess, of interoperability and the convergence of the administrative standards adopted under HIPAA and some of the standards adopted by ONC under promoting interoperability as well as standards adopted elsewhere in Federal Government.

But it described this ideal state, and that state would enhance the patient experience, safety, and health outcomes. It would ensure patient consent, privacy, and security. It would use digital capabilities for automation, improve transparency and timeliness of information flows. It would build and extend current standards. And it would harmonize national health care policies, vocabularies, and transport standards. That was the big vision.

To take steps toward that vision, ICAD proposed 15 specific recommendations. I will not go into those. You can read them on the slide. But these recommendations were all the essential steps that ICAD felt were – had to be done in order to move the industry toward achievement of that vision. And these steps were all aspirational in nature. ICAD specifically and explicitly left to others to be named later to actually operationalize these recommendations, in other words, go through each recommendation and say who are the stakeholders here. What actions need to be taken by whom, under what timeframe, at what cost, and through what governance or approval mechanism to actually achieve the – to make the vision happen?

Coming out of ICAD, the Subcommittee on Standards again had some things that were coming up forward for the next couple of years' workplan. First was to continue to collaborate with ONC and the

discussions going on the last few months indicate there may be a possible ICAD 2. If ONC and ICAD and HITAC decide to convene another follow-on taskforce for ICAD 2, certainly NCVHS and the Subcommittee on Standards are more than eager to collaborate to whatever extent fits in with the mission of that taskforce.

The other piece of work that the Subcommittee is doing is to initiate a new project. Actually, it is not exactly a new project. It was always considered a follow on to the work that ICAD 1 did. It would then take the information that we have learned through ICAD 1 and add it to the information that we already acquired through our industry outreach under the various aspects of the Predictability Roadmap work. Then we would bring back to the Full Committee for approval of that project scope.

The Subcommittee had a scoping document drafted about a year and a half ago. This is pre-ICAD 1. Everything that has happened in the past year and a half, including ICAD what we learned from industry and the impacts of the pandemic response and some of the developments in the industry and some of the developments in the regulatory field, have rendered that initial project scoping document way too narrow and obsolete. Later on today, we will be bringing up the current draft of a completely revised and retitled project scope.

We are calling this the Standardization of Information for Burden Reduction and Post-Pandemic America, which is a mouthful. The shorthand title for it is Convergence 2.0. We will seek and hopefully attain the consensus of the Full Committee to move forward with that project scope and that project will include data requirements for HIPAA administrative transactions, clinical data, public health, privacy, and social services use cases.

As I mentioned, we will get more into the detail later, but just some highlights to Convergence 2.0. The purpose is to continue work of the Predictability Roadmap, identify some solutions where the traditional HIPAA standards and the clinical data, which includes prior authorization attachments and other emerging of the standards, where those all come together and how they coexist and not just coexist in the ecosystem, but can also be implemented that they do not collide with each other, that they work together happily, and that – two important points. That they fit into the workflow of those organizations that must implement those whether they be providers or payers or any of the other actors in the health care arena. And then we will monitor HHS activity on the recommendations that we have already made on the -- previously, NCPDP, the attachments, the pilots, and the other opportunities.

Another part of the project will be pursuing new opportunities for standards. A lot of the development in HL7's FHIR. That is Fast Healthcare Interoperability Resources, which is a type of application programming interface. That is a new technology. When I say new, I am meaning relative to the technologies that were in place for the adoption of the current X12 and NCPDP HIPAA standards.

Then the modernization of administrative and clinical data exchange standards. The technology and the transport are a lot different today than they were 10, 25 years ago. We will include the topic of all payers claim databases, APCDs, and talk about the ACD common data layout. This is all – there are some pending HHS rule making on this already so we will be looking at that.

And we will be talking about the integration of – here we see the term we talked about just before lunch, social determinants of health. That is really the factors that Jamie Ferguson was talking about and how to integrate those into the EHRs and the HIPAA standards.

And then finally, we will be meeting hopefully an ongoing dialogue with the CMS National Standards Group, which is part of the CMS Office of Burden Reduction.

Now the project envisions a couple of quick wins. These, of course, are very tentative. One is something in the social factors, SDOH initiative realm. And the other specifically later this year, we are thinking about convening an industry-listening session around opportunities and challenges for integrating APIs into the HIPAA transaction standards, meaning everything in the regulatory process, how did the HIPAA transaction mandate, how would they look in an API world or a partial API world.

Besides the convergence project or Convergence 2.0, there are a couple of other things we will continue our work around ICD-11. Just quickly, World Health Organization a year ago has voted to adopt ICD-11. There are implications for the US both for mortality use, which happens under US treaty, but also for the morbidity use of ICD-11 under HIPAA. ICD is a medical code set and there are some issues with ICD-11 that need to be vetted. NCVHS had sent over a year ago a letter to the secretary advising a research agenda and a communications plan. We will be looking into updating that and later today we will be hearing some presentations and have discussion around ICD-11 that I think are going to be very informative and seeing where we are at now, a year and one pandemic later.

In the coming year, we will be talking about the terminologies and vocabularies. We will hear about that at the end session of today's agenda, semantic harmonization, and classifications. That will build on also the work we have done on curation of some of the data sets.

And then finally, it is a standing issue. We will also address any requests by the designated standards maintenance organization or the operating rules offering entities for any updated HIPAA standards if we get them. There are none that we are aware of at the point that we could get those any time from the SDOs, the DSMO, or the operating rules authoring entity.

That is a quick overview of the Subcommittee's recent history and current forecast. Denise, let me invite you to add anything if I have missed anything. Denise is co-chair.

Denise Love: No, Rich, you did a great job, and I cannot see where you missed anything. Thank you.

Rich Landen: If there are question by the committee members, I think we will get to those later as we get into more of the specifics in the sessions later this afternoon because I want to get quickly to the introduction of Micky Tripathi.

Micky is the newly appointed National Coordinator for Health Information Technology in the Office of the National Coordinator. He leads the development of federal health IT strategy, coordinates federal health IT policy, standards, and programs. Micky has over 20 years of very diverse experience in public and private sector, knowledgeable on standards, standard organizations, industry collaboration. He is very well versed in HL7 FHIR and LOINC, the Regenstrief Institute, logical observations, identifiers, and nomenclature codes, health information exchanges, and in sum, he is a pretty multilingual guy and a world that speaks many different languages in health IT.

The purpose today is to introduce Micky to the NCVHS and vice versa to do kind of the – what travel agents call a familiarization tour of the Subcommittee on Standards' work, history, and progress, and then importantly, to build on the past collaboration and continue that collaboration for nationwide success of both ONC and NCVHS. Without further ado, Micky, welcome.

Micky Tripathi: Thanks so much, Rich, and thanks to everyone for joining. I really appreciate it. It is nice to see a lot of familiar faces and new faces. Thanks again.

I just thought I would – and I did when spoke to Rich earlier, just describe that when I first got into health IT in 2001 and 2002, it was sort of at the knee of Clem McDonald, which was an experience in and of itself. But also, it was ingrained from my very early education in health IT that NCVHS is critically important part. I am really delighted to be here today to say the same thing that NCVHS is a critically important part of this. I really look forward to ongoing collaboration and deeper collaboration in all ways that make sense and we can do.

I thought I would give a little bit of just an overview of things that we are working on at ONC and then would love to open it up for questions. I do not want to take up too much time because I do have a hard stop at two for a meeting I have to be at. But I will try to make my comments brief just to give people things to react to, but certainly want to hear things that are on your mind.

Obviously, COVID is a very large priority of ours and as it is across all the federal agencies. ONC has been playing a pretty big role in a whole bunch of things. One of them is the public health data system executive order. We are working very closely with the CDC team. We are co-leading the work there to evaluate the current state of public health data systems. Think about what gaps came to the surface during the pandemic that we are in and to help that to inform what a future public health data system will look like. I kind of think of it as maybe the transition from public health data systems to public health ecosystem, which I think has a lot embedded in it. But as we start to think about that, that is at least the context that we are hoping to think about here that we really need to think about much more different in expansive ways in thinking about public health.

We also are doing some work – this is, again, related to COVID, in social determinants of health and equity, pushing all of my colleagues and my team to help define an operational definition of something that we have been calling health equity by design, which is all of you are somewhat technical so I think you know the concept of security by design, other things by design where it is something about having it be a core principle, not something that you design to, not something that you add on later.

I think there are a lot of different dimensions in the areas where ONC is involved certainly as we think about data, in particular, and how we can think about leveraging as much data as possible and make that actionable through the systems that we are involved in. That is one of the things that we re digging in on as well.

We are doing a lot of evangelism with respect to FHIR and scheduling systems. I say it is evangelism because we do not have any authority over any of this. As many of you may know, vaccination scheduling has been a real pain point across the country. We are certainly not pretending that we can fix that problem. I think, as all of you probably appreciate, the right time to have done that would have been about 12 months ago. But we are certainly not going to try to wipe the slate clean or expect that we can. Different states provide organizations, pharmacies, others have moved ahead as they have had to with those systems.

What we are doing is following on President Biden's speech, I guess probably, it feels about a year ago, but I think it was just a couple of months ago where he talked about May 1st being eligibility for all individuals to get a vaccination as well as being able to make some kind of improvements in individual's experience with respect to scheduling vaccinations.

We have been working with our partners at the U.S. Digital Service to evangelize having a FHIR-based approach to making an incremental improvement over the way that appointment data is made available today. I am happy to talk about that more if people are interested in that.

We are going to be hosting a coalition of the willing(?) connectathon. ONC is going to be hosting a connectathon in the next few weeks to bring together technology vendors, both EHR vendors as well as other vendors who are new to this space, like pharmacy vendors and others, but who are involved in vaccination scheduling – administration and scheduling to try to iron out the last details of a very simple, but clean scheduling slot availability implementation that the team from HL7 and particularly Josh Mandel have been working on.

We have been reaching out to stakeholders, talking to every organization we can think of to raise their awareness about this to see if we can get better alignment on that because that I think as all of you will appreciate being in the standards world, one of the concerns that we have was that different states were going off in different directions with the proprietary spec. And even though it seems like it is something small and something simple, I think, again, as all of you appreciate being in the standards world that becomes a deviant path.

Once you put that in place then people – people always want to do more on top of what they have built. It starts off with, oh, it is just appointment availability. Now, we want to do this. Now, we want to do that. All of a sudden you have a portion of the industry going off in this direction over here where you were trying to just say, if you just start with a basic FHIR JSON representation based on FHIR structures then you can have forward adaptability. You can build and integrate with all the other systems that we, as a country, have invested $40 billion on to put into place.

As I am sure you have seen in the news, we are somewhat involved in the area of vaccine credentials. We are helping with an interagency team that is developing core foundation principles. I think some of those principles you have probably seen in the news, but just if you have not. The approach of the federal government is based on a set of core principles and we are forming an approach now. But some of those core principles are not having a central repository so we will not have a central government database of vaccine credentials nor will we be the single issuer of credentials.

We are placing ourselves basically between the laissez-faire, let the market trample on individual rights side of the equation, which we do not agree with, or the other end of the spectrum, which is the state of Israel's approach, which is great for the state of Israel, but really, we do not think it is the right model for the U.S. as a whole. Certainly, certain states like New York have gone down that path, but from the federal government perspective looking at the country as a whole, very heterogeneous, I think as all of you know. We have a complex and decentralized health care system and not surprisingly, that means that the vaccine credential system probably needs to be complex and decentralized as well.

We are talking to a lot of stakeholders around a set of core principles related to an approach that would enable – following the path of the 21st Century Cures Act and APIs and apps and patient enablement, being able to follow the path of that so that an individual can have possession and control of their credentials to be able to present.

And, again, we are still in an interagency process, so all of this is under consideration. Welcome any feedbacks or thoughts you have. We are taking in stakeholder input now as we try to get our arms around this and finalize the decision making.

We also had a ton of things on our plate even before we started to think about COVID. Some of those are related to the 21st Century Cures Act. I think, as many of you may know, the April 5th applicability data for information blocking is finally just around the corner. I say finally because as many of you may know, that law was passed when President Obama was president. I am not going to place the year, I will just say that. That, at least, to me feels further back than if I just say it was passed in 2016. It feels like two generations ago. That is when the law was passed and now here, we are finally at the point where we are able to say that the first part of that law will start to go into effect.

We are doing all that we can to help to inform the industry and education and prepare the industry for that. It is the April 5th applicability date.

As you may know, OIG has a whole separate – ONC defines the policy and then OIG is responsible for enforcement and compliance. They have their own rule out. That is public. You are welcome to see that that reflects the timing of that. But April 5 is an important date for us to the industry. We are looking forward to continuing to work with industry on that.

One of the things I think is really important about information blocking is that hopefully it helps to eliminate confusion and doubt about what is shareable. I know in the near term, it will not do that and I appreciate that. But I am hoping that over the longer run, it starts to flip the default assumption about – the assumption now is I do not share except under special circumstances to I do share except under special circumstances. That is obviously a cultural and paradigm change that will take a lot of time. Because it is going to take a lot of time, we need to begin as soon as we possibly can. HPIs are obviously a huge part – an important part of that as is TEFCA.

A couple of other things that I just wanted to touch on and then I will stop because, again, I really want to be able to have discussion with all of you. We are doing a lot of work also aligning with federal partners. That was something that I did not appreciate being for 20 years in health IT on the other side of the wall.

Now, that I have crossed over to this side of the wall, I appreciate how important the role, the capital C role of ONC with respect to coordinating health IT activities across the Federal Government is both because of all of the incredible activity going on in the Federal Government and especially with respect to FHIR and EHRs.

Many federal agencies have gotten the message and are seeing the vision and that represents the next set of challenges, which is how do we have alignment and not have splintering in our nascent standard here that we are hoping will be a part of the portfolio of standards that everyone is able to use on a routine basis. Suspending a lot of time and just figuring out what is the best way to coordinate federal activities, working deeply with key federal agencies who have a lot of involvement in the space and trying to make sure that we are helping to work with them to say how can we use the levers that we have, the soft and hard levers with respect to standards and interoperability to help them accomplish their goals.

The last thing in the world I want us to be is the standards nanny to go in and say you did not follow standards. I do not think that is the position that I want to be in nor is it a very helpful position. It is much more about saying let us talk about what it is you want to accomplish. ONC has a certain set of levers that we can pull to help you to accomplish your goals and how do we figure out the best way to do that, all with an eye toward helping CMS and the CDC and FDA and the VA and DoD and all these

different agencies be able to accomplish their goals, not for them to accomplish our goals, but for them to accomplish their goals. That is a really important part of what we are doing.

That gets me to NCVHS and the great work that you have been doing. I was able to review with our clinical and medical team and the ICAD report on version one, which was great. I think some of the things that are in the report as well as some of the things, Rich, that you had just talked about in terms of a Predictability Roadmap kind of concept. That is one of the things I feel is really important as well, an important role that ONC can play, working with partners like CMS and CDC and these different areas of how do we give more foreshadowing to the industry about what the roadmap is from our perspective at least so that having been on that side of it, working for companies is always hugely helpful because it is always a set of decisions you have to make about where you are going to invest. It always nice to know that there is a little bit of a north star even if it feels like it is far away at least directionally.

Looking at the ICAD report, I think it was just a terrific work there and some amazing things that I think were pulled out of it. We are now anticipating the ICAD 2, I think, Rich, as you had alluded to, which is about how we get from the "what" because I think it did a great job of documenting. Here are all the "what's" and how do we move that to the how. Let us figure out the prioritization. Let us figure out the how and then let us have ICAD Version 2 work on that.

I think that the plan right now is for that to be later this year. But many of you may be more involved in that direct conversation than I am right now. I have not had a chance to talk with everything, everyone about every program at ONC. We certainly look forward to continuing our work together and getting the benefit of all of your experience and expertise, which I know has been hugely valuable and hopefully will continue to be.

Let me stop here. I do not want to take up all the time. I know I have five or six minutes. Sorry if I took up too much time. Really welcome any of your comments or suggestions both now as well as offline. I am always available to any of you.

Rich Landen: Thanks, Micky. You crammed a lot into a few minutes. I am just sitting here shaking my head at everything that is all of a sudden on your plate and so many of those priorities have arisen in the past 6 to 12 months. I am really happy to hear you talk about ICAD. You did not say anything bad about it. You talked about the success of ICAD. We look forward to talking with you about the road that is going to take when the time is appropriate. And certainly, you have our support. Mr. Chairman, I should not be speaking for the Full Committee, but I believe based on past practices will be eager to collaborate with you.

Quick question, was there anything in the ICAD recommendations or future state that is already obsolete. I do not want to pin you down to any specifics, but was there anything that stood out as being really eager to get to or something that even in the short time since that report was finalized, things have changed and might warrant a relook?

Micky Tripathi: I cannot think of anything offhand. But I will say we spent an hour going through the presentation and looking at the priorities, but I do not feel like it would be responsible of me to say here are things that we think are obsolete because I just do not feel well informed enough about that. That is certainly an important part of the work going forward though.

Rich Landen: Let us open it up to questions from other committee members.

Nick Coussoule: This is Nick. Micky, thank you again for coming and joining us today. When you talk about the significant push towards health equity, it will be interesting as you start seeing not just priorities, but how you plan on attacking that. You talk about health equity by design. But as that starts fleshing itself out, I think it would be really important to be able to have a better understanding of exactly what that means from ONC's perspective because it may help guide some of our work as well over time.

Micky Tripathi: Thank you, Nick. I totally agree. Like with a lot of things, you start with a core concept and then start working with all the teams to say how do we operationalize this in all the various areas that we are involved in. A lot of it has interdependencies with our federal partners and others as well, as well as looking at industry. I look forward to talking in greater depth about that.

I welcome any ideas that you have on that as well. I welcome unsolicited comments or guidance on that too. It is not as if we can figure it out within the walls of the federal government. We need all of you.

Nick Coussoule: If you notice from our robust discussion, there is not a lot of shy people here so we are happy to weigh in.

Rich Landen: Jacki, I see your hand is raised.

Jacki Monson: Yes. Hi Micky. Jacki Monson. I have a question for you related to COVID. It seems a little wild to me from a technology standpoint that we are passing around paper passports for those that have gotten vaccinated for COVID. Is there a plan to discuss an electronic immunity passport of sorts versus – I think I just saw an article yesterday telling us to take pictures of the COVID vaccine passport and carry it around with us, which just seems a little wild. I am just curious if you have been involved in discussions around that and have any insight.

Micky Tripathi: Yes. Thanks, Jacki. That is what I was talking about before about this idea of vaccine credentials. I really do not like calling them vaccine passports because that has the connotation that it is issued by the federal government like your passport is. That is definitely not the approach that the US is thinking about here.

What we are doing is again we are focusing on a couple of key principles there. And one is just recognition that the market is already moving ahead. The market is moving ahead, and we want to encourage that, but have a set of core principles around that. We want an open and better marketplace for this because the federal government does not have any intention of creating a central approach to that. But we also want to encourage the upgrade from that paper record, I have got mine right here, to a digital version that you are talking about.

Some of the core principles – we would love to get your feedback on this. We are looking really hard at some different approaches, one of which is the SMART Health Cards Framework, that you may be familiar with. And the idea of that would be in some ways that it is a digital upgrade of the CDC vaccination card that is filled out today.

But following the path that ONC and CMS have pursued like the 21st Century Cures Act of enabling patients to be able to have control of their record and then once it is in their possession in the state form, being able to do with it what they want. We are really looking at that and saying your vaccination record is just a part of your medical card. If you look at that in that context then a lot of those paradigms start to flow in the same way. Definitely a lot of consideration given to it.

I think that from the Federal Government perspective, we are hoping to have a set of voluntary principles that we would put out, which is essentially voluntary principles for the market by the end of April and that those principles would also be things that we, as the federal government, would make as contract requirements in any federal government activities related to credentials.

That is at least right now the approach we are taking to figure out how you encourage the market to keep innovating, but in a way that protects patient privacy that allows the individual to control their credential and not have a central database where people get – one of the concerns that we have. As you know, there are large segments of our society who have a lot of suspicion about how central databases handle their information and that could end up deterring people from getting vaccinated. All of you have seen the data on vaccine hesitancy. That is the last thing in the world we need because anything that will help to create more vaccine hesitancy. That is a big part of the consideration as well is to say the U.S. is very different than a place like Israel. We need to recognize that a more decent – there is more coming on that, but I just wanted to give you that sense of the approach and look forward to talking more about that.

I am actually going to have to pop off for my 2 o'clock thing. I really enjoyed being here. I really appreciate it and look forward to continuing our conversation about collaboration going forward.

Rich Landen: As do we. Look forward to working with you and your staff and many, many years to come.

Nick Coussoule: Rich, the floor is still yours.

Subcommittee on Standards Update

Rich Landen: Moving on to the next segment of the afternoon's agenda. We are going to be talking about the proposed project scope for the standardization of information for burden reduction and post-pandemic America, aka, Convergence 2.0. If we could bring that up on the screen. The draft project scope that the Subcommittee on Standards has at this point is about three pages. I thought it would be easier just to walk down it and get comments as we go rather than go through a Power Point version. It is not that long.

We start off with a background statement about HIPAA and the purposes and describe what has happened. We have described what happens in the 25 years since HIPAA was passed in 1996 and then regulations were promulgated beginning a few years later. We have had one major and a couple of minor updates for some of the standards and operating rules since then.

Administrative and data is no longer siloed like it was back in the '60s. In the '60s, we had paper standards for claims and some of the other transactions. But this was really the nation's first attempt at standardizing electronically and the X12 and 837 and then NCPDP on the pharmacy side took the paper claim forms that existed at the time. NCPDP had its own claim form. Hospitals used the UB, form and then there was the HCFA 1500 on the professional side. That was the basis.

But then things happened over time and businesses change. A lot has happened. We now have a lot of providers that are also payers. We have payers who have picked up aspects of providers. We have value-based purchasing, which is away from fee for service and means new information flows among all the participants, including both the financial side and the clinical side. And then we have things like the state all payer claims databases. We have the public health and population health considerations.

When we, as the subcommittee, presented the project scope a year and a half ago to the Full Committee, it was a lot narrower. Now, it is broader and we are putting in the kitchen sink and we are thinking about –- I use that term a little bit flippantly. I should not. It is not the kitchen sink, but it is as – I think Mickey used the term. We are looking at the data ecosystem rather than looking at specific data systems. The scope has expanded tremendously.

What the subcommittee is envisioning is to start from what we learned with the roadmap to incorporate the learnings that we got through the ICAD process, both division and the recommendations, to take what was in the – there were a couple of – some rules that ONC and CMS proposed and then adopted finally but were pulled back during the change of administrations that had to do with adoption of some of the FHIR standards by some of the industry for prior authorization and other purposes.

The subcommittee stepped back, looked at the charge, and decided that we could not really amend the charge as we presented to the Full Committee a year and a half ago and we are starting from scratch here.

Let us just walk down – start again back at the top and let us just walk-through paragraph by paragraph and see what you think. We are starting off with the problem statement. Framers of HIPAA had a vision for harmonized federal standards to achieve efficiency, simplicity, and burden reduction in the health care system. Groundbreaking at the time HIPAA was enacted. In certain areas like billing and payment, and a national identifier for providers, the law and its implementing regulations succeeded. However, in other areas like prior auth and health care attachments, it has yet to offer industry sufficient efficiencies to adopt at scale. What that means is some of the other transactions had been adopted by some of the industry, but not widely adopted as was anticipated by HIPAA.

In the clinical systems, the American Recovery and Reinvestment Act began the process of creating standardization of common clinical data flows from provider to provider. Again, those are EHR based and regs done by the Office of National Coordinator, not by CMS under HIPAA.

Any comments on that so far?

Continuing on down then. In the 25 years since HIPAA, industry business models, data flows, and technologies have changed such that administrative and clinical data flows are frequently co-mingled and used in the same systems. Data can no longer be considered separate and distinct or in silos.

The electronic exchange of both administrative and clinical data has perhaps exceeded some of the uses envisioned for health plans, providers, and patients by the HIPAA framers. For example, aligning components of clinical data with administrative processes (for instance, patient name and demographics) is critical for patient care in any setting, from acute care to public health to mobile apps.

The actors involved in data exchange are very different today than they were in 1996.

Transaction processing technology has migrated away from mainframe computing (on which the basic X12 transactions like the 837 Claim were modeled) and data sharing is further migrating toward new technologies such as Application Program Interfaces, APIs, based on Health Level 7's Fast Healthcare Interoperability Resources or better known as FHIR data standard.

Regulatory structures established under HIPAA are less relevant to business needs in the 2020s. NCVHS has determined that here is broad industry need to modernize the standards adoption framework to

support current needs, including harmonizing clinical, public health, and other standards with HIPAA standards.

There is a statement of fact in there that we have determined and that comes from the letter of recommendation that we sent to the secretary.

Furthermore, the recognition of social determinants of health and again based on this morning's conversation, we can look at that terminology. Recognition of social determinants of health as a key factor in patient wellness and the fragility of the state-operated public health and vital statistics systems exposed by the pandemic (public health emergency) is affirmation for our belief that there is a need to revisit the HIPAA framework. Again, the statement about the fragility, that comes from previous letters that NCVHS has sent. That is not something the committee created.

Finally, the rise of the internet and empowerment of patients in the bidirectional flow of their data between and among providers, health plans and others, demands rigorous reflection non the Privacy and Security of data in general, and HIPAA specifically. Data flows common today did not exist at the time the HIPAA privacy and security frameworks were adopted by regulation, e.g., how HIPAA is statutorily limited to covered entities, but patient data now flows routinely to other parties who are not covered entities and are thus outside the safeguards of HIPAA. In our previous work, we referred to that as privacy beyond HIPAA.

Therefore, the NCVHS in conjunction with industry and other governmental affects agencies, for example, ONC, CMS, and NIST, proposes to embark on an expanded convergence project. The end product would be actional recommendations for specific federal agencies, states, localities, and industry groups to collaborate in support of convergence goals.

Timeframe for the project is two years. Scope issues. The scope of the data. The project includes data requirements for HIPAA administrative transactions, clinical data, public health, privacy, and social services use cases.

Scope of the use cases. First, APIs and FHIR used for consumer access and data sharing, provider data sharing and transactions, payer data sharing and transactions, data interchange with public health agencies.

Second, existing administrative and clinical data exchange standards, for instance, X12, NCPDP, IHE, that is Integrating the Healthcare Enterprise, and Health Level 7.

Third, administrative data capture requirements and data reporting requirements for the X12 claims and encounters, the 837 transaction, for the All Payer Claims Databases, APCD, and Common Data Layout, CDL.

Fourth, data required for value-based care coordination, risk sharing arrangements, and price/cost transparency.

Fifth, public health laboratory and encounter reporting including syndromic surveillance and reportable condition data.

Sixth, electronic clinical quality measures, ECQMs.

Seventh, integrating social determinants of health or social factors and social/community services data standards, behavioral/mental health and integrating the SDOH factor standards into electronic health records and other appropriate systems.

Eighth, nationally standardized cross-maps of clinical semantics, for instance, SNOMED CT, LOINC, and RxNorm, to administrative semantics, ICD-10-CM and PCS, HCPCS, and CPT.

Ninth, national compendium of harmonized value sets and semantic sub-sets for all purposes encompassed in this effort. Remove the "Made It Up" syndrome. "Made Stuff Up" syndrome.

Tenth, privacy and security within and beyond HIPAA related to the above scenarios and use cases.

Eleventh, expansion of covered entities under HIPAA. That is a concept. That is not a commitment to expand the covered entities, but to address that issue.

Interoperability between EHRs and vital record systems, including national vital record system.

Then the scope of the standardization efforts. Improved coordination of standards development projects in standard development organizations to meet convergence goals.

Improved communications and promulgation of standards, see our previous Predictability Roadmap recommendations.

Toolkits and resources to assist standards convergence and for stakeholder input in standardization.

A plan for national conformity assessment and enforcement of standards. Conformity assessment can include certification and accreditation as appropriate to the program and/or system.

Workforce recommendations based on an assessment of current workforce capacity to implement the recommended standardization and identification of related workforce needs.

Benefits. Benefits to patients, providers, payers, and the system as a whole. Improve public heath, heath policy, price transparency, coordination of care, burden reduction, privacy, and the usability of personal health information. Obviously, those are aspirational, not guarantees.

Who would we partner with? Standards development organizations, X12, NCPDP, Health Level 7, by extension, the DSMOs, possibly the operating rule authoring entities, and specifically, the Health Level 7 accelerators like DaVinci and Gravity. National Institutes of Standards and Technology, American National Standards Institute, especially for conformity design work. Industry groups, WEDI, American Medical Association, American Hospital Association, America's Health Insurance Plans, American Health information Management Association, American Dental Association, and others. That is a partial listing obviously.

Health and Human Services and other federal agencies, for example, ONC, CMS, FDA, CDC, SAMHSA, NIST, VA, DoD, Federal Trade Commission, and the Census Bureau and others as they are identified.

What are some possible quick wins? Possible interim deliverables within the two-year timeframe. For social determinants initiative, again, social factors initiative to support the work already underway through the Gravity Project, which seeks to identify data elements and associated value sets which

represent SDOH information documented in electronic health records across four clinical activities, specifically screening, diagnosis, planning and intervention, focusing on food insecurity, housing instability, and quality, and transportation access.

Second, a public health data packet to support recommendations for a national floor or minimum of public health data for reportable and surveillance data standards. Recommendations to state public health agencies, for example, a floor or minimum that states abide by. Again, we recognize that we have no authority over states. We are not proposing in this a mandate. We are proposing leadership.

Three, recommendations pertaining to alternative standards for HIPAA.

And four, other topics or possibilities as they present itself during the process.

This is the draft of the project that the subcommittee is bring to the Full Committee, hopefully getting some good conversation and ultimately leading to a consensus green light to engage with this project coming out of this meeting.

Let me first open it to questions for general questions.

Denise Love: Rich, thank you for doing all the heavy lifting today for Standards. I appreciate it very much. And I think what I would just add – I forgot how much is in there and that reflects our conversations that have been robust with the Standards Subcommittee. And I am seeing it as we are trying to get at and it is very evolutionary because there – HHS that are evolving, including leadership and some other priorities. I also recall our conversations as we would make adjustments as needed as things – but I see the scoping document really as kind of a framework to bring all these diffuse ends together somehow because there is a lot happening and it does make my head spin a little bit. I think it is an attempt to tie all of the standards-related development together as we go forward.

Rich Landen: Thank you. Clearly, the intent here is not to duplicate effort being done by others. If in the course of the project we find that work has been undertaken elsewhere, we would simply collaborate. We would definitely avoid duplicating.

Nick Coussoule: Rich, this is Nick. Just a couple of thoughts. One, this is a pretty ambitious scope. One of the things I would – I know you tried to set up some quick wins. I know I tend to ask those questions regularly when you start framing things up that are pretty longitudinal in nature. But how would you see this playing out as far as do you see some kind of an environmental scan activity initially or some level setting of something? Again, also trying to think about how it might play itself out over a couple of years, to then also recognize what we might be able to get as far as interim deliverables that can provide some value in the marketplace.

Rich Landen: I would invite other members of the Subcommittee to respond as well. I would see kind of an environment scan. We have done partially a scan, but so much has happened recently that I think we need to look and see where we are, what is going to happen with the federal rules that I mentioned that were pulled back that specifically looked to adopt some FHIR-based standards for certain sections of the industry and taking a step back and look at maybe trying to get our arms around what is the ecosystem that we are talking about now. HIPAA was very specific about who covered entities are and then subsequent legislation expanded those. They did not change covered entities, but they expanded some responsibility to the business associates.

But in looking at where we are now, how does the HIPAA approach fit with ONC's approach? We recognize that so much of the data is really sourced out of the electronic health record. We get into the interoperability aspects and we get them by extension into when we look at integrating the data demands into the workflows of the providers and the payers. We are starting now to look at more different systems than HIPAA ever looked at. We are talking more about practice management systems, billing systems, and others. Yes, to the environmental scan as looking at the impact and all the flows of these data. Some of the things about in here are new about how would we interact with social service programs? What do we do about interacting with the state of payer claims databases? We got a lot of research we do, some of the environmental scan to get the issues down and then start looking for how we move forward and what to do with the way that the HIPAA rules are promulgated.

I think certainly at a minimum one of the things we are looking at is an outcome where we, as the subcommittee, have talked several times and have a reasonable although not well spelled out or final consensus that we are looking at a future state where the regulatory framework would allow both the X12 type transactions and the API type transactions coming out specifically FHIR and supporting multiple versions of them and looking at something consistent with our previous recommendations about how we could get a more industry-driven approach to updates to the standards, not adoption to new standards, but updates to existing standards. That is problematic.

There are some heavy lifting in there and some long conversations. But those are the kinds of recommendations I see the group coming up with along with on the way collaboration with the ONC and some of these other entities we have identified. That was long winded. I hope that is a little bit of an answer to your question.

Nick Coussoule: Rich, I will ask another one. What will you envision in the first couple of steps in the process? Because there is clearly some framing that will be done as this goes along to try to understand a little more of the specifics of the deliverables. But what would you say the next 6 months or 12 months what kind of things would you envision happening then?

Rich Landen: I think the first six months would be more along the lines of what you described as the environmental scan. It would not be a full-blown scan, but it would be bringing together all things we know, laying them out and looking at what are the components we have and then determining how they fit together and then within the subcommittee, working to assign responsibilities for I guess digging down deeper into those other initiatives like the data modernization and some of the things that Micky Tripathi just envisioned and some of the things where Denise is active with the states and how the pending regulations around the all payer claims database is in those linkages so we get a current snapshot of where things stand. That would be step one.

That is probably – we launch after we – the subcommittee launches after we get the Full Committee blessing and then that would be probably a good couple of months just for that step. That would position us to come back then to the Full Committee with a progress report at our September meeting.

Denise Love: There is a lot that I do not even know what is going on. Jamie may speak to this, but NDI has started cross mapping a lot of these disparate databases. If we can partner or learn more about that and fill in those gaps and start building on a product that actually will help the folks in the field with their convergence of these various data streams. It sounds mind blowing but it looks like we can build on some work, as I understand it, that is already underway.

Jamie Ferguson: Hi. I like the idea of the environmental scan upfront. I was going to recommend that in addition to that another – what I see, I think, as a different activity within the first six to eight months would be convening stakeholders. We listed a lot of the stakeholders or rather the proposal list a lot of potential stakeholders and involved parties. I think getting their input on what they see as urgent priorities so that we not only understand from the environmental scan what is going on and how we would not duplicate existing effort, but also so that we could refine the initial deliverables within the two-year period or either refine those, change them if needed or confirm what we see as the relatively quick short-term wins.

Rich Landen: Just to add a comment on that, yes, we are definitely envisioning a listening session with industry, within this fiscal year.

Nick Coussoule: I think that makes good sense. Again, I will weigh in a little bit more. That makes good sense. I am going to turn an optimist, but I think even two years is probably not long enough for this year's scope. Do not get me wrong. I am not trying to suggest we put a five-year project together and think we can know what is going to happen three years from now, but I do want to try to make sure we get focused on things that have sequence of events that will ideally provide some interim value along the way. I think what you are talking about makes good sense to me from a structural standpoint. I think it is certainly doable. And then along the way you can better refine the scope in any given time period.

Rich Landen: I am thinking at the end of two years what we will have is a framework. Obviously, if we are talking about adoption of standards or even modifying the way standards are adopted or including additional parties somehow whether by mandate or by social persuasion, that is going to take a lot longer than two years to actually do. But I think at the end of the year, we should have a pretty good framework of a vision and an understanding of the past that we will need to walk, or the different parties will need to walk in order to vet the vision and to then start building to achieve the vision.

Rebecca Hines: Rich, in answer to Nick's question around what is the first step, the other piece I see is there are many organizations working on pieces on this. We need to find some rational way or some systematic way of creating an outreach process. For instance, I heard a webinar with ONC talking about their work around standards for social determinants data. It seems like part of the initial six months is just identifying partners and who is already doing what, not only for duplication concerns, but just to figure out the environmental scan piece of this and where do we – how do we want to work with all that.

Rich Landen: Are there other questions to be raised? If not, I will turn it back to the chair and see if we can get a consensus around moving forward with this as a project.

Nick Coussoule: Rich, great presentation. Good work by you, Denise, and the rest of the Subcommittee. I do not know that we have a real formal and structured process, but I think it is an excellent start. I would like to ask if any other committee members have an opinion or we say this as a go and let the Standards Subcommittee continue to frame this out and start talking in detail about a workplan, all the nitty-gritty details associated with actually starting the initiative.

But I will give you my personal take because I think this clearly fits into the framework of what we can do as a committee and where we can add value with real challenges that are out there, and we can make it something that is both attainable and valuable over a relatively short period of time as well. I think it is a positive and I will ask others to weigh in if we think it is all positive or hand raises.

Rebecca Hines: Put your hand up on your thing. We got a bunch of hand raises. I do not know if Jim Cimino is still with us.

Melissa Goldstein: A point of information, when we revise as we go, the scope of projects, do we bring it back in the next committee and say this is where we are going, this is what we have decided to focus on for the first year or is that done more in the workplan? How does that work?

Nick Coussoule: That is a great question, Melissa. And certainly, for those who have not been around this one a long time, we tend to be evolutionary instead of revolutionary in our work. I think the general consensus the Standards group is looking for today is is this important enough and scoped in a way that we understand what we are trying to accomplish to start to process.

In each one of our Full Committee, we would obviously provide updates and contexts and anything that needed to be challenged. We have regular review during the subcommittee meetings as well as monthly at the Executive Committee meetings, as things get refined and we continue to work on that. Somewhat of the behind-the-scenes processes if you want to call it that, that would happen on a weekly and monthly basis would continue to demonstrate that and obviously at the Full Committee meetings anything that was either particularly changed or challenged or those types of things. We would expect updates there.

Rebecca Hines: Nick, I will just add. We normally put these on the website and we have a place for current project scoping documents and archived project scoping documents. It is up to the Subcommittee if you want to different versions available to show the work. That is fine. It is really for transparency to show people what the committee's work is focused on. But in the end, we have not made – every two months, we have not updated the scoping documents historically, but we certainly can and add versions to them, depending on the druthers of the subcommittees and co-chairs.

Melissa Goldstein: That is helpful for – because both subcommittees now have new projects that we are scoping. We should expect possibly for both of us to narrow down or focus perhaps on a hearing or whatever comes up, whatever is happening because it sounds like this one will be not necessarily narrowed, but focused on the near term versus the far term. Then we would bring it back to the Full Committee to let everybody know what is going for more comments from the Full Committee at our next meeting.

Rich Landen: If I could just add to that. Part of this project scope is we do not know what we do not know. As we learn, all this is iterative and as Nick said, the subcommittee will provide regular updates to the Full Committee and if there are radical changes to the scoping document, we will propose those as well. I am not in favor of turning a document for the sake of turning. But any necessary changes as we learn will be fully discussed like we are doing today with the Full Committee and then if it is significant, reflected in a revision to the project scope document.

Nick Coussoule: And then part of the other side is – I think some of the people on this call probably know, but even from the public standpoint as well. When we meet as an Executive Committee, which is made up of myself and the other subcommittee chairs, we regularly go through the projects. And part of the reason we do it there is because there is usually some amount of overlap or things that span the committee across any given subcommittee's work process and work endeavors. That becomes also a good communications vehicle for us to either raise or challenge both scope or scale or timing and sequence.

And then obviously, if we need to engage the Full Committee in the substantive discussion prior to our next Full Committee meeting, we always have the ability to do that as well either through communication or something like that. That has not necessarily been necessary, but we always have that option if something really truly different came up like that and we thought it was a radical change to what we were doing.

Our objective is to be as visible as we can with a lot of these things because frankly it does not make sense not to. We need all kinds of help in industry engagement and input. I do know our Executive Committee notes are public. When we talk about high-level things like that then that is certainly – to communicate that – make sure I am not stepping out of bounds –

Any other comments, concerns, questions? These are good questions. This is also one of those – unfortunate we do not get to meet in person because a lot of this stuff naturally comes up and we are on breaks and lunch and those kinds of things. This is really helpful.

I think we are good to go. We are a little early. We have our next presentation coming up at 3:15. What I am going to suggest is we get people a little longer break. Sometimes we all can get Zoom fatigue for a long day. We have some really good conversations coming up in regard to the Gravity Project and ICD-10 and more. What I will suggest unless there is a particular objection is that we will go ahead on break now and reconvene a little before 3:15 so we can make sure we start up right at 3:15 and make the rest of our afternoon work.

(Break)

Nick Coussoule: Welcome back, everybody to the last but not least, segment of our day and afternoon. We have a couple of very interesting and special outside speakers.

Let me introduce the first one of those. It is Evelyn Gallego, who is leader of the Gravity Project. Let me give you a little bit of a background. I am going to read you some of Evelyn's bio. Then I will let her do her own duty about focusing on things and introducing herself. But she is the founder of EMI Advisors, an AT certified small minority-owned business. It was started to further Evelyn's mission of delivering value-driven health data management advisory services to government and commercial clients. She is a trusted advisor and helping her clients bridge the gap between health information technology policy standards and business requirements. She has a strong ability to work across and build consensus with diverse stakeholder groups, to include multidisciplinary providers, policymakers, health care payers, researchers, system vendors and implementers and standard development organizations. I think that means we are going to recruit you for the committee here before you know it, Evelyn.

She is a thought leader in the areas of care coordination, social determinants, health IT policy, analysis, and development, HIEs and interoperability and standards development. She is currently program manager and subject matter expert for several interoperability projects, including the HL7 Gravity Project, which we are going to hear about, ONC's STAR HIE technical systems program, and the NIH AHRQ multiple chronic care plan project. It does not sound like she has much going on today.

Evelyn, thank you very much in advance for coming to speak to us today and I will turn it over to you.

Gravity Project Update

Evelyn Gallego: Thank you so much for a lovely introduction. Thank you to the NCVHS Committee for allowing us to come and present on the Gravity Project. I do want to acknowledge my two colleagues. We are all tag teaming today on this presentation because we all play our roles within the project. I am joined today by Dr. Sarah DeSilvey, who serves as our clinical informatics director. She will speak on the terminology work stream and activities to date. And then we have Bob Dieterle, who serves as our technical director. And he will do a deeper dive on our work with HL7, working on the FHIR implementation guide.

We will move forward with our presentation and they will say hello. And from my end again as noted, thank you, Nick, for the lovely introduction. I currently serve as a program manager for Gravity as well as other national standards initiatives. My background has been in health IT policy and data interoperability.

For today, we want to walk through what the Gravity Project, but orient you to who we are as a team, give you some background on the why of what we are doing, the what of what we are doing, and then go through what we have accomplished to date as well as how you can engage in this public work.

I will start by acknowledging our project team within the Program Management Office. I want to recognize the Gravity Project initiated under the leadership of the Social Interventions Research and Evaluation Network otherwise known as SIREN at University of California San Francisco. SIREN still plays a key role. I serve as the program manager. Carrie is our project manager. Mark Savage, who is not on the call today, is our SDOH Data Policy Lead. And then you will hear form Sarah and Bob within their respective roles.

In August of 2019, the Gravity Project became a FHIR Accelerator Project and thereby required us to reorganize the project under a new governance structure. I mentioned SIREN has played a key role in initiating this work and with funding from the Robert Wood Johnson Foundation, but in August, we transitioned over to this new structure to support our work with HL7. Here is a snapshot of how we are currently organized under the guidance of three governance committees: the Executive Committee, the Strategic Advisory Committee, and the Technical Advisory Committee. All three committees consist of representatives from our six stakeholder groups, which are patients, our consumers, providers, payers, health IT vendors, which include HIE vendors, community referral platforms, community-based organizations, and the Federal Government.

Each of these committees have distinct roles as outlined in our Operational Guidelines. There is a link there on the left-hand side. I also want to recognize all the federal agencies that currently participate across our three committees as listed there.

We have several entities that sponsor our work through financial and in-kind as well as providing in-kind support. We cannot do what we do without their support. We always pause to acknowledge who they are and a link to all our sponsors is there at the bottom.

Let us talk about an overview – to many of you. The term SDOH has become common and I know there is a lot of interest on social determinants of health. For those not familiar with the term, it refers to the conditions in which we are born and live that affect our overall health and quality of life. We know that over 50 percent of overall health is driven by socioeconomic factors and the physical environment. We have seen a growing interest from health industry stakeholders around addressing SDOH in clinical

settings, especially as more health care organizations are being pressured to produce better outcomes and more value per dollar spent.

We know unmet social needs negatively impact health outcomes. Our current COVID pandemic shines a big light on these as we re hearing more and more about the increasing health disparities as a result of unmet social needs.

But even with the business case and social impact made clear, clinical systems have not been able to consistently and effectively address social needs because of existing challenges round social determinants of health and exchanging them, especially within the systems that we predominantly use now, electronic health records. These include many challenges. Here is a list of those outlines in the NASDOH report, which is the National Association of Social Determinants of Health. I do want to acknowledge what we will talk about is that one of these involves the lack of standards available to collect and store the data.

This brings us to what the Gravity Project is. The goal of our work is to develop consensus-driven data standards to support the use and exchange of SDOH data within the health care sectors and between the health care sector and other sectors. These other sectors include human service sectors, education, labor, all those that provide services and capture data about an individual.

We are focused on developing data standards for multiple SDOH domains. You see a snapshot of these here with those icons. These do not include all social determinants of health domains. We are working closely with our community and our advisors on what should be the next domains that we work on and we prioritize. We initially focused on the domains of food insecurity, housing instability, and homelessness and transportation and have since grown to a larger list.

The Gravity Project was launched as a public collaborative in May of 2019. Our scope is to develop data and interoperability standards to represent and exchange patient or person level SDOH data across four activities we would call screening – refer to screening or assessment, diagnosis, goal setting, and interventions.

Our initial target is the capture of this data in electronic health records or health IT systems; however, we understand there are other IT solutions emerging with capabilities to support these activities related to screening and referral management.

We do all our work by convening a very large public collaborative of now over 1800 participants from across the health and human services ecosystem. These include representatives from community-based organizations, standards development organizations, federal and state government, health plans, payers, and tech vendors. We meet with our public collaborative every other Thursday from 4 to 5:30. Anyone can join us – free to join us and contribute.

We describe the work of the Gravity Project as two workstreams. You will be hearing about that next. The first is terminology or SDOH domains. And the second one is technical or FHIR. Both workstreams function in parallel, but they intersect in the center in the publication or upcoming publication and use of value sets.

The Gravity Project was initiated to address the coding gaps identified by health systems. This was work initiated by SIREN that identified that gap. Therefore, our coding activities that Sarah will walk through are truly critical for what we do. But at the same time, we need to support the interoperability of this

data across different systems and different system activities. This is where FHIR plays a critical role. It supports both the representation of SDOH data and the exchange and sharing of this data across disparate systems using FHIR-based APIs.

Our 2021 roadmap shows the trajectory of these two workstreams and our upcoming pilot workstream. I know this is very small. Probably you all are squinting your eyes to look at it. It is just to highlight where we are in that green line. If you can see it, we are right at the end of March.

I want to acknowledge that we completed food insecurity in 2019, completed housing instability and homelessness in 2020 and in January, we completed the domains of inadequate housing, transportation and security, financial insecurity, and demographics. Initially, we started one domain at a time and then last fall we switched to multi-domains. That is why you see more than one.

We are currently working through material hardship and stress and are about to start the two domains of intimate partner violence and social isolation.

Bob will talk to the technical workstream, which highlights here that we have just completed ballot reconciliations through the HL7 process of the FHIR implementation guide. We are in the process of developing a reference implementation. We are getting ready to test at the May FHIR Connectathon. And our goal is to publish the FHIR IG by summer or June of this year.

With that, I am happy to hand it over to Sarah.

Sarah DeSilvey: Thank you, Evelyn, everyone. It is my honor to be here today. As Evelyn mentioned, my name is Sarah DeSilvey. I am the director of the Clinical Informatics Division of the Gravity Project. I am principally a family nurse practitioner, rural family practice in Northern Vermont. And after working for many years in medical social care integration, I call myself an accidental informaticist. I have been working in informatics in order to address the problems of social risk and social data sharing over the last five years or so.

I want to talk briefly regarding the intentional design of the Gravity terminology collaborative structure. The reason why is that it is pretty fundamental to the soundness of our outcomes. As we develop our data sets and again if you can remember that kind of infinity wheel where the intersection is the publication of our data sets and value sets, there are basically four different lenses that we utilize in order to ensure the data sets are consensus and evidence based. One is clinical informatics. Myself and our many clinicians across the spectrum. When I say clinicians, I mean transdisciplinary, social workers, nurse care managers, physicians, nurse practitioners, care coordinators. We have the lens of both clinical practice and informatics and process.

We utilize also terminology experts. We are very lucky to have the insight of internal to our team terminology experts and the direct collaboration of external terminology experts and the direct collaboration of our terminology standards organizations such as SNOMED-CT and Regenstrief and the collaboration of NCHS and the Division of ICD-10-CM. This is to ensure that as we are proposing identifying data concepts that are ground to the taxonomies that they will eventually align with.

We also very importantly – this is one our claims to fame – ground every single data element we suggest in the data. This is the data of social determinant measurement so psychometrics and measurement of social risk, but also the data of health outcomes. We combine both of those two areas of evidence and expertise in our approach to data to ensure that we have both semantic and syntactic consistency, but

also that we are building what matters. Whenever we are thinking about our data elements, we really are trying to think within a use case of necessity and representing the risk that social risks contain in our data elements and in our data streams.

The last element is the community that 1800 collective are incredibly good at making sure of the things that we are representing and asking for are practical. We have this ongoing cross check with this amazing collaborative to make sure that we are building what is necessary for this iteration, understanding that the design will be iterative as we implement it in our pilots and refine and revise our data sets over time.

As Evelyn mentioned, we organized our data into four different activities and collate a master set. We organize our screening elements, our standardize screening panels into one tab because eventually those will be built into LOINC. We organize our diagnostic and assessment concepts in order to eventually build them into SNOMED CT and ICD-10-CM. This is also again because we consider different elements across those two different kinds of data build. For LOINC, we want to make sure it is standardized. We highlight whenever there is a gold standard tool. Again, for SNOMED and ICD-10-CM, we are really thinking through a risk-based lens and we are thinking about diagnostic concepts that align with what is measurable and significant. For goal setting, we consider and build in both LOINC and SNOMED CT. For interventions, it is largely within SNOMED CT.

For data within each domain, we ask the same questions. What concepts need to be documented across the four activities? What codes reflecting those concepts are already currently available? We start with this compendium paper that I was honored to author with the UCSF SIREN team in 2018. And then we asked what codes are missing. And our charter is to go forward and build those concepts into US terminology.

I do want to make a note that oftentimes because of the novel nature of this world of social risk terminology, the concepts that we are authoring are making into international SNOMED CT simply because we are trying to create order out of a system that really did not have very much order prior to our arriving.

I also want to make sure that beyond that intentional structure that you saw in the team, we also think about the ecosystem we are building data within. We ask what kind of data does the provider need to care for their patients. The hospital needs to study the effects of provider interventions. A community-based organization need to address the needs of their clients. As we often say in the Gravity community, we might identify these needs in clinical settings. We solve them in communities. Getting the voice of our community partners throughout our work is critical.

We also ask questions. What kind of data the state might need to plan for population health needs and what are the principles we need to consider keeping patients at the center at all times?

A really good example of some of the terminology that is existing right now because of our work, is on this slide. You can see that we have those four activities: screening and assessment, diagnosis, goal setting, and interventions. You can see elements of the standardized screening we have built with the Hunger Vital Sign offered by Children's HealthWatch, which is a component of the USDA Gold Standard Food Insecurity Module. The USDA modules are all built in as well.

I do want to state just as Evelyn mentioned prior. Working with our federal partners in every single stage with every domain is very critical whether it be USDA for food insecurity, HUD for housing instability and homelessness or Administration of Community Living for elements like elder abuse and social isolation.

And then when you go on to diagnosis, you can see there was already food insecurity SNOMED concept, but there is an upcoming submission for ICD-10-CM that I will talk more about in a couple of seconds.

For goal setting, you can see our initial proposals for goal setting statements. And, again, we are considering and working very closely with our colleagues across the ecosystem to ensure we are considering both patient-centered goals and provider goals and the ways goals and goals data are utilized right now in initiatives such as CCMMI, Accountable Health Communities Initiative, and Community Care Coordination and Care Planning.

You go on to interventions, these are some of the new concepts that have come into SNOMED in a very recent release. You have the representation of critical social risk persona such as the community health worker, which did not exist in US terminology prior. You have the representation of provision of food vouchers and for every single element, again, we consider federal programs like child and adult food programs or SNAP or WIC just to make sure that these are in US terminology.

You can find all of our published Gravity data sets on the confluence organized by the domain. Again, as Evelyn mentioned, there are many sets that are already complete and there are some sets that we are working on at present.

And then one last highlight. On March 10, the Gravity Project was honored to present our multi-domain social risk ICD-10 submission to the ICD-10 Coordination and Maintenance Committee. It represents the collation of two and a half years of work to develop consensus recommendations for ICD-10-CM that again represent risk and critical concepts for social risks that are critical for patient care. That is now in the common phase. We are trying to advocate for it to get released as part of the October 2021 release. There is information about that in the confluence as well and we are very grateful for all of our coordination and collaboration with Donna Pickett and her team.

I think that that is the end of my bit. On to Bob. Thank you, Evelyn, and everyone.

Bob Dieterle: Thank you, Sarah. I appreciate you handing it over. I am Bob Dieterle. I am the technical director for the Gravity Project. I am also one of the co-founders of the DaVinci Project and one of the co-founders of the FHIR At Scale Taskforce that has been sponsored by the ONC.

What we will do today is we will talk a little bit about what we do to take the semantics that Sarah is creating and working on the terminology – for social determinants of health and put it into the structure that we get by using FHIR as a way of defining the way we do interoperability to exchange social determinants of health information.

We, over the last year, have created an implementation guide, focused on exchanging social determinants of health information between providers and community-based organizations. It is a framework guide that supports all of the domains that Sarah is working on and that Sarah and Evelyn have mentioned. It allows us to go and basically depending on the particular domain specify specific value sets that Sarah is working on to go and have very specific terminology associated with and values associated with each one of the descriptions of assessments, health concerns or problems or diagnoses, goals, referrals, or interventions. We also are dealing with consent and aggregation for exchange and

reporting. We took this implementation guide to ballot in the HL7 January cycle. It completed its ballot on the 18th of January as a standard for trial use level 1.

This represents again the information that we are supporting. At the bottom, we have the assessments and surveys LOINC coded both for questions and answers. We have health concerns and problems or diagnoses. As Sarah said, these are ICD-10-CM coded.

We have goals that we can establish, or the provider can establish. These are both LOINC and CM coded. And then interventions, which are SNOMED-CT, CPT, and HCPCS coded and interventions we show here, which are representing on FHIR as procedures that have been performed. Those are also SNOMED-CT, CPT, and HCPCS coded. These produce the outputs that are necessary to go and create input to quality measures. As you will see on the right, we have consent. What we have done is we work with the idea that consent needs to be available between the patient and the provider to decide to release information from a HIPAA-controlled environment into a community-based environment. We have a certain mechanism for doing that – exchange that consent.

On the left-hand side, we show aggregation of the creation of cohorts of individuals, in particular, so that, for example, the responsible payer can understand the social determinants of health information that is appropriate and available to them for the patient they are providing coverage for.

One of the things we did early on was to turn around and take the idea of a survey incident that Sarah has been talking about to assess the risk of an individual for a particular domain or multiple domains and automate the process of taking that survey, having it LOINC coded – make sure that it is a LOINC survey and then using NLM open source tools to be able to take those LOINC-coded surveys, convert them into SDC questionnaires, FHIR questionnaires, using, again, an NLM tool to go and deliver that questionnaire to an individual and ultimately to produce a reproducible set of outputs, a questionnaire response, the observations, which are the individual question and answers and condition resources to the health concerns which will be in consultation with the patient, potentially promoter – ultimately to have goals developed and to define interventions.

This is the representation of the work that we have focused on for the January ballot. The blue lines are the interchanges or exchanges that are covered by the implementation guide. The ability of the provider or the patient to have a survey delivered. The ability to record that in an EHR. Also, the ability to exchange information between a provider-based organization and community-based referral organization shown directly below. Be able to exchange it with a community-based organization – such as a food pantry or the ability to – individuals identified and exchanged out with a responsible payer.

Since we have done that work, we have expanded the scope – to include support, FHIR-based exchange support for all of the arrows that are represented on this diagram, including the ability of payers to go and send requests or interventions to community-based organizations or community-based referral platforms and have the ability to exchange information between community-based referral platforms as well as the platforms and the community-based organizations to deliver the services.

We are looking at creating smart applications, smart phone applications to be able to support community-based organizations that do not currently have technology that they can reliably use or communicate with FHIR-based APIs and also look at the ability to have an application that could be used by an individual to receive and follow the referrals and interventions that are designed for a particular individual.

This is where we currently are. Evelyn walked through the overall timeline. As we said, we went to ballot on the implementation guide in January. We had 63 affirmative votes, 30 negative votes. We met the 60 percent threshold to be able to publish a standard for trial use level one. We had 227 ballot comments, 72 were negative, 155 affirmative comments that were typos, questions, suggestions, et cetera.

We are in the middle of the ballot reconciliation process. We have roughly 80 of those comments to go out of the 227. Our expectation is we will have that work done by the end of April. We will have the technical portions of the implementation guide updated in time for the May Connectathon, HL7 Connectathon. We are in the process of developing a reference implementation that will be complete and available for that Connectathon also so that the reference of location can simulate both sides of all of the exchanges that we have been talking about. And individuals who want to come and test against that will be able to test from any of the platform stakeholder views, tested in the EHR, tested community-based referral organization as a payer or as a community-based organization or as a patient.

Work we are doing now is to continue to refine the NLM work the way Regenstrief is supporting these LOINC survey panels. Work with the community to establish the clinical content required for multiple SDOH domains – advance the development of the reference implementation. Incorporate dispositions from January ballot into the actual implementation guide in preparation for publication. Prepare for the May Connectathon. We have a Gravity Track that will be part of that May Connectathon. The reference is here. And then we do have every Wednesday afternoon, as Sarah indicated, a session that works on the implementation guide, the FHIR implementation guide that is open and available to everyone to come join.

I believe at this point I am going to hand it back over to Evelyn to talk about our accomplishments and success factors.

Evelyn Gallego: Thank you, Bob, and thanks, Sarah. I will conclude with a few slides. We have been really busy since we have launched in May of 2019. As I shared, we have grown substantially. We have over 1800 participants. This is just the ones we directly track that predominantly sit on the public call. But as Bob has been moving forward with the FHIR ID, he has had also a growth of HL7 members and HL7 interested parties participate in those calls.

Even with all our accomplishments to date that both Sarah and Bob walked through and this growing interest around SDOH data standards, how we measure our success has truly come down to how the standards we are developing are integrated and used across multiple areas as listed here. It is how the standards will be integrated in policy. I will talk through some examples, payment models, and programs, and other standards.

We talk about – FHIR accelerator – integrating our work with other FHIR accelerators and grants. I will give some examples of that. In practice, which we have not done, but hopefully, we can work on creating repeatable processes for the adoption and the implementation of SDOH data at the practice level and lastly around innovation. We want to be able to influence, encourage the development of new tools for capturing, aggregating, analyzing, and using SDOH data.

From a policy integration perspective, one of our first accomplishments has been the inclusion of the SDOH data class in the ONC USCDI. We made a formal submission on October 23. On November 4, ONC categorized it as a submission as a Level 2 as shown on the right-hand side. In January, ONC did not include this in the draft version. However, we continue to work very closely with our ONC colleagues

and the USCDI Task Force to determine what should be included even for this Version 2 or for next year's version or the next Version 3.

In December, CMS included a request for information on social risk data standards as part of their NPRM. The Gravity Project team responded accordingly based on our work. The request was regarding the integration, use of social risk data standards. We prepared questions again. It was during the holiday break and those were submitted and the link is there to see. We also encouraged our very large community to submit responses and they did so. Again, just highlighting potential for future integration and rules.

In January, CMS is very busy, they also published guidance for states on opportunities under Medicaid and CHIP to address SDOH. This guidance clarifies how states can use federal match or match funding to support the implementation of a technical infrastructure that integrates health and human service programs. The letter directly encourages states to review and incorporate SDOH standards as published in the ONC interoperability standards advisory and as being developed by the Gravity Project. The Gravity Project is called out in this guidance.

In addition to policy integration, Gravity standards have been incorporated in two recent grant programs. The first one is the Administration of Community Living Social Care Challenge Grant. And, actually, I submitted these slides earlier. They just recently, two days ago, actually, published the awardees. For those not familiar with this grant, it actually has a requirement for those who submitted it to adopt the Gravity terminology standards. It is an example of how the standards are integrated in grant programs.

Those 12 grantees are kicking off their Phase 1. They will serve as our pilots under the Gravity Project as they will be testing. A few of them will also have indicated they will implement the Gravity FHIR IG.

The second grant is a recent ONC Leading Edge Acceleration Project or LEAP that includes referral management to address social determinants of health aligned with clinical care. The information also acknowledges and encourages the use of the Gravity terminology standards as well as one of many FHIR IGs and includes the Gravity FHIR IG.

I will conclude on how to engage. We shared that we have a very large public collaborative. We ask anyone – is welcome to join. You can join the public collaborative calls on Thursdays. Every other Thursday – FHIR IG calls are every Wednesday. We are always looking for new sponsors and partners.

We also have data principles that we ask for our community to give us feedback on. This is on the – really considering the ethical use of SDOH data and of course not furthering disparities by the use and capture of this data.

As we work on domains, we always are looking for those – that need domains. And we have two social media handles. We are always looking for organizations to work with to publish on our work.

With that, I conclude. I think we have nine minutes for questions. If you go to the next slide, it is our information. I will pause and it hand it back to the team.

Nick Coussoule: Evelyn, thank you, and team, for that presentation. A lot of stuff wrapped up in a short time period. Let me open it up to committee members for questions. I see Denise Love is first.

Denise Love: Thank you. Thank you for the presentation. It is really wonderful that we have great minds and groups working on this retractable or long-term – area.

A couple of things. I am impressed with all the domains and data elements. But as a former data policy person, I am concerned about sustainability and crowd out. The more we ask of our data suppliers, the less we get or usable we get. Have you had the concept of a minimum of a floor that is independent of FHIR and technology because a lot of the systems that we currently have out in the community and public health are not FHIR enabled and they are pretty – some of them are legacy systems, but those capture a lot of information that could be useful. I guess the first question. Minimum or floor so it is not so robust.

Sarah DeSilvey: Would you like me to answer this? Evelyn was nodding. She said, yes, I do. We really appreciate the question. I would like to say that I represent that use case. I am rural family medicine in Vermont in a non-FHIR-enabled world, which is drastically trying to use our HIE to try to leverage this information, but very desperate from accountable communities for health model to figure out how to care for patients well. I always cross check against my own self.

Basically, our approach is always considering both simple and complex methods to achieve our goals. If you look at our data sets, first of all, they cascade from minute levels of data that one could use if you had a system that wanted to differentiate different types of programs to very macro concepts that represent just the domain. These also from a domain perspective correlate to questions and answers that do the same. Very quick, simple questions and answers that are easy to implement that give a broad swath of risk to gold standard tools that give deep dives into more subtle – like ramifications of different domains that you would be able to correlate with research on food insecurity or housing instability.

To the best of our ability, our data approach and our domain approach considers that easy to complex kind of logic stream and everything cascades. But of course, there is a lot to be discovered in piloting. We are very clear to say that we consider piloting both in FHIR and non-FHIR-enabled models. Many of our piloting communities will just be doing terminology sharing and giving us feedback regarding that.

I hope that answered your question. The answer is yes. We consider necessary and visual approaches because the last thing we would want to do is create inequities of tech as we are trying to solve inequities in health. We do not want to build systems to answer this question that cut off whole communities that are actually in desperate need of the information we are building.

Anything else from my team?

Denise Love: I have more, but I will let others and then if we have time, I will come back. Thank you very much.

Nick Coussoule: We have until 4:15 so we have time for questions.

Valerie, you are up next.

Valerie Watzlaf: Thank you. Thank you so much. I really appreciated your presentation, the beautiful examples and slides. My question was really around ICD-11 and with that establishment. Have you looked to see if it will continue to capture the codes and continue to capture really the components that you are looking at as we may move into that direction?

Sarah DeSilvey: The answer is yes. It would be a lot of effort to not look ahead into ICD-10-11. I do want to state that even though we offer very robust expansions of international ICD-10, all of our concepts are aligned. We think about ICD-10-11 and look forward to ICD-10-11 with all of our work in ICD-10-CM. The answer is yes.

We are thinking both now and future states. There are all kinds of mapping tables I could show you with that mind. That is absolutely part of our work. Yes.

Valerie Watzlaf: Thank you.

Jim Cimino: I will keep my question short. I am all for controlled terminologies and data that are captured in controlled terminologies if the data are high quality, if the terminologies are usable and useful. I am wondering what kind of validation, verifications being done to make sure that the terminology, especially in a new area like social determinants of health and disease are providing adequate coverage, adequate granularity, and are used appropriately by those capturing the data.

Sarah DeSilvey: Should I go again, Evelyn? I know it was a lot of information to cover in a very short period of time. I could talk about the terminology approach alone I think for an hour and Evelyn knows it. You could just set me off and I would just keep on talking.

Again, thinking about that initial question regarding bandwidth and capacity, we ground all of our work and terminology really in knowledge of social risks and their outcomes and psychometric methodologies. When I say we ground our evidence and our build in measurement, it is literally referencing the USDA approaches to food insecurity module development and ensuring our terminology alliance with that degree of validity when possible.

I do want to state like we are very aware that we are working in a novel – that the enthusiasm to address social risks is way ahead of the science of measuring them. We understand that there is a great humility in this work. I can say we are very lucky to reference and apply our terminology approach to the USDA food insecurity module. We also recognize that after that that is now gold standard tool. You leave food insecurity, and it is the Wild West.

But then we also work with our colleagues on emerging tools. We work very closely with George Carter and his team at HUD on the emerging American housing security module to make sure that our concepts that we were choosing and building, would align screening methodology that is going to be coming from HUD over the course of the next few years.

And then when that is not possible, we really reference just the risk and the literature. We do a really careful audit of the known health risks and associations of social risks and then ensure -- terminology is aligned with those risks and from the continuum. From the moment of asking standardized screening questions and answers to the determination of the diagnostic concept, we both anticipate social risks, consider psychometrics, but also make sure that from a very simple implementation perspective, you can ask this question and get this diagnostic concept that is aligned with it and then walk away.

As much of the thought process that we put into the terms we choose and why we choose them and whether they are semantically clear to the end user and align with screening tools, it is really to enable the development of good data because if we do it well on this side again from a clinical staff perspective in rural Vermont, I could choose this tool, ask these questions, get this outcome, and then I would be on my way. I can go off more if you want me to.

Jim Cimino: That is great. Thank you.

Wu Xu: Thank you for a great presentation. Very good project. My question is regarding the – you have a community organization also part of this data sharing loop. I wonder, are they HIPAA-covered entity or they are social services whether they have some (indiscernible) So aiming policy challenge for sharing this data across different domains? That is my question.

Evelyn Gallego: I can answer that one. Thank you, Wu. As I mentioned, we have a very large public collaborative, and we also have the three committees that we have established from a governance perspective. We purposely designed our project to incorporate the viewpoints of these various stakeholder groups. So including the community-based organizations, federal government, state governments. We actually find that we have more participation from community-based organizations that are some not using any technology. As Sarah noted, they are very interested in using capturing, sharing this data even though the policy, the programs are not yet there. I think we do still have a lot of work to do.

Sarah also mentioned that she works very closely with the Department of Housing, HUD, and Urban Development. We looked at other – have other agencies supporting this work, other departments. We looked at a lot of – at the state and local county level. Besides public health agencies, you have local service agencies that have also come to the table. Part of it is getting that robust viewpoint from the different stakeholders but acknowledging that they still – regardless of how this data moves across, there still needs to be an established governance structure for any implementation.

That is something that we are actually working with our partners at the Administration of Community Living, ACL. It is purposely looking as well as ONC. ONC currently has a technical expert panel, looking at the foundational elements to support community information exchange, support social data exchange. They currently have a technical expert panel and they intend to – a toolkit for states by the end of summer.

Sarah DeSilvey: I am just going to add one little bit there only because I think it is important to know that when we do our environmental scans of who needs to be part of this work. For instance – environmental scan for housing instability and homelessness. We knew that in anticipating successful interoperability perspective, we could not do that well without leveraging the knowledge of our HMIS, Homeless Management Information System network.

Whenever we consider a domain, we do an ecosystem analysis of the current community technologies that are functioning in that space that are really critical for the domain. I am not going to say we do it as comprehensively as one might be able to do. But we do ask those questions. Who are the critical community agencies that are sharing this data now? What does the technology need to consider? What is the language we need to consider too? The folks from HMIS were very critical in our homeless data set development to ensure that the data we were building aligned with their needs as we were building it for clinical considerations.

Nick Coussoule: Back to Denise.

Denise Love: I have a lot of questions. One of them – the first one. Would these data sets or elements be collected at every encounter or visit or what is the point of collection?

Sarah DeSilvey: Do you want me to try to answer that, Evelyn? Evelyn and I are nodding to each other. It is important to know that Gravity is one piece of the successful medical social care integration system like we are the language builders. There is a lot of really wonderful data. The world I come from prior to being a social determinant informatic – is medical social care integration. There is a lot of really wonderful data regarding frequency of screening, how to share screens like screening burden. The UCSF SIREN, the non-profit out of UCSF that spawned the Gravity Project, are so robust in that work. That work issues from them. That is the general answer is the literature of how to do this well is again fairly novel and we are discovering it over time.

I can say that I have had a few lectures on this over the course of the last 90 days, so it is very apropos. We look for things such as clinical quality, measure development regarding social risk to assist us in this. We are working with colleagues at NCQA and NQF regarding clinical quality measurement development.

We also look for our pilots to give us information. Part of what we know from an ecosystem assessment is the burden of multiple screens happening in multiple places. There is a lot of research right now about how in the simplest sense whether you are FHIR or not FHIR, how to share that information through community data exchanges.

Humbly, we are not the experts in the answering of that question. Our colleagues are. But if you consider the projects that we are aligned with, the answer is usually it is screening at the clinical encounter whether it be in alignment with state Medicaid programs, accountable community health programs, patient-centered medical home programs or otherwise and is usually screening once a year. Less acuity means you have to rescreen.

I think it is important to know that as abstract as this might seem, currently, as a clinician again in rural Vermont, there are four different programs I am accountable to social risk screening for already right now as a family practice provider. This is my present moment that I am supposed to do these things.

As much as we can build the data to make that seem reasonable because there is nothing more frustrating as a clinician to be asked to do something and have it be not – to be not able to do it well as a family practitioner.

Denise Love: That answers screening. But on the encounter, you get into that crowd out that I mentioned because we cannot get a full reporting of immunizations and reportable diseases out of clinicians now. You add 20 different data elements on the encounter. You are going to get that crowd-out issue.

That leads me to primary data collection, which you are talking about. I agree that we need to do a better job. But I do think meanwhile while we are waiting for the world to catch up, there is going to be a lot of linkage across data sets to fill those gaps. That is going to have to occur or we are just never going to get to where we need to be. I will end there.

Sarah DeSilvey: And the only thing I want to say is again there are many people who are really researching this like my colleague, Rishi Manchanda, from HealthBegins, who is a consultant with CMMI, has a really lovely spectrum of social care integration across communities and health service areas because the ideal is -- we built the data with the WIC office in mind, with Head Start in mind, with Area Agency in Aging in mind, with your home health nurses in mind because if we are all being asked to ask this data for different reasons to the same people – for the patient burden, for provider burden, for understanding, we should be able to share it.

Denise Love: Thank you. I agree.

Nick Coussoule: I had one question that maybe extends that one just a little bit. What kind of educational materials or help or assistance are you all putting together, providing for folks that want to take this up in a more detailed way?

Evelyn Gallego: That would be me. That is a great question. We need to do a better job of getting education materials out. As I mentioned, we are funded to various sponsors. We are not a government – it is government contract sponsorship. Part of it is right now we are focused on the execution of our work streams and have done – rely on these education – thank you, Lorraine, for inviting us, is really to get the word out. But we want to do better.

Sarah actually has a few – the slides she actually put in July, a break for dissemination, for us to pause and start developing more education materials because we have not been able to do it as quickly as we need to.

We do have the website, a general website now that we have launched. It is like a high-level layman, layperson's, what the Gravity Project is, and we are trying to get more education that way, but it is coming and we hope to do more this year.

Sarah DeSilvey: I do want to say we are collectors that leverages the wisdom of our partners in this. Our team is actually quite small. But we have colleagues such as the National Association of Community Health Centers, which are really amazing at disseminating of end user education. We have colleagues such as HealthBegins that do academic detailing approaches to social risk education. We have our colleagues at UCSF SIREN. It may be many hands make labor light thing.

The project that actually started from my perspective because way back in the day, I built a coding guide for community-based organizations for food insecurity codes. How do you talk to a health care system regarding sharing data in order to take care of patients who are insecure? Hopefully, this is to come.

We have been so busy building that we are ready to start writing this summer. It is going to be a writing summer.

Nick Coussoule: That is exciting. We probably have time for one or two more questions from the members.

Denise Love: I should have never downloaded the icon. You guys will be sorry. How can NCVHS help? Because one of our workplans is social determinants. We promised to learn from you all and others. There is a lot going on in a lot of different sectors. Is there anything on the NCVHS end that we should know?

Evelyn Gallego: To help us with or to support?

Denise Love: Well, as we look at standardization of social determinants of health, obviously, we will look to your work, but there are other activities going on. How do we bring that all together or reconcile that?

Evelyn Gallego: Sure. I shared the slide with all the different areas or success factors. We are not focused on – we just focus on the data standards. Any presentation we do, it is like we are a data standards

project. But we are focused on developing and testing the standards and we know there is more work that needs to happen on – we will have pilots to evaluate whether we are applying the standards correctly, whether they are useful. A lot of this is really – it is helping with dissemination, helping with testing. We do need to find entities that want to adopt standards that have that in their glide path to come and validate with us and look at implementation. It is not only standards for standards sake, but really get to a place – we really want these used in the community, in the field, and validated.

In the FHIR implementation guide, we will need to mature. All these things are not going to happen in the next year. It will be ongoing work that we will need to work with committees like yourself in advancing.

Denise Love: Thank you.

Nick Coussoule: That is really excellent. I would like to – I think we have to wrap it up. I would like to thank Evelyn and Dr. DeSilvey and Bob Dieterle for the time and attention today. This has been really enlightening. It is exciting work. It is good to hear that none of you are very passionate about it. But really, it is exciting work and I wish you all the luck. I think our paths will cross because I think there is definitely some more roll out to things that we are doing and undertaking as a committee and some of the great work that you all are doing.

Thank you again for your time today and presentation and great answering questions.

Evelyn Gallego: Thank you for having us. We appreciate it.

Nick Coussoule: We will move on to the next topic on our agenda, which is Comparative Analysis of ICD-10-CM with ICD-11 for Morbidity Coding. We have a guest speaker, Kin-Wah Fung, coming in. But I will start out with one of our own members, Margaret, to lead this section off.

Comparative Analysis of ICD-10-CM with ICD-11 for Morbidity Coding

Margaret Skurka: Thank you. I will just take a few minutes to get you up to speed on I-11 and then I have the privilege of turning it over to Dr. Kin-Wah Fung.

Some key points about ICD-11. It is a WHO publication, as I think everybody knows. But big news on the second line there. This system in 11 will be fully electronic. There are no books. It is too big. There are 17,000 diagnostic categories, over 100,000 medical diagnostic terms, and the index-based search algorithm interprets more than 1.6 million terms. I think that is mind boggling. I think they thought of everything.

In our discussion of social determinants of health today that we had before lunch, I just peaked over lunch time – takes one second to look up a code. If you want to have fun some time, just download ICD-11 coding tool. It is free. It is sitting out there. It will download. You will put it up in a second. Then I typed in homelessness. And in a nanosecond, I had the code, the IL-11 code for homelessness and it is QDT1.0. You can sit there later on today and relax and just put in anything you want and your code will come up because it is that comprehensive.

There is a fact sheet available online, but that was in our large packet. You can look at that in terms of the materials we received before the meeting. WHO is saying that IL-11 is easy to install. It can be used on or offline and it is very comprehensive obviously with just an incredible amount of data in there.

We will adapt it for mortality. But an unknown -- for underlying cause of death coding – but an unknown is our countries like us and three other countries, Canada, Germany, and Australia can we accept as it is this time without an official modification. Ours was a CM that we did so we did ICD-10-CM, which was for morbidity side. Canada did it and made a CA edition. Germany made a German edition. Australia made an AU edition. We have had some preliminary discussion with colleagues in Canada and Australia anyway and there are some unknowns there. But hopefully, it is comprehensive enough that we will be able to adopt it in its final format.

We spent years developing that clinical modification I just referred to. We were a little later than some of the other countries in our morbidity adoption. We were okay with mortality. I think we did that in maybe ’99 or something – that late. Australia adopted for mortality in ’98, but they were there and ready for morbidity in ’99. Canada adopted the CA edition in 2000 and so did Germany. Some countries adopted ICD-10 as early as 1994. We were officially last, I think, when we finally adopted after a couple of years and back and forth because we have only had the system since 2015. I know people in the US will say we just got here. We just learned this. How can we be going some place else already, but that is because we were a little late to the table.

What caused our delay? We added a lot. We added codes in Chapter 19 in injuries and poisoning, lots of detail, and we added a lot in Chapter 20 also and that is the consequences of external cause and external causes of morbidity. That made us officially last.

What were some other reasons for our delay? Certainly, it was the detail that was added. Then for a several-year process beginning in ’08, there was a Notice of Proposed Rulemaking published. In ’09, came the Final Rule saying we are going to do this in 2013. October 1 is always the day we go to the code set.

But then in September ’12, another delay came and the Final Rule and said no, now, we are going to extend it out to 2014. Then in April of ’13 yet one more delay, prohibiting HHS from requiring ICD-CM before 10/1/15. I was doing some training for AHIMA around the country. We had started doing the training in ’11 or ’12 and it kept extending and extending because of the delays.

Where we are now is that there has been progress. It is both available in English and Spanish online. Many countries are finished with translations. China was done last year. They have invested millions and they are ready to go.

We have some mid-year meetings coming up soon with the WHO of both the morbidity and mortality reference committees. We will address and talk about next steps so I can report back after those mid-year meetings. Everything is virtual of course this year and last year.

For mortality, we will be required to implement for Underlying Cause of Death. For the US, we will need to address the implementation. NCVHS has been on top of this. We convened. NCVHS convened. The experts there convened a working meeting, I think it was the summer of 2019, to obtain a broad range of input from experts and stakeholders. They issued some recommendations to support a timely and what I would call an unprotracted implementation as opposed to the kind of protracted experience we went through in the final years before we did.

There is an official letter that we sent that NCVHS sent to the Secretary in November of ’19 with three recommendations that said we must have a smoother, simpler, less burdensome implementation.

The three recommendations were that number one, HHS conduct research to evaluate the different approaches to the transition of the implementation for mortality and morbidity. That HHS provide timely leadership on strategic outcome and communication to the US health care industry about transitioning. And that the HHS Secretary ensure appropriate federal priority, as needed, for efforts to negotiate the ICD copyright issues and ensure that copyright will not be a barrier to our adoption and our use of I-11.

That takes us to the presentation, and I will turn it over Kin-Wah Fung, physician, scientist, and more. Thank you.

Kin-Wah Fung: Thank you, Margaret, for that introduction. I am Kin-Wah Fung. I am from the National Library of Medicine of National Institutes of Health. First of all, I would like to thank NCVHS for giving me this opportunity to present the findings of this study, which is collaborated research work between NLM and National Center for Health Statistics, and CDC. I would like to acknowledge my colleagues at NLM, Julia Xu and Olivier Bodenreider and our collaborators at NCHS, Donna Pickett and Shannon McConnell-Lamptey.

WHO adopted officially ICD-11 in 2019 and is supposed to be implemented in member countries starting in January 2022. As Margaret mentioned, we have always been creating our clinical modifications since ICD-9 so ICD-9-CM and 10-CM for morbidity, because the international core is considered not precise enough to describe the clinical details necessary.

But there is something new in ICD-11. Margaret mentioned that it is bigger. It is almost 40 percent bigger than ICD-10 with over 4000 more codes. One other feature that is significant is that ICD-11 also supports post-coordination. I will talk more about post-coordination later on. So, suffice it to mention that there are actually over 14,500 extension codes just to support post-coordination in ICD-11. It prompts the question whether clinical modification is still necessary.

This is the letter that Margaret mentioned from NCVHS to the Secretary of Health and Human Services, prompting research on whether ICD-11 can fully support morbidity classification in the US without a clinical modification.

This research is an attempt to answer the question. We are coming at it from a purely content perspective. We are not considering other considerations that will be relevant in installing ICD-11 for morbidity coding. Here is an overview of our method. We first identified the most commonly used ICD-10-CM codes in the US and we will re-code every ICD-10-CM code in ICD-11 to assess the coverage and level of equivalence between the two. And then we carried out a review of the coding guidance accompanying these codes to look for subtle differences in the meaning of codes.

One of the biggest collections of ICD-10-CM codes used in the US will be the Medicare claims. Medicare claims data have been made available I think since 2013 to researchers through a platform called the Virtual Research Data Center. However, there is some drawback in using Medicare data in this research because most Medicare patients are over 65 and the data will be lacking in codes in three chapters, namely, Chapter 15, pregnancy, childbirth and the puerperium, 16, certain conditions originating in the perinatal period, and 17, congenital malformations, deformations, and chromosomal abnormalities.

We have defined an alternative source of ICD-10-CM codes for these chapters. Luckily thanks to James Campbell and Ellen Kerns from the University of Nebraska Medical Center, we are able to use their data

to supplement the three chapters for the Medicare data. All data we use in this study are aggregate data and they do not contain any patient identifying information.

From the Medicare side, we use the full year of 2017. The reason we use 2017 is that usually there is a lack of between one to two years before Medicare data is available for research. At the time of our research – this is the last year that we can find full year data. And the data covers 61 million unique Medicare patients and 28,000 unique ICD-10-CM codes. And all 10-CM codes are captured and being used as principal or secondary diagnosis. All the codes will come from all the chapters except 15, 16, and 17.

From the Nebraska University Medical Center side, we use all the data we can get, starting from October 2015, that is the start of use of 10-CM. The data set covers 778,000 unique patients and 23,000 unique ICD-10-CM codes. Again, we take every 10-CM code, be it primary or secondary diagnosis and we on take codes that are from Chapters 15, 16, and 17.

From the two sources together, we look for the most frequently used codes in each chapter of 10-CM that will cover 60 percent of unique patients. All together we are paying 962 10-CM codes. And 19 of those codes have become obsolete. We excluded them from our study and that leaves us with 943 10-CM codes to work with.

Sorry. This is a bit small, but obviously readable. This is a breakdown of the 943 codes among the different chapters of ICD-10-CM. The first observation is that there is a big variation, a big difference in the number of codes contributed by each chapter. Chapter 19, which is injury and poisoning, is the biggest chapter in 10-CM with over 40,000 codes. It is not surprising to find that they contributed over 300 codes to our sets. Chapter 3, which is diseases of the blood, is the smallest chapter and it contributed only five codes.

Another factor that affects how many codes each chapter will contribute to our data set is the spread of usage. This is indicated in the last column on the right. This column is calculated by dividing the number of codes in our set that covers the 60 percent usage by the total number of codes in that chapter. This is a spread of usage among the codes in that chapter. The higher the number, the higher the spread.

As you can see from the last column, the biggest spread is found in Chapter 18, symptoms and signs. And you need 7.8 percent of all the codes to cover 60 percent of usage. And the smallest spread is found in Chapter 20, external causes of morbidity and you need .3 percent to cover all the codes to cover 60 percent of usage.

For each 10-CM code, we will recode in ICD-11 by two terminologists, Julia and Shannon. They did it independently and the results are compared, and any differences will be discussed until consensus is reached.

We follow the following guidelines in recoding in ICD-11. We use the online WHO ICD-11 browser, and we follow the ICD-11 coding reference guide for morbidity. In both ICD-10-CM and ICD-11, we ignore the parts of the names that conveyed absence of information. For example, gout unspecified. We ignored the unspecified part. Zoster without complications, we ignore without complications.

Generally, we would look for ICD-11 codes that are equivalent to or broader than ICD-10-CM codes. If no equivalent code is found, we will try post-coordination as directed by the 11 browser to complement the code that we have chosen.

What is post-coordination? Post-coordination is a brand-new feature in ICD-11, which is not present in any of the earlier ICDs. Basically, it allows the combination of codes. In ICD-11, it is called "code clustering" to represent new meaning. And ICD-11 allows two kinds of post-coordination. The first is the combination of two or more main codes. Also call the main codes "stem" codes. And in syntax, the two codes would be connected by a forward slash.

One example of that is if you want to code urinary tract infection due to extended spectrum beta-lactamase producing Escherichia coli, you do it with two codes together. The first one is GC08.0 urinary traction infection, site not specified due to E. coli. And the second code you would use is MG50.27, meaning extended-spectrum beta-lactamase producing E. coli.

The second type of post-coordination allowed is the combination of a stem code or a main code with one or more of the extension codes. In this case, the connection is signified by ampersand. An example would be tuberculosis of prostate. We would code it as 1B12.5 tuberculosis of the genitourinary system together with extension code for prostate gland.

This is just a screenshot of the browser because post-coordination is tricky. Not all the combinations of the codes will make sense obviously and not all of them would be useful. How do we know what kind of combination is allowed? We use the online browser as our reference. If a code allows post-coordination, it would be shown as an option on the browser. As in this case, the urinary tract infection code allows post-coordination to define the kind of antibody resistance. It is shown here that you can combine the two codes together.

We define three levels of representation. The first level is that ICD-11 is able to fully represent the ICD-10-CM code meaning without post-coordination. An example is like microcephaly is coded as microcephaly in ICD-11 so it is an exact match.

The second level of representation is full representation with post-coordination. An example is myopia, bilateral – bilateral – for myopia example, the main 11 code is myopia and we need the extension code bilateral to complete the meaning.

And the third – representation is partial representation. An example is abrasion of right knee, initial encounter in I-10. And that is coded as abrasion of knee and right. This is already a post-coordinated expression. But still there is something missing, which is the initial encounter. We only classify this as a possible representation.

Overall, among the 943 codes, we have 23.5 percent that can be fully represented in ICD-11 without post-coordination. 8.6 percent can be fully represented, but only with post-coordination. And the rest can only have partial representation.

Since the distribution of codes is very variable among the chapters, it is also helpful to look at the distribution of different levels of representation by chapter and this is such a table. The extremes among the chapters are, for example, in Chapter 3, disease of blood, we have 100 percent of full representation without post-coordination. And the other extreme is Chapter 19 and Chapter 20. We have 0 percent without post-coordination.

In this table, I have put in bold type the dominant category for each chapter. As you can see, a lot of the bold types are actually in the first two columns. Among the 21 chapters, in 13 chapters, there are more

codes that could be represented in ICD-11 fully without post-coordination than the other categories. This is the first observation.

And the second observation for the overall order of chapters, there is an average of 47 percent of the codes in each chapter that can be fully represented without post-coordination.

A third observation is that I have another column called usage here. Usage here represents the percentage of usage that is correspondent to the number of codes in that category. You can see from the last row that the total number percentage of usage that can be fully represented without post-coordination is 53 percent. Since this is bigger than 47 percent of codes that can be fully represented, one inference of that is the codes that are more likely to be fully represented without post-coordination, they are also more frequently used. They tend to be more frequently used.

To give us an indication of the kind of coding variability we would expect in ICD-11, we also measured the difference between the two terminologies in the coding. Out of the 943 codes, in 716 codes, the two terminologies chose the same ICD-11 main code. That means 75 percent agreement on the main code. And out of the 716 codes, in 253 cases, the two terminologies both use post-coordination. For the post-coordination codes that they come up with, 199 of them are exactly the same. In post-coordination, we notice percentage of agreement of 78 percent.

Looking at the literature, there is a lot of reports on coding variability on ICD-9 and ICD-10-CM. And the numbers are quite variable. Most of the studies report variability of agreement between coders from 68 to 80 percent. If we take our findings at face value, the agreements are quite high with both the pre-coordinated codes, the main codes, and also the post-coordinated codes.

For each ICD-10-CM code that we cannot achieve full representation, we would review them to see why we cannot achieve full representation. We categorize the reasons into different categories. The biggest category is that some information is missing in post-coordination.

In this category, we further subdivide them into three kinds of situations. The first one is that post-coordination is not allowed. An example is tinnitus, bilateral and the code we found is tinnitus in I-11, but this code does not allow post-coordination.

The second situation is that the addition of existing extension codes is not allowed for that code. One example is pain in left hip. The best we can code it in I-11 is to post-coordinate the code for pain in joints and the extension code for hip joints. But we cannot further specify the laterality by adding the modifier left, which is not allowed on the browser.

The final category within this type of failure is that there is no existing extension code to capture the kind of information. Here are some common examples. The first one abrasion of nose, initial encounter. The initial encounter part signifies the episode of care, but there is no extension code in I-11 to capture that information.

The second example is unspecified maternal hypertension, third trimester. In ICD-11, there is no extension code to capture trimester of pregnancy.

And in the last example, which is about harmful effects of drugs. Apart from the initial encounter, which is not captured, the adverse effect part is also not captured in ICD-11. This is because ICD-11 only is a general code for harmful effects of drugs, not like ICD-10-CM. ICD-10-CM distinguishes between

different kinds of harmful effects in relation to how the patient is exposed to the drug. If the drug is taken properly as administered, the harmful effect is classified as an adverse effect. If it is improper use, it is classified as poisoning. If the patient is taking less than required then it is classified as underdosing. But none of that information can be captured in I-11.

The second group reason for failure to achieve full representation is that it is because of residual categories. What are these? In both 10-CM and ICD-11, we have so-called "catch-all" residual categories to ensure that there is a code for every situation. And usually these kinds of codes – they have what other, not elsewhere classified in the names such as ascites or difficulty in walking, not elsewhere classified.

The meaning of these residual categories is tricky because the meaning will depend not only on the code and the name. It would also depend on the neighboring codes, particularly the siblings of the code.

Even apparently equivalent codes can have different meanings. An example is other specified cataract. The code H26.8 in ICD-10-CM and 9B10.2Y in I-11. This is because if you look at the two sub-branches here below, you can see that in ICD-10-CM, a drug-induced cataract is coded as H26.3. This means that other specified cataract in ICD-10-CM does not include drug-induced cataract. On the other hand, in ICD-11, there is no specific code for drug-induced cataract. It would be coded under other specified cataracts. The two codes in ICD-10 and ICD-11 are not equivalent in meaning.

The last reason for not achieving full representation is that in some cases, we are forced to use in ICD-11 code that is more specific than ICD-10-CM. I remember that I said earlier that we usually choose codes that are equivalent or broader than the 10-CM code. But in some cases, the coding guidance in ICD-11 forces us to use a specific code. One example is rhabdomyolysis. If we look up rhabdomyolysis in ICD-11 index, it points to FB32.20 idiopathic rhabdomyolysis, which is more specific than rhabdomyolysis, but that is how unspecified rhabdomyolysis is coded. In ICD-11, it is coded as idiopathic. We have to use that code.

Note that post-coordination is not helpful in these kinds of cases because it can only refine a code and make it more specific, and we cannot make more general by post-coordination.

This is the summary of the failure analysis. The biggest category is missing information in post-coordination. And among them, episode of care, laterality, mode of exposure, and trimester of pregnancy made up the bulk of the missing information in post-coordination. Overall, the residual categories, they make up about 14 percent of the cases and the ICD-11 code more specific only made up about 1.4 percent.

Based on the failure analysis, we can see that if we make some small changes in ICD-11, we can really make a big difference in the coverage and the level of representation. If we add only nine extension codes, three episode of care, three trimester of pregnancy, and three codes for mode of drug exposure, and if we allow laterality modifier, left-right bilateral, and we allow them to add to all anatomic entities that are applicable for (indiscernible) then we will have a very different picture.

If we do this, we can increase the percentage of full representation with post-coordination from 8 percent to 35 percent, more than four-fold increase.

The last analysis we carried out is that we also reviewed the coding guidance in both ICD-10-CM and ICD-11. Coding guidances are things like inclusions, exclusions, and index that provide guidance to coders and delineate basically the boundaries of a code.

These are important to understand the full meaning of the code. In addition, ICD-11 also has a description like something like a definition for most codes and this also has understanding of the meaning of the code. Because of this, we carried out a detailed review of the coding guidance between the ICD-10-CM and the corresponding ICD-11 codes for potential conflicts.

In the review of the ICD-11 definitions, we compared them to the inclusions and exclusions of the ICD-10-CM code and its ancestors. In this review, we did not find any conflicts for the definitions.

Also, in the inclusions and exclusions review, first of all, we reviewed the inclusions of the ICD-10-CM code and its ancestors and contrast them with the exclusions of the I-11 codes and its ancestors.

Here is an example of a conflict. The 10-CM code A41.9 sepsis, unspecified organism has an inclusion of septicemia NOS. NOS, meaning not otherwise specified, which we acknowledge because it does not convey any positive information.

And this code in ICD-10-CM is we code it as 1G40 in IL-11 for sepsis without septic shock. But note that this code in IL-11 has an exclusion septicemia, which points to MA15, meaning that if the patient is suffering from septicemia, in I-11, you should not use 1G40 and you should use MA15 microbiological findings in blood, blood-forming organs, or the immune system.

The next evaluation we did for inclusions or exclusions is that we compared the exclusions of the 10-CM code and its ancestors against the inclusions of the ICD-11 code and its ancestors. Here is an example of a conflict. The 10-CM code K59.00 constipation, unspecified has an exclusion of fecal impaction. In 10-CM, fecal impaction would be coded as K58.41. The K59.00 code is we code it as ME05.0 constipation in I-11. But this code has an inclusion of fecal impaction.

Indexes are also another possible source of conflict. We define an index conflict as follows. We look at the 10-CM index and find the index terms that points to the 10-CM code that we are trying to re-code. If the same index term occurs in the I-11 index, but that index entry is pointing to another ICD-11 code other than the code we have chosen, this will constitute an index conflict.

Because there are many index terms in both ICD-10 and 11 so we were not able to do a comprehensive review. Instead, we did a focused review. First of all, all the index terms were normalized by the UMLS lexical tool called luinorm. In normalization, we mean that we removed differences in the terms due to punctuation, capitalization, inflexion, and word order, et cetera.

And the same index entries in ICD-10-CM and ICD-11 would be found by matching the normalized index terms. In all cases in which an index term in ICD-11 pointed to a code which is different from the chosen ICD-11 code would be reviewed.

This is an example of an index conflict. The 10-CM code Q25.0 patient ductus arteriosus is we code it in I-11 as LA8B.4 patent arterial duct. In the 10-CM index, aneurysm of the patent ductus arteriosus is also pointing to the same code, Q25.0. But in the I-11 index, the entry patent ductus arteriosus aneurysm points to another code, which is LA8B.Y, other specific congenital anomaly of great arteries including arterial duct. This would be a conflict.

Among all the coding guidance conflicts that we have identified, some of them are actual conflicts, meaning that with this conflict being (indiscernible) we have to change the type of code that we chose originally.

One example is this. The 10-CM code B19.20 unspecified viral hepatitis C without hepatic coma is we code it as 1E5Z viral hepatitis, unspecified in I-11 because that is the best we could find.

But in the 10-CM index, there is an entry hepatitis C. There is viral within parenthesis. But in the convention of ICD guidance, things in parenthesis are called non-essential modifiers. Basically, the same code would be used with or without these non-essential modifiers. In this case, the index entry would just be hepatitis C.

Look at the ICD-11 side. Hepatitis C NOS, which we ignore, points to the code 1E51.1 chronic hepatitis C. This means that unspecified hepatitis C in ICD-11 is assumed to be chronic hepatitis C and 1E51.1 code is used instead of more general code.

But most of the guidance conflicts that we found are actually potential conflicts. This means that the target I-11 code that we use is correct in general, but would be incorrect in some specific situations. We further classify this kind of potential conflict into three types. The first one is – the example I have given earlier in the sepsis example where inclusion of septicemia is in exclusion in septicemia. In this case, in I-11, the septicemia points to a general code so MA15 is a general code. It is not for septicemia. We call this partial overlap between ICD-10 and 11.

The second type of potential conflict is caused by granularity difference between ICD-10-CM and I-11. In this case, this is the same example I showed earlier about constipation. In this case, fecal impaction has its own code in ICD-10-CM. This means that the codes for constipation and various types of constipation are more finely grained in ICD-10-CM compared to I-11, which just is a general code for constipation.

The third type of potential guidance conflict is due to different default assumptions. Here is an example. The 10-CM code of O03.9 complete or unspecified spontaneous abortion without complication is we code it as JA00.09 spontaneous abortion, complete or unspecified, without complication in I-11. Notice that in the 10-CM index, there is an entry, abortion. We ignore the non-essential modifiers. Abortion in 10-CM is coded also as O03.9. This means that if the abortion is unspecified as to whether it is spontaneous or otherwise, it would be coded as spontaneous. On the ICD-11 side, the unspecified abortion has its own code. It is unspecified abortion code. This is a potential conflict between the codes that were mapped.

This is a summary of the coding guidance conflicts results. On the left side, I am showing the conflicts found by inclusion and exclusion analysis. In total, we found ten cases of conflict, but most of them are potential conflicts. And only one case of actual conflicts.

We identified many more cases of conflicts in the index analysis. But, again, most of the conflicts are not actual conflicts. They are only potential conflicts. Overall, we found in about 10 percent of the codes that we looked at there can be potential coding guidance conflicts.

Here is a summary of the findings from our study. Based on 943 frequently used 10-CM codes, representing 60 percent of usage from each chapter, ICD-11 can achieve 23 percent full representation without post-coordination and 8 percent full representation with post-coordination, but this can be

increased significantly to 35 percent with just minor enhancements in I-11. And the rest are just only partially represented.

We reviewed inclusions, exclusions, and indexes. We found about 10 percent conflicts mostly are potential conflicts.

Before I end this presentation, I would like to share some thoughts that I induced by the results of the study. But I have to emphasize that these are only my own thoughts and they do not represent those of NLM or NCHS.

Going back to the main question we are asking here, can I-11 replace 10-CM for morbidity coding? If you use the transition from ICD-9-CM to 10-CM as a reference, based on the general equivalence maps, which are published by the CMS to help to transition effort, only 24.3 percent of ICD-9-CM codes have exact matches in ICD-10-CM. This is very close to our finding of 23.5 percent of full representation in I-11 without post-coordination. Based on this, it seems that the transition from 10-CM to I-11 may not be more disruptive than the transition from 9-CM to 10-CM. If we can use post-coordination, the disruption can be even less than this.

However, there are several caveats about post-coordination. First of all, post-coordination has never been used in ICD coding. This will be the first if it is ever implemented. This will definitely have impact on tooling design, and also coder education.

Also, post-coordination may increase coding variability as shown in our study. The coder variability in post-coordination is about the same as for the main codes, but this will add another dimension for codes to vary.

What are the advantages of using ICD-11 for morbidity coding? First of all, we can avoid the cost of creating and maintaining an ICD-11-CM. We can use an up-do-date and international medical classification because we do not have to wait for CM.

Another important advantage I think is that if we use also I-11 for morbidity without creating ICD-11-CM, we could avoid potential divergence of the US CM from the international core. Theoretically, ICD-10-CM, if you look at 10-CM as an example, should be totally compatible with ICD-10. However, over the years, significant differences can be observed between ICD-10-CM and ICD-10.

Here are two examples. The code E14 unspecified diabetes mellitus is not found in ICD-10-CM because in 10-CM diabetes unspecified is coded as type 2 diabetes. The code K68 disorders of retroperitoneum is only found in ICD-10-CM and is not found in ICD-10.

Based on our analysis of the coding guidance, it is very likely that there are other differences that exist because of the differences in inclusions, exclusions, and indexing between ICD and its clinical modification, which are uncovered.

The last advantage of using ICD-11 for morbidity is that there is a possibility of making use of the foundation component of ICD-11 for some useful purposes. I do not have time to go into foundation component. But suffice it to say that the foundation component is like a logical underpinning for all the entities in ICD-11. All the codes can be derived from the same logical underpinning.

Since the logical underpinning will give a definition to the codes in terms of logical attributes, if we can make use of the foundation component, it is possible that there would be an easy way to align ICD-11 with logic-based terminology such as SNOMED CT.

Another possibility is that the foundation component, which is very rich in attributes and other definitions of elements, can help in developing automated coding tools for ICD-11.

Even if ICD-11 cannot totally replace ICD-10-CM for morbidity, there are some alternatives to a full-fledged ICD-11-CM, which might be worth considering. One of them is ICD-11-CM lite. By this, I mean can we adopt just some chapters of ICD-11 as is and only modify chapters that have more significant differences from ICD-10-CM.

Another possibility is instead of maintaining full-fledged ICD-11-CM, can we just maintain an extension of extension? Because based on our analysis, the coverage of ICD-11 or ICD-10-CM can be significantly improved or increased with addition of extension codes. If we just add more extension codes to ICD-11, meaning that we are just maintaining an extension of extension of ICD-11, maybe that would be adequate for morbidity coding.

The last possibility I listed here is can we make ICD-11-CM like the rest of ICD-11, meaning that can we derive ICD-11-CM as a linearization of ICD-11. Remember that foundation component is the basis for all the entities in ICD-11 and all the code sets that are used in ICD-11 can be derived from the foundation component as linearizations.

If ICD-11-CM can be modeled with the same logical underpinning, the same foundation component and ICD-11-CM can be derived in a similar way as linearization, it will be very likely that ICD-11-CM would be very tightly aligned with ICD-11.

Thank you for your attention and I will be happy to answer questions.

Nick Coussoule: Thank you all for the presentation. It makes us all realize just how daunting an effort this was the last time and what we will be going through as an industry in the not-too-distant future. Let me open it up. First question from Jim Cimino.

Jim Cimino: Very nice presentation. I know you are familiar with the Desiderata for controlled medical terminologies. I do not want to go through all 12 of them. But I would say that ICD-9 was always my whipping boy for being able to point out all the ways it failed to Desiderata except for content coverage because it had a code called disease so it technically covered everything.

Then 10 came along and they totally ignored the advances in medical terminology sort of rules and regulations.

ICD-11 actually do it pretty well, but there is one that I am wondering if you know about – and that is concept permanence. ICD-10 and 9 have the annoying habit of changing the meanings of terms of codes for adding modifiers to them after the fact or deleting them, even reusing codes sometimes. I am wondering whether or not ICD-11 is doing that?

And the other thing is the ability to match ICD-10 is kind of a low bar. That is like saying you learn how to hand write like I do, which is not very good. Maybe the things that 11 cannot do may not be worth doing.

Kin-Wah Fung: The last question. Can you repeat the very last question that you have?

Jim Cimino: The last question is is being able to make sure that we do what ICD-10 can do really the right goal or should we try to do better than what ICD-10 does? For example, ICD-10 is a (indiscernible). ICD-11 has a surface appearance of a (indiscernible), but actually has multiple hierarchies so that you can do better ways of retrieving ways.

The term diabetes is meaningless. It does not mean type 2 diabetes. It is a meaningless word. It means something sweet. There are ways that 11 is probably doing things better than ICD-10 and maybe we do not want to try to drag it down to that level.

Kin-Wah Fung: Thank you for the compliment. Yes. Your desiderata is being embraced as far as I can see, by the developers of I-11. At least concept permanence I think is much easier to maintain in I-11 because of the foundation layer. Because all the definitions are there. If they change something like changing the name of code to mean something else, if the definition changes and the code does not change, it would be much easier to spot instead of 9 or 10, that there is no easy way to spot the change and meaning.

If they are true to what they are saying and if they do really do a good job in making sure that the logical definitions in the foundation component are representing most of the questions, then I think this problem would be much easier to track.

But it is early days yet, because I-11 is just in its second or third iteration, and it is not even officially used. You need to look long term to look whether they are actually using codes or not. But I suspect that they really have the determination of not to commit the same mistakes of reusing codes.

On the second question of what we can achieve, I think we achieve a lot with the new way that information is being represented in I-11, particularly with the foundation model because one big sticky point for classification is that there is only a strict hierarchy, only one parent for disease. Like hepatorenal syndrome. You can only classify it to liver or kidney, not both.

But with the foundation component, it gives them this flexibility of maintaining the two lineages from two different parents at the same time not violating the principles for classification, which is only one parent per code to avoid double counting. I think this is a really smart move.

And that is why if ICD-10-CM can follow the same pattern and derive its codes from an underpinning logical component, I think these kinds of issues would be much less important in the future.

Of course, post-coordination – I think a lot of what – the main reason why we need to look at ICD-11 seriously to replace 10-CM is that the capability of post-coordination. I think this is potentially a game changer because like in your desiderata you mentioned that coverage, coverage, coverage is most important. Post-coordination is the most efficient and elegant way to increase coverage.

But of course, there are some caveats. You have to use it carefully; otherwise, you end up redundant, ambiguous codes, different representation of the same meaning, and so on. But I think this opens up a very powerful ability for I-11 to increase its –

I think, in general, ICD-11 has a lot of nice features that can offer to the world of morbidity coding. And I think if we do ICD-11-CM as we did before, I think we are missing some opportunities here --

Nick Coussoule: Thank you, Kin-Wah. We are going to have to call time here because we need to move on to the next topic. But thank you very much for the presentation and education. Always helpful again and – makes some of us who are tuned to having implemented this before a little scared of what is coming next. But thank you very much for the education. Margaret, thank you as well.

We will move on to the last topic of the day prior to our public comment, which is our standards discussion led by Jamie for the semantic harmonization and classifications. Jamie, I will leave it to you.

Denise Love: Could I just say, Nick, just to segue this excellent discussion? I know it brought happy memories back from ICD-10 for so many of us. I just wanted to remind folks that the Standards Subcommittee did send a letter November 2019 to HHS to prepare for the adoption of ICD-11. This presentation was right up the alley of those recommendations. Those recommendations in brief were to adopt for mortality, set next to adopt for morbidity, and call for the research and evaluation, which we just heard the very beginnings of and quite informative.

We talked in this letter about use cases and timelines and the potential of ICD-11 to support convergence of clinical and administrative data and called on HHS to provide timely leadership and strategic outreach at the correct time.

What I wanted to say was the Standards Subcommittee will most likely not send this letter, but send one that I have informally titled updated, call to action on ICD-11. And that we hope to have that by September. We will be taking the learnings we had here, digesting those, looking at what we learned from our workshop, which was pretty in depth and reconfigure recommendations to HHS given that information. I just wanted to close that loop before I turn it to Jamie to talk about the standards scope of work going forward.

Standards Discussion: Semantic Harmonization & Classifications

Jamie Ferguson: Thank you, Denise and thank you, Kin-Wah. You are a very hard act to follow. I will try to bring us home with this last section, which really is intended to reflect some of the discussions of the Standards Subcommittee and to generate some additional discussion from the Full Committee.

I think that the basic concept here is that in order to improve and increase the validity and usefulness of health statistics, the country needs a more broadly harmonized and converged set of semantic standards and a set that can operate across all kinds of different use cases both clinical, administrative, social services, and public health use cases.

Thinking back to the ICAD report that we discussed earlier, this would involve the implementation of ICAD recommendation number three of the ICAD convergence report. But since then, since that really was developed I guess about a year ago, the pandemic has exposed the need for broader convergence beyond the specific regulatory authority of ONC and CMS for EHRs and HIPAA and really needs to then involve multiple institutes and offices within, for example, the CDC, AHRQ, NIH, as well as CMS. Because what we found through the pandemic is that we have a situation of unsustainable variation in reportable conditions and health resources data that has to be gathered and reported and of course states and counties do their own thing and the idea here is not to propose something to dictate to them, but to create resources that they could choose to adopt in order to improve the quality and utility of our health data.

As the ICAD report envisioned, this would require nationally standardized cross maps among multiple terminology standards where the same concept may exist in multiple places in different ways. Obviously, ICD-11 will play a role in this and it cannot be implemented without these standard mappings.

The ICAD report recommended a standard cross map for administrative and clinical purposes primarily between ICD and SNOMED CT. But now the scope of semantic harmonization really has to include things like the public health reportable conditions. We now have demands for sexual orientation and gender identity data. I would note that today's transgender visibility day as well as the social factors data that we heard about earlier. I think this is really what is needed to address this kind of variation in data collection to improve the quality of our data and statistics.

With that introduction, I will just open it up for committee discussion.

Nick Coussoule: Jim, your hand is up. I am not sure if that is still hanging over from last time or not.

Rebecca Hines: I have a question, Jamie. And that is what you just outlined, where does that fit in to the project scoping document that was discussed earlier today?

Jamie Ferguson: I think that is squarely within that project scope. Determining the priority of that particular piece of work would be part of the initial interactions with stakeholders and getting input.

Rebecca Hines: Basically, what you are saying is what you just – the need – the situation you just outlined would actually be encompassed in that project.

Jamie Ferguson: That is right. It would be a part of this project if we take the broad scope of the project that Rich introduced.

Rebecca Hines: That is helpful. Thank you.

Denise Love: I told you that you would be tired of my icon. It sounds like it is really similar to the ICAD, but kind of on steroids – and, again, this was said before, but I just want to make clear. It is the same concept but just a bigger lens. Right?

Jamie Ferguson: I think that is right. And the other thing is that it would create a set of resources that could be available to state and county jurisdictions so that they do not have to mix stuff up. It would provide a better set of standardized cross maps that could be used for multiple use cases and scenarios and not just strictly the limited scope that was envisioned within ICAD, which is about the EHR certification program related standards to the HIPAA-related standards.

Rich Landen: In thinking about what Jamie is just describing, it ties so well back to the ICD-11. It ties back to the Gravity Project. I think there is a C change in the way we think about data flows. It has permeated all the different views we have taken of data flows this afternoon and we are now I think as NCVHS, we are in a thought leadership. We are looking at data flows as part of an ecosystem and not as separate transactions as HIPAA envisioned. Our thinking has to be geared about not only solving the problems of today as the ICAD report said, but building for tomorrow. When we think about building for an ecosystem rather than a specific data flow, that is a challenge in developing the use cases because when push comes to shove and you are an HIT in your programming, it is binary. It is either on or off. And the programmers have to have the information to be able to make those decisions.

But at the same time, the use cases have to be extensible so as we develop additional use cases, they can build on a common framework rather than a newer case creating a new need or somehow conflicting with an older need. I welcome Jamie's concepts as part of our convergence 2.0 project and thinking about that. It is really going to be a challenge and we are building very much for the future, but incorporating the lessons learned. Thanks, Jamie.

Jamie Ferguson: Thank you, Rich. One thing I would just add to support what you just said. Something that came up both in your report out on the project proposal. It came out in the Gravity Project. It came out in other discussions is the concept of setting a national floor of expectations for I might call minimum data set for particular use cases with the associated standards.

I think what we are looking at here is an opportunity within that project scope for semantic harmonization to set the minimum set and it might be a combination of value sets and mapping, et cetera, for different use case scenarios, but to put that together in a unified collection that makes sense together rather than in silos where we have social factors, community silo versus a public health silo versus a HIPAA silo because as you mentioned earlier, we see that data flows across these use cases and sometimes needs to be used together.

I think Tammy might be next with her hand up.

Tammy Banks: You had me at semantic. Obviously – you do not necessarily get the business need met. Semantic is such a pleasurable word to hear to actually resolve the issue that you are trying to resolve.

The question for you I have, Jamie, is if we move forward with this, what do you see the impact on machine learning, AI, natural language processing? Do you see this as being a building block to get more standard ways of automating?

Jamie Ferguson: It certainly could be. Actually, I think ANSI has just published a report on data standardization for AI. NIST also is working on creating frameworks for data standardization in order to be able to have standardized characteristics of data sets that are used in artificial intelligence and automation and health care more broadly so that we could detect bias, which you cannot do if you do not have standard definitions of the characteristics of the data sets that are used both for training, for operating, and as output of the AI.

I think we are actually pretty far away from being able to have those objective measures. But this clearly is a necessary component of that kind of framework that NIST is building.

Nick Coussoule: Quick question from me. How does this play off on the work we had done back in 2018 or 2019 when we had some of the T&V work including the recommendations that came out?

Jamie Ferguson: I apologize. I was not on the committee at that time. I am not completely familiar with those recommendations.

Denise Love: Is that the terminologies and vocabulary workshop?

Nick Coussoule: Correct. Yes, where we had done an environmental scan, I believe, and published that in 2018 and then did a lot – guidelines for standardization back in the early 2019.

Rebecca Hines: I will find the link and put it in the chat.

Denise Love: But I think a lot has changed since – the last year seems like ten years of changes to me.

Nick Coussoule: In my mind it clearly falls within the sphere of the outline as we talked about earlier today – the question is going to be how much bandwidth do we have to undertake? Does it become part of that? Is it a separate thread? Do we look at where else there might be some of this work being done, et cetera?

Jamie Ferguson: Exactly and what are the priorities within it and what can we do that is not duplicative or overlapping of other efforts. I do see it as a way of knitting together things that are already going on in various silos.

Nick Coussoule: Rich.

Rich Landen: Nick, going back to your question on the terminology and vocabulary letters. I have not looked at those for several months. I did look at them as we were starting to re-draft the project scope. And essentially, I think the key considerations in there were some of the concepts. We recognized a lot of what we are calling silos in this conversation. Those recommendations talk for a little bit more consistency in the way in which independent groups develop their terminologies and vocabularies and also call them for, again, national leadership, not anything more specific than that, in trying to bring all the different development curation groups together so that the products do harmonize a bit better ideally and then at the bottom – that they at least do not conflict. That would be setting the stage for an evolutionary journey to what we are talking about here.

Nick Coussoule: Other comments or questions?

Jamie Ferguson: Hearing no more questions, we are back on time.

Nick Coussoule: Thank you, Jamie. I appreciate that. Rebecca, maybe I will turn it over to you now.

Public Comment

Rebecca Hines: We are two minutes before the public comment period. We could have the slide up with the instructions. If you would like to submit public comment, click raise your hand to have your audio unmuted or use the Q&A to request an open audio line. I think we might have one person on the phone right now. I am checking email right now. I do not see any comments to NCVHS mail. Actually, members of the audience, I do not think you can raise your hand, but you can use the Q&A. Now you can. Our wonderful logistics guru has given you the ability to raise your hand to have your audio unmuted.

Greg Richards: We see several people who have raised their hand to public comment. I will unmute one at a time. Please state your name and organization before you begin. David Wilderman, I have a request to unmute.

Rebecca Hines: David, please go ahead.

Greg Richards: David, would you like to make a public comment? I will move back to the next person. David, if you would like to make a public comment later, just please re-raise your hand.

Katherine Isbell.

Katherine Isbell: This is Katherine Isbell from Lexington, South Carolina. LexiCode is my company. I just wanted to state how much I appreciated Dr. Fung's presentation on ICD-11. And speaking for myself as a coding educator and for lots of coders, I am sure we will be just fine. We just need to learn a new system, but we are certainly up for it. We really look forward to it. Thank you.

Rebecca Hines: Thank you, Katherine. We appreciate the comments.

Greg.

Greg Richards: I do not see have another raised hand. Actually, David has just re-raised his hand. David, you should have permission to unmute yourself.

David Wilderman: Can you hear me? Thank you. Wonderful. It has taken me quite a while. I am representing the Defense Health Agency military health system. I just wanted to ask if you had any insight into expected rulemaking. I know there has been both recommendations and announcements or talk about expected notices of proposed rulemaking. I wanted to ask if any forthcoming that the committee was familiar with.

Rebecca Hines: I am going to defer that to our lead staff from the Centers for Medicare and Medicaid Services, Lorraine Doo.

Lorraine Doo: On what topic? Could you be a little more specific?

David Wilderman: Yes, ma'am. Attachments is the one that we have been kind of looking out for on the daily, but certainly any others related to the administrative simplification set of activities would be some we are looking out for.

Lorraine Doo. Okay. We do not know anything further about the timeframe for attachments. I would just continue to look at the Federal Registry. To the best of my knowledge and I do not think my colleagues from the National Standards Group are on. The last I heard it had not yet gone to the Office of Management and Budget, which would be its next place. We have not heard anything further on that.

And right now, because we do not have an administrator, that also is part of what – a lot of things are pending based on having an administrator at CMS for other kinds of rulemaking.

David Wilderman: Understood. Thank you very much.

Rebecca Hines: Greg, do we have any other hands up?

Greg Richards: I do not see any at this time.

Rebecca Hines: Okay. The public comment period has come to a close. To the members, you were emailed the slides a little while ago that just asked from Marietta Squire. For the members of the public, many of you have asked. We will be putting all slides shown during the meeting up on the NCVHS website. They do have to go through what is called a 508-compliance process. That takes a little time, but look back in a week or so and hopefully our team will be able to get those up.

With that, any other questions from members before we adjourn until tomorrow morning? Nick.

Nick Coussoule: Thanks, Rebecca. I think we are officially adjourned for the day. Let me give my appreciation to all of our members who did lots of preparation and a lot of good efforts today as well as our outside speakers who were really informative and helpful. We thank our guests for coming in and listening and hopefully engaging with us as they always do.

With that said, we will adjourn and come to order tomorrow morning at 10 a.m. Members, please be on a few minutes early so we can verify all the sound checks. But we look forward to seeing everybody at 10 o'clock Eastern Time tomorrow morning and we are formally adjourned. Thank you.

(Meeting adjourned.)