National Committee on Vital and Health Statistics Standards Subcommittee Listening Session Listening Session on Healthcare Standards Development, Adoption and Implementation

Transcript

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Virtual

SPEAKERS

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Denise E. Love	Individual	Co-Chair
Debra Strickland	Conduent	Member
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Jamie Ferguson	Kaiser Permanente	Member
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Presenters		

Name	Organization	Role
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Lane Hallenbeck	ANSI National Accreditation Board	Executive Director
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Frances E. Schrotter	American National Standards Institute	Senior Vice President and Chief Operating Officer
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Shawna Webster	National Association for Public Health Statistics and Information Systems	Executive Director

Welcome, Call to Order

Rebecca Hines: Good morning and welcome to members of the public, committee members, and staff. It is so good to see you. It is a treat in these pandemic times. I hope you are all staying safe and well. My name is Rebecca Hines and I serve as the executive secretary and designated federal officer for the National Committee on Vital and Health Statistics; otherwise known as NCVHS.

Today, the Subcommittee on Standards of the Committee is holding a listening session on health care standards, development, adoption, and implementation. Building on recent work, the Subcommittee is gathering input today to inform Phase 1 of its two-year project, focusing on the standardization of information for burden reduction and what soon will be hopefully post-pandemic America.

The information provided during today's listening session and through public comment will be used by the Subcommittee to inform its work and may be used to inform recommendations to HHS by the Full Committee.

With that, let us move to roll call, beginning with our chair, Nick.

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

Rebecca Hines: And let us move to the co-chairs of the Subcommittee on Standards, Rich Landen.

Rich Landen: Good morning. Rich Landen, co-chair of Subcommittee on Standards. No conflicts.

Rebecca Hines: Denise Love.

Denise Love: Denise Love, co-chair of Subcommittee on Standards and no conflicts.

Rebecca Hines: Thank you.

Deb Strickland.

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

Rebecca Hines: Jamie Ferguson.

Jamie Ferguson: Good morning. Jamie Ferguson. I am the vice president of Health IT Strategy and Policy for Kaiser Permanente, member of the Full Committee, member of the Subcommittee on Standards. I have no conflicts; however, I do want to mention there will be someone speaking here today from Kaiser Permanente so I will recuse myself from any discussion that is specific to Kaiser Permanente.

Rebecca Hines. Thank you, Jamie.

Jim Cimino.

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

Rebecca Hines: Margaret Skurka.

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

Rebecca Hines: Tammy Banks.

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

Rebecca Hines: Thank you.

Wu Xu.

Wu Xu: Good morning. I am Wu Xu, a retired state health informatics director. I am adjunct faculty with the University of Utah. I am a member of the Full Committee. I have no conflicts.

Rebecca Hines: Valerie Watzlaf.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I am with the University of Pittsburgh as an associate professor and vice chair of education. I am a member of the Full Committee and I also serve on the Subcommittee for Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Denise Chrysler.

Denise Chrysler: 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 for Privacy, Confidentiality, and Security. I have no conflicts.

Rebecca Hines: Thank you. Are there any other members on that I may have missed?

Let us move to staff, beginning with Lorraine Doo.

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

Rebecca Hines: Thank you. And just to note that Marietta Squire and Geneva Cashaw are here behind the scenes. Is there anyone else on the NCVHS team I may have missed?

Just a brief note for members of the public, the agenda today will include time for public comment at the end of the agenda, which right now is looking to be 5 p.m. We will do our best to adhere to the agenda so that members of the public can plan to be available at that time. Sometimes we are off by a few minutes, but we will do our best. When it is time for public comment, we will provide instructions. They are showing here now. If you prefer to send a written comment, it can be read into the record at

NCVHSmail@cdc.gov. There will be an open line for the public comment period. With that, we are done with the welcome and roll call.

Opening Remarks/Agenda Review

Rich Landen: Thanks Rebecca. This is Rich Landen. For myself, my co-chair Denise Love of the Subcommittee on Standards, I would like to just give a little background about what it is we are doing today. As Rebecca mentioned, this is a listening session. This is the first major event of the Subcommittee's project on looking at standardization of information and burden reduction in post-pandemic America. It is a fancy title for we are trying to look and get a sense of the landscape, what are the issues out there, issues both in terms of what is not working correctly in the interoperability and standards landscape in US health care. Who is doing what as far as innovations? The term FHIR comes to mind. We will be hearing much more about that later from the panelists and specifically from HL7.

The new actors in the health care landscape, state data agencies, all-payer claim databases, many partners who both provide and consume data and information that were not considered part of the system when the HIPAA regulations were enacted. It is a brand-new world now 25 years after the enactment of HIPAA. We are a decade or more into the clinical standards for the Office of National Coordinator under the HITECH Act.

I would like to talk a little bit about the charge of the Subcommittee. We talked some of the history with the Predictability Roadmap that was mentioned before. We talked a little bit more about the project. We will hear from Aaron Miri, who is joining us this morning. Aaron is the co-chair of ONC's HITAC Advisory Committee. It is a sister FACA, Federal Advisory Committee, in the clinical data and associated realm.

We will talk a little bit about the requests for public comments to which so many of you have responded. And then the bulk of the day will be spent on various panels to hear from industry segment representatives, talking about lessons learned. The first panel will be lessons learned from other areas besides health care. We will get an update on the standards. We will talk about semantic harmonization and then public health and social risk data.

Finally at the end of the day, we will have a Subcommittee discussion on next steps. As Rebecca mentioned, at 5 p.m. or thereabouts, we will have an opportunity for public comment.

The charge of the Subcommittee on Standards. It monitors and makes recommendations to the Full National Committee on Vital and Health Statistics in the areas of identity issues, opportunities, and health data standards. We provide outreach, liaison, consultation with, and serve as a public forum on health information technology, standards for health industry with federal, state, and local governments.

We make recommendations related to electronic standards and operating rules under HIPAA. And working with the Privacy, Security, and Confidentiality Subcommittee, work in privacy and security standards. We also work on health terminologies and vocabularies.

We make recommendations on strategies to promote a continuing process of developing, coordinating, adopting, implementing, and maintaining standards. The strategies may include public information and educational efforts as well as research and development efforts. I need to stress that we are not an operating entity. The Subcommittee and NCVHS advises the Secretary of HHS. We do not do or manage development projects ourselves.

We do participate in development of publication of a Report to Congress generally biannually. That is centered around HIPAA administration but does touch on other aspects of the health data environment that impact on the administrative simplification transactions and code sets.

Finally, we collaborate with other federal advisory committees on cross-cutting issues as appropriate and then delegated by the Full Committee.

The current initiative, the current project is building upon work we have been doing over the last four or five years that we refer to as the Predictability Roadmap process. Many of the organizations on the panels today and many of those among – I think about 100 people who are participating on the listening session via the web were part of those deliberations.

The Predictability Roadmap focuses on immediate and longer-term needs, identified by industry and within our charter. It is intended to improve the availability and access to updated versions of standards, to address clinical, administrative, and other data intersections, to support the move to interoperability, to improve regulatory processes, to enable access, to updated or new standards as the technology and the business needs of the industry evolve, to improve the standards updating and adoption processes, and overarching as an objective to reduce administrative burdens.

The project that the Subcommittee is currently engaged in now is to build on the Predictability Roadmap and identify current industry innovative activities, priorities, and burden. It is a survey of the landscape.

Today, both the oral panel sessions and the written comments that we have received – this will inform the Subcommittee about what is going on, what are the opportunities, what are the barriers, what are some of the issues, what should be maintained, what should be changed.

After today, the Subcommittee will analyze the information we get out of this listening session and begin the process of identifying issues and identifying opportunities.

As we get into the identification of issues and opportunities, we will start conceptualizing about potential solutions to improve the efficiency and reduce burden and part of that then would be consideration of do we make recommendations to the Secretary of Health and Human Services.

Once we are into the process and have analyzed the information from today, we will develop a work plan for what we are calling Phase 2, which is essentially our work for the coming year. After this information from the landscape and has been completed and we are kind of cognizant of all the moving parts then we move forward with a development of a specific work plan for us to follow next year. I will point out here that it is our intent to do more specific follow up in industry outreach. You will notice that we have a one-day session today. We have tried to cram as much information as we can into that. But there are certainly a lot of activities and a lot of organizations and a lot of groups and a lot of issues that simply could not fit into a single day calendar.

As we get into Phase 2 when we get more specific information, we will be reaching out to many of the organizations on today's call for further information or to delve deeper into some specifics of what we are hearing today.

Phase 2 next year will be to develop and refine recommendations based on our assessments of the standards input, the industry consultation and the information, discussion, and dialogue we get from our peers on the Full National Committee.

In the standards' area, we will be looking at development, regulation, implementation, and enforcement aspects on the convergence of the data streams, HIPAA, and non-HIPAA. We will coordinate our efforts with the Office of National Coordinator and HITAC. And then we will also in Phase 2, identify other opportunities related to other HHS priorities.

Standardization page 2. Additional things that we will take a specific look at, as you might well guessed, FHIR, HL7's FHIR, and APIs in general. A rising issue is all payer claims databases, including the common data layout, consistency of reporting and/or exchange of social risk data. As I mentioned before, conformance or enforcement of improvement opportunities. And we are going to look hard at sanctioned exceptions to the mandated HIPAA transaction sets for alternatives to the HIPAA transaction sets. Again, I will turn it to such things as FHIR and other emerging things that are promising as far as more simple, less burdensome or basic improvement over the adopted HIPAA transactions.

And then finally, health data flows beyond traditional HIPAA and HITECH trading partners. We will be looking at the social and structural determinants of health, looking at patient's social services programs and how the health data needs tie into the current ecosystem and regulatory environment. We will be looking at public health, infectious diseases, and vital statistics. This will be lessons learned from the pandemic experience. And then finally, we will be looking closer at what is the patient role in this health data ecosystem.

We will get into more detail later, but there are four listening session panels we have today. National standards process outside of health care, information exchange and HIPAA, semantic harmonization, and updates on national initiatives on public health and social determinants.

I do want to thank all of you who have sent in written comments. We have a little over 30 letters to date. Several letters had multiple signatures. We have a wealth of information – both high level and detail to weigh through. I assure you. The Subcommittee will do that. We have already started that process and we will talk a little bit more about that later this afternoon with some of the themes and some of the comments.

And for those of you who have the interest, you can view all the submitted letters at the link that is on the bottom right of the screen here. It is on the NCVHS website.

I also want to take this opportunity sadly to note the passing of Laurie Burckhardt. Laurie was a long-term member of the health information technology community. Leadership position. She was one of the chairs of the Designated Standards Maintenance Organization and had board and leadership roles within many of the industry activities. Laurie, for those of you who did not know, worked for Wisconsin Physicians Service Insurance Corporation, also known as WPS Health Solutions. We think fondly on Laurie. Wish she were still with us. But we do want to recognize her contributions to the HIT community.

I am going to turn it over briefly to Denise Love and Denise will give a high-level outline of what we are going to do with the panels later today.

Denise Love: Thank you, Rich. You have covered the train very well. I just want to say the Standards Subcommittee has been working hard on this day for months. I want to thank the NCHS staff and the Subcommittee for all the work leading to this day.

We call it a listening session, but as I listen to Rich's opening remarks, for me, it is a learning session. I am really excited to hear from these excellent panelists that we put together today.

We have curated these panels carefully and populated them with experts from the relative domains. Panel 1, as Rich said, is learning from national standards and the moderator is Jamie Ferguson.

Panel 2 is HIPAA and present-day challenges and future opportunities moderated by Tammy Banks.

Panel 3, semantic harmonization of standards. Jim Cimino will talk about the latest and greatest in that realm.

And then I will be moderating Panel 4, update on national and HHS initiatives on public health data systems and social determinants of health.

Due to time limits, unfortunately, we have limited the panelists to six to ten minutes. We really do not have a lot of time and that is unfortunate. But as Rich said, we would like to have had two days, but we have one. We are making the best of this and then combining with the public comments that have come in. I think over 200 pages of thoughtful insights and comments.

After each panel discussion, we have left time at the end for the committee to ask questions of the panelists or the panelists or the panelists to ask questions of each other, followed by a 5 o'clock public comment period.

Without further ado, I would like to turn it over to Panel 1.

Rebecca Hines: Actually, Rich, are you and Aaron going to take it?

Overview of Federal Health Information Standards Convergence

Rich Landen: Yes. We are not quite at Panel 1 yet. Sorry about that. I know we are eager. I am anxious to get there too, but we have – a couple more level-setting activities to do before we get into the meat.

Over the next ten minutes or so, I am going to talk a little bit more about other things that the Subcommittee on Standards is into and then I am delighted to have as our guest, Aaron Miri, who is co-chair of HITAC. Aaron will spend a few minutes just describing all the many things that HITAC and by extension ONC have on their plate.

I have already talked about the Predictability Roadmap, but a little bit more detail. NCVHS has made some recommendations to HHS already. These recommendations include envisioning a more industry-driven standards development and adoption system. It includes a recommended shift to more timely updates, more frequent, but smaller and what we are calling more digestible bites.

We are calling for enhanced pre-adoption testing. That has been a strong message from the industry in the discussions we have had over the years. Recommendations talked about building in return on investment into the standards development and regulatory processes that in a way that is much more streamlined and meaningful. It includes testing of emerging standards in a real-world environment. And then recommendations from the Roadmap also include discussion around enforcement activities and/or conformance testing with standards.

Related but separate, the Subcommittee has been engaged and is now doing pre-work, let us call it, on ICD-11. World Health Organization/World Health Assembly has adopted ICD-11 and before the outbreak of the pandemic, NCVHS sent some recommendations to HHS. But because of the disruption caused by

the pandemic, our reaction to our recommendations has not been forthcoming. We are in the process of updating our recommendations.

And the recommendations include two components. One is recommending a study of ICD-11 to determine the goodness of fit for the US applications in the morbidity area and whether or not ICD-11 would enable us to not continue with a US clinical modification. There is a whole list of research topics that we are recommending that HHS look into either directly or by contract.

And the other thing that we recommended is a professionally developed communications plan so that the health care community can be much better informed about the pros and cons, the advantages and tradeoffs of ICD-11, much better informed on that than they were in the run up to ICD-10. As many of you will remember, the debate over the ICD-10 adoption led to a prolonged period of uncertainty and many false starts and stops again. In essence, it is a lesson learned. We do not want to repeat the same mistakes. Our recommendation to the secretary will help do – help present an evidence-based platform for the discussion around US implementation as a code set under HIPAA.

The mortality and the morbidity reporting outside of the health care payment and reimbursement is a different story. That is a matter of – essentially, it is an international treaty obligation. That is a component of membership in WHO. That is outside of our scope. But we do address the issue in our ICD-11 recommendation letters.

Also, as this program today represents, we are very much focused on the convergence of the administrative, the clinical, patient, and other health data interoperability standards and again stressing our collaboration with ONC and HITEC with specific reference to the ICAD Task Force, who submitted a report last year.

And then finally, I want to mention that we are – the Subcommittee on Standards is in continuous contact and interaction with our sister subcommittee, the Privacy, Confidentiality, and Security Subcommittee, in our work as our work touches on privacy, security, and confidentiality. And then regularly we report out and brief the Full Committee and get the reactions of all the membership directionally and with specific – the committee is good with constructive criticism.

I think that is it for NCVHS Subcommittee activities and I would like to turn this over to Aaron Miri of HITAC.

Aaron Miri: Good morning, everybody. I appreciate the committee inviting me here on behalf of HITAC and talk about some of the activities that we have going on with the committee related to standards and of course public health and pandemic that is in front of us and what not.

Some quick grounding for you all. I know several of you will probably be familiar with this, particularly folks like Jamie and others, who I had the pleasure of working with in the past. HITAC was born out of the 21st Century Cures Act. It was basically a provision to streamline what was an existing process with the HIT policy committee and centers committee. There were two large committees at that time that were operating under the Office of National Coordinator to advise both the secretary and the coordinator on various things related to health IT policy, which at that time is around meaningful use and others and then standards development, which were literally the standards around view, download, and transmit and those kinds of things.

The 21st Century Cures Act streamlined a committee and basically set forth a FACA that will recommend to the National Coordinator several items, one, policies, standards, implementation specifications, and criteria, certification criteria related to implementation of health IT. What does that mean in English?

It means several things. A couple of things. Number one, we do have an interoperability standards priority taskforce that looks at and looks for various gaps and what there from an ISP perspective needs to be developed or considered in terms of policy levers, in terms of technical standards and specifications, in terms of gaps to address and coordinate across federal agencies.

Next, we have our EHR Reporting Program Task Force, which is literally looking at how do we measure the outcomes or the outputs of what is the value proposition that we want to measure to show progress, incremental progress across various dimensions of quality, financial, other savings and consideration points across the US landscape, basically, measuring how well you are doing.

Three, public health data systems task force. This is exactly what it sounds like. What are the gaps in public health data? What is in interesting is in my day job, I am also the chief information officer for the University of Texas at Austin with Dell Medical School and for UT Health Austin. We are also one of two major vaccine hubs for Travis County, serving two and a half million people and we are doing contact tracing in a large population of the city in partnership with Austin Public Health. It is amazing the discussions that we had at this task force related to standards and lack of standards both within a state and across the country that everybody seems to be facing. I am going to address that a little bit more here in just a second, but I will definitely point you at some of the outputs from that task force if you want some detailed measures.

And then last but not least is the US Core Data for Interoperability Task Force, USCDI, which you recently saw that published Version 2 and now we are working on Version 3. I am proud to say that a lot of that task force really considers social determinants of health and other dynamics that we need to be measuring in a much more granular basis in a standards way across the country.

These committees are in active sync as well as the annual report work group because by law, we are required by statute to report back to Congress annually what we are working on and what the gaps are.

A couple of other things, Rich, you asked me just to comment on to give voice over. If you said, Aaron, if you had a magic wand, what would be a few of the areas you have seen thematically from a HITAC perspective that really NCVHS should consider?

First, I would say that this affects all domains, both public health and traditional care. It has always been there. There is a lack of standardization around how to do patient matching. Is it a unique patient identifier, strategy of several common characters? You see the ONC taking on the US@ Project or USa Project or however you want to pronounce that, which tries to standardize US postal address, using service codes from the post office so that we can standardize just where is Aaron Miri's home address in electronic medical record.

I would say number one would be patient matching. What does that look like? How do we come up with a set of standards or recommended standards that people can adopt? This has come up numerous times as an issue, preventing pandemic care and rapid access to care, particularly with the delta variant and others now around the country. This is critical, getting people's information.

For example, here in Austin, we would have a tough time correlating to get people's prior test results for COVID-19 or not, especially if they want to a private practice of some sort that is not sharing information across a superhighway of some sort, common or other. Big issue there trying to identify people.

The second issue I would definitely point this committee to is truly trying to look at how do we reduce any inequities of care related to data and standards. I gave an example. Right now, defined criteria for gender. You have male/female. However, what we found in practice particularly here in Austin, Texas is there are numerous others. Same thing with race. Same thing with other specifications and demographic information. It just needs to expand to be a common set of criteria so we can reduce inequity to care and inequity of systems and design.

The third item I would say I would love to simply eliminate or remove with a wand is I think you already referenced it once, Rich, which is the privacy and security consideration across the country where we are running into, particularly as it relates to public health is just a general insistence by folks to hide behind HIPAA and other constructs that are simply misnomers.

A better specification and understanding of where things rely in terms of when you are governed by the California Consumer Act or when you have to deal with GDPR when dealing with information internationally or when it is just a state's information related to electronic protected health information disclosure or any other type of PII. I think it is important. It is important for both the developer landscape as well as the patient landscape to begin to understand.

I would point this committee at those three items as specifics as to what I would look at if I were you in the early days in addition to some of the other outputs of HITAC. HITAC, again, really appreciates the partnership here. I know a lot of work is going on behind the scenes across all of HHS. But, again, we stand here to help and to collaborate and move the ball forward. Thank you for the few minutes this morning.

Rich Landen: Thank you, Aaron. Much appreciate it. Yes, we recognize there is a ton of work going on in so many different locations, but certainly HITAC and ONC are one of the foci of incredible amounts of activity.

I also want to react that – in your three priorities, those themes came up very frequently among the 30 or so letters of public comment that we got. In some sense, it is not surprising because people share common issues. But it is kind of reassuring to understand that in some sense, the community does share a strong degree of consensus about what the priorities are that we collectively need to address in the near future.

Thanks again very much. As you said, we look forward to continuing our collaboration. We learn so much. Hopefully that works both ways. We will move forward together.

Aaron Miri: Thank you. I appreciate it. Thanks for the time, guys.

Rich Landen: With that, Denise, I think now is the time we are going to move into our first panel.

Denise Love: Yes. Now, we will go to Panel 1. Jamie, it is all yours. I appreciate the work you put into this and your panelists.

Panel 1: Lessons Learned from National Standards Coordination (Functions and Processes)

Jamie Ferguson: Thank you. And actually, two minutes early. Wow. Perfect.

Good morning. Hello everybody. First of all, this panel is seeking input and information on successful sector-wide standardization and conformity assessment just broadly.

Second, we are seeking to understand more about the possibilities for collaboration and coordination of standardization in health care outside of HIPAA.

And then third, we are looking at understanding and learning about opportunities for interagency coordination and cross-sector coordination with both public and private sector stakeholders.

We have a really distinguished panel that it is my pleasure to introduce. I will not go through detailed bios. I want to say thank you to each of our panelists in advance. First up, we will have Fran Schrotter, who is the senior vice president and chief operating officer of the American National Standards Institute, ANSI. Then we will hear from Lane Hallenbeck, the executive director of ANSI National Accreditation Board. Then we will hear from Scott Colburn, the director of Standards and Conformity Assessment at FDA. And then we will hear also from Dan Vreeman from RTI, who is the chair of the Health Standards Collaborative.

And then I am hoping that we will also have time for some questions and answers and discussion after those presentations. I am really looking forward to the presentations and discussion.

Now, I will give the word to Fran, and I understand she has a few slides to present.

Fran Schrotter: Thank you very much, Jamie. Good morning, everyone, and thank you for the opportunity to be with you today to provide an overview of ANSI's approach to standards coordination for national priorities and emerging technologies.

I would like to begin with a high-level overview of the US Standards and Conformity Assessment System. One of the greatest strengths of the US approach to standards and conformance is the public-private partnership that underpins it. It is through working together and respectful cooperation. We are able to most effectively respond to the strategic needs of the nation. This dynamic makes us pretty unique in the world. We see that as we engage internationally that the strong public-private partnership is strongest here on this turf.

There is no single government agency that has control over standards. Each agency determines the standards that best meet its needs and its mission.

The National Technology Transfer and Advancement Act of 1995, Public Law 104-113, directs all federal agencies to use for regulatory procurement and other agency activities wherever feasible, standards and conformity assessment solutions developed or adopted by voluntary consensus standards bodies. This is in lieu of developing government unique standards or regulations.

The NTTAA also encourages government agencies to participate in voluntary standards development processes where such involvement is in keeping with an agency's mission.

OMB Circular A-119, which was revised by the Office of Management and Budget in 2016, spells out the government strategy for standards development. It promotes agency participation on standard bodies, specifies reporting requirements on conformity assessment activities, and informs agencies of their statutory obligations related to standards setting. NIST is responsible for coordinating standards and conformity assessment activities within the Federal Government and reporting government-wide progress annually to the OMB.

Now, I would like to spend a moment or two, providing some background on the American National Standards Institute. We were founded back in 1918, over 100 years ago, to address the need for coordination of standards activities.

We are a private, not-for-profit membership organization, whose mission is to enhance US global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the US voluntary standardization system.

Our reach is quite expansive. ANSI represents and serves the diverse interests of more than 270,000 companies and organizations and 30 million professionals worldwide. This includes businesses, professional societies and trade associations, standards development organizations, government agencies, and consumer and labor organizations.

ANSI is also the sole US representative to the two largest non-treaty international standards organizations known as ISO and IEC.

While ANSI's by-laws define a number of purposes of ANSI, for today's audience, I would like to focus on just three of them. First, to serve as the national coordinating institution for voluntary standards, conformity assessment and related activities in the United States.

Second, to provide the means for determining the need for new standards and conformity assessment programs and to promote activity by existing organizations that are competent to resolve the needs and to work towards the establishment of suitable groups to address such needs when such do not already exist.

Third and of particular importance, to cooperate with departments and agencies of federal, state, and local governments in achieving optimal compatibility between government laws and regulations and the voluntary standards of industry and commerce.

I would now like to focus specifically on ANSI standards coordination activities. One of the ways in which we carry out our coordination activities is through the establishment of standards collaboratives and workshops. We provide a neutral forum for bringing together the public and private sectors to address specific standardization needs.

These collaboratives and workshop will identify current as well as in development standards and related conformity assessment activities and where gaps exist will recommend solutions. They will also identify organizations that can perform the needed work and address the priorities.

Collaboratives and workshops are typically convened in response to needs that have been identified either by government, industry, or SDOs. One very important point that I would like to emphasize is that the collaboratives themselves do not develop standards. They also do not make policy

recommendations. Rather, they focus on how standards and conformity assessment can support the evolving policy framework.

Participation in the collaboratives and workshops is open to all interested stakeholders. When ANSI forms a collaborative, we do extensive outreach to identify as many of the affected stakeholders as we can to be part of the initiative. All decisions of the collaboratives are based on consensus.

This slide just shows the various collaboratives and workshops that have been formed by ANSI over the years to address various national standardization priorities. As the work of each of these groups is completed, we sunset the group and then move on to the next identified priority area of interest.

I should note a couple of things. One, we had a major initiative back in 2005 with Healthcare Information Technology Standards Panel that we convened and worked on electronic health records.

I should also note that we are currently working with the task group that is co-chaired by Jamie Ferguson of Kaiser Permanente, who is moderating this panel, and Lisa Carnahan of NIST to address standardization empowering AI-enabled systems in health care.

We convened one workshop back in September of 2020 and a second one is being planned for later this year. The areas of focus for that activity have been data quality and data analysis challenges, trust, transparency and explainability, governance and risk management.

Let us spend a moment focusing on workshops. These are usually one-off standardization events such as the one I just mentioned or a series of them that are convened under a collaborative for the purpose of information sharing and networking. A written report is produced that describes what was discussed as well as any specific recommendations that were made.

This format enables timely information exchange but does not undertake the same level of analysis that would be done in the development of a standardization roadmap. It is also less resource intensive for volunteers and staff. This approach makes sense when there is a less urgent need for coordination and comprehensive analysis and when issues are able to be addressed sequentially.

A roadmap is a document that is normally developed over the course of a year. It is the timeline that we usually assign to it and that describes the current and future standardization landscape. It provides an in-depth gap analysis and a series of recommendations where standards are needed and also assigns priorities to those needs.

Most of the work is done virtually and the subject matter experts are responsible for drafting the gaps as well as the recommendations.

A roadmap exercise is far more resource intensive than workshops. There may also be a series of working groups formed to focus on a particular area of need. These working groups may be required to meet biweekly. You need to have a strong commitment here.

This approach makes sense when there are a number of different standards development organizations involved in the particular technology area of focus and also when there is a need for comprehensive analysis of the issues. We see that engaging in the roadmap exercise because of its intensity does take a fair amount of commitment from the participants who come to the table.

Following the publication of the roadmap, there may be the need for some promotional activities, progress reports by the SDOs to address the recommendations and perhaps the need for roadmap updates, which we have seen in our experience.

Here is just one example. This one focuses on the roadmap that was done in the area of unmanned aircraft systems or UAS. Responding to a need that was identified by the Federal Aviation Administration, ANSI established this collaborative to coordinate and accelerate the development of standards and conformity assessment programs to facilitate the safe integration of unmanned aircraft systems into the US national airspace system and to coordinate with work going on internationally.

It was determined that a comprehensive roadmap was needed to describe the current and desired future standardization landscape for UAS. Version 1 of the roadmap was published in December of 2018 and Version 2 in June of 2020. Seventy-one gaps on standardization needs were identified and a gaps' progress report was published in June of this year. The document is available for free download at the URL indicated on the slide.

I would like now to take just a moment to share with you what we view as the key ingredient for the success of these collaborative efforts. First, there must be a demonstrated need for coordination. There also must be broad stakeholder support as well as clearly defined objectives, timelines, and deliverables. Absent those ingredients, we will not be successful.

So too, there must be a stable funding mechanism to support ANSI's work with the collaboratives. Since we are a 501(c) organization, we are not for profit, so we do need financial support to undertake these initiatives.

This would include potentially direct support from the stakeholders themselves or a sponsorship from the appropriate recognition and benefits to those who agree to provide such sponsorships.

In conclusion, I would like to recommend that the Subcommittee on Standards consider ANSI as a resource as you embark upon your efforts. You heard a number of the priorities. But when I was reviewing the scope of the work of the subcommittee, I identified two that I thought perhaps we could assist with. And one was assessing the current standardization landscape in light of federal priorities for interoperability and then the second one is to identify gaps or opportunities for improving the adoption, implementation, and use of standards to accommodate the changing health information ecosystem. Certainly, we heard from Rich Landen this morning that clearly that is a major need and one that needs to be addressed and is being addressed and there is a lot of work already going on.

But if you believe there are things that ANSI could do to be of assistance, please do not hesitate to let us know. Sometimes you just need an extra group that can focus on a specific aspect of what has been identified as a need and that can be done. You have your own subgroups that work on these initiatives. But we certainly can provide a forum for that as well.

I would like just to conclude by thanking the Subcommittee for the opportunity to make the presentation today. As Jamie has indicated, I will be happy to answer any questions as we move through this panel discussion here today.

Thank you for your time and attention. I appreciate that.

Jamie Ferguson: Fran, thank you very much for that presentation. I really appreciate it. We are going to hold questions until the end of the panel, however.

Next up, I believe we have Lane Hallenbeck on deck. Lane, I believe you have a few slides as well.

Lane Hallenbeck: Yes Sir. Thank you, Jamie, and good morning, everyone. It is an honor to be here. I am grateful that the committee acknowledges that standards are just creative writing unless somebody has an expectation of complying with them.

To that end, I have been asked to do a brief overview of conformity assessment fundamentals and as leader of the ANSI National Accreditation Board, our role in conformity assessment.

I am given pause a little bit with regards to fundamentals that I might come across as captain obvious right off the bat here. Just starting with some ISO definitions with gleaning all the extraneous words. The point is I am trying to make off the bat is conformity assessment is not the alchemy that some people think it is. Simply put, standards are documents that provide characteristics and conformity assessment demonstrates that those characteristics or requirements are fulfilled.

Continuing on the simplification, maybe oversimplification, in the next slide – I apologize to the Rolling Stones and maybe make a nod to Charlie Watts, but my vision of conformity assessment is always getting what you want. We all know that is not a realistic vision. But this teeter totter metaphor essentially captures the balance and negotiation going on between all the links in the global supply chain in terms of value for the providers and trust and confidence that the buyers will get what they want and certainly influenced by other stakeholders and certainly regulators and scheme owners as well. That is the oversimplification.

In the next slide, I will switch gears and at the risk of complicating things, this nebula or Rorschach test, I call the framework for conformity assessment essentially. But it is all about trust and confidence as the vision again. And as previously mentioned, it all starts with the requirements. They are shown at 3 o'clock. This might go here and this chart here is to provide a bit of a Rosetta stone for a lot of the terminology and just acknowledging that all standards are not alike and vary in formality from some of those words there, guides, standards, certainly regulations, simple specs. Certainly, the ANSI community believes in the multiple path approach. Those foundational requirements are certainly tailored to address the object of conformity assessment of what you see at about 10 o'clock there and can be anything from products and services and systems and certainly software is an object of conformity assessment that ANAB is involved with regards to ONC and HIT. I think people know.

And then the various methods that are used to get to the bottom of compliance with those standards. You can see those at the bottom there. And some of those terms. I will say some more about the term certification and accreditation, which are all often confused.

The context of who the holder is for second or third party up at 2 o'clock is certainly different applications with regards to the seller and supplier's declaration or the buyer and third party independent and second-party audits and consumer and specifiers of different acceptance authorities.

With regards to issues, the risk management is central to the magnitude of conformity assessment required there and different aspects of impartiality and more frequently intellectual property and cyber security issues are essential considerations.

I warned Jamie that I would mention block chain there and I see the digitization of trust is certainly on the horizon for the evolution of conformity assessment with regards to tools and technology there. There are some additional terms for consideration on –

Just applying those relevant framework terms to what we do in ANAB and noting there is a lot of confusion about the pecking order and whether you see accreditation at the top or bottom of that hierarchy. In the ISO vernacular, accreditation bodies assess the competency of conformity assessment bodies, who in turn depending on the methods and the object of conformity that you see at the bottom there through one of those action verbs determine conformity with those standards. Hopefully that clarifies that in the ISO sense. But this again is in the context of third party.

Also notice that specific to ANAB and all other internationally recognized accreditation bodies, we have to comply with ISO 17011 standards. Standards for conformity assessment are the bridge, as it were, between standards and conformity assessment, which leads us to the next slide, which depicts the CASCO toolbox, the Conformity Assessment Committee at ISO, which has the 17000 series of standards, some three dozen standards that again reiterating some of those terms and methods of conformity assessment there in that waterfall of boxes and noting, again, which method to use is determined by and specified by the different stakeholders. Certainly, preeminently, the customer requirements as modified by any regulatory requirements that may exist and the risks of non-conformance with the standard.

This shows moving into ANAB's role. We have pretty much a complete portfolio of accreditation programs, again, as defined by 17011 and towards assessing the competence of these different conformity assessment bodies noted here and assessed to the requirements of those standards shown in the right-hand column.

Lastly, the ultimate answer to who is checking the checker of the checkers. I know that may seem a little over the top. It is not for all programs. It is voluntary to the extent that it is up until it is adopted by scheme owners and regulators as part of their schemes or programs. Historically, there are three major regional accreditation groups and two overarching international groups whose sole purpose is to establish equivalence and equal reliability between all these oversight groups by virtue of a peer assessment to ISO 17011. The Europeans obviously is shown here, the EA. The western hemisphere has the Inter American Accreditation Cooperation. In the Asia-Pacific region and connected to the APAC MRA, the Asia-Pacific Accreditation Cooperation.

The two international groups, ILAC and IAF, are actually in the process of merging. There are more than 60 signatories to those multi-lateral recognition arrangements. That is a quick dance through the fundamentals of conformity assessment and ANSI's role. I appreciate your attention and at your service for any further contributions I can make.

Jamie Ferguson: That is great. Lane, thank you very much. Thank you for being here today. I am sure we will get back to you during the follow up discussion as well.

Next, I would like to turn to Scott Colburn. Scott, I understand you will be speaking not from slides, but just talking, which is refreshing actually. Welcome. We are looking forward to hearing from you today.

Scott Colburn: Thank you. Welcome everyone. Good morning. My name is Scott Colburn. I am with the US Food and Drug Administration, and I am the director of our Standards and Conformity Assessment Program that oversees our engagement and the voluntary consensus standards and other conformity

assessment activities and the focus with medical devices. But we do collaborate across our entire agency in helping share best practices and understanding of where we can keep advancing some of the key areas of what we find in standards and their use. I will walk through our program, our role in working with organizations and where you would see us fitting into what was described earlier by Fran and Lane, who FDA works very closely with.

In fact, when I see going into panels for our first time in an organization such as this, I feel like I am talking with my family because a lot of the same faces are together and we see a lot of each other. In fact, I think, Jamie, we have two to three meetings a week now it seems like. That is one of the refreshing things of the standards environment in that ecosystem is that you get to see what the entire life cycle of products are needing and where a regulator such as FDA can utilize such tools in an impactful way that helps drive innovation and lowers burden to product skimming into the market, but not in the way that lowers the quality and safety standards that we all care so much about especially as a regulator and an agency within the Department of Health and Human Services. In fact, we feel quite the opposite. We feel standards are a key ingredient and a driver for product quality, consistency, and patient safety. It is a means for us to use those in a way that we can help drive getting products into the market that are safe and are meeting the objectives and missions of us as a public health agency.

Our priorities obviously are trying to get standards to help enhance regulatory science, promote quality, as I mentioned, and improve patient access to the types of technologies and products whether it is devices or drugs or biologics or even just how we use standards to help support things such as our EMR or driving new technologies that are coming down the pike such as figuring out artificial intelligence and how does that work.

Standards are engaged in all these different areas. But as regulatory agencies and as Fran mentioned earlier, those do come from some poor aspects of what we look at to help drive our push to make sure we are doing what is in the best interest of the public and in the private sector as we look at standards.

As Fran mentioned, we have the National Technology Transfer and Advancement Act as well as the OMB circular, which help drives how a federal agency should consider the use of voluntary consensus standards. In fact, in looking at the comments, I did see a number of comments that pointed to FDA's voluntary consensus standards program, which I helped to oversee. I will speak a little bit to why is that important for us and why do we recognize 1444 current standards versus incorporating those into reference as part of regulation. But those are important aspects.

Furthermore, we also want to talk a little bit about what do we do in terms of sharing our experience and gaining the experience of our sister agencies and departments who also are highly involved in standards whether it is the Department of Defense, Homeland Security, EPA, OSHA, and other areas as well. We do this through a coordinated effort under NIST Standard Coordination Office with the Interagency Committee on Standards and Policy. I am trying my best not to use four-letter acronyms.

We are also very thankful though that at FDA, many years ago even predating myself, we had in our Food and Drug Modernization Act, statutory authority in the medical device area that tells us that we shall recognize standards and we shall recognize them in a means that will permit a submitter to declare conformity to that standard to demonstrate how they are meeting a part of a premarket requirement. That really opened up the doors for us because prior to that authority, we were in statutory language told to create those standards on our own, government-unique standards essentially. And over the course of nine years during that law from 1990 to 1997 during those years, we actually wrote zero

standards because we realized how difficult that is to do on your own and why working within a voluntary consensus standards environment bring in all your stakeholders together is so critical to making sure that how you communicate what your requirements are really require everyone that is involved in that area. That is real critical and has become a bedrock principle to how we engage in standards, why do we engage in standards, and what does that all mean.

Why do we help develop standards? There are obviously things that I have already said. But I think a lot of what we do try to purport too is that it does help reduce time to market. It helps make safe and effective products especially in the medical device area that I oversee.

But further we also believe that appropriate standards and standards development with the right stakeholders at the table really facilitate product design and performance and from that, the high levels of quality that we can help measure into areas like patient safety that are so important.

We can continually raise the bar on safety and effectiveness with these new technologies as well. Standards are consistently being looked at, evaluated, and seeing where could we keep driving what it is that we are seeing in the market to help improve quality. If we were to look at how we do regulations, not only does it take several years to get a regulation on the books, it takes just as many years to update those regulations sometimes. And if we are incorporating standards into regulation or developing our own unique standards and putting them into regulation, as a regulatory agency who cares about public safety and patient safety, that makes it very hard for us to have a communication tool on what would be the best and least burdensome way to approach such areas without being able to have something nimble like our recognition program that we use in the Center for Devices and Radiological Health.

Another big advantage though that we find is not only is using the standards a wonderful tool to help products, but it also keeps our agency involved with our stakeholders and it is also a means for professional development. We have wonderful experts within the center. But we also want to continue to stay up to speed with where is the technology going from and working with our stakeholders in this environment is a benefit for everyone. Our stakeholders get to learn from us, what is a regulator looking for in these areas. But we are also getting to see how our technologies and new areas of how we can drive this discussion in the process of standards development and in how it is looked at in conformity assessment a way for us to understand how to best set up our regulatory pathways to help products get into the market.

One of the things that I always harp on is being at the table is important. But do not show up at the end of the process because by that time, things are pretty much buttoned in place. You are not going to have that chance to provide your flavor to what you feel needs to be in that standard. We really strive to be involved at the earliest stages of standards development and even engage in the policy areas of standards whether it is through ANSI or a number of the different areas of standards developing organizations that we are a part of.

Looking at standards too, one of the things that we have evolved in over the last ten years is not just being engaged in standards developing and recognition of standards to which we accept what we call a first party conformity assessment platform where we will accept a declaration of conformity with evidence to support a standard. But we have also engaged in the conformity assessment platform so working with organizations like Lane with ANAB and other accreditation bodies in the US and working with the testing laboratories that are accredited to many of the standards that we have recognized.

We have found that we can also bring value to bringing that perspective that is important to understanding how a testing plan is developed, what goes into the discussions between the manufacturer and the testing organization, but even more importantly, how are those testing organizations seen as competent to be able to do testing in those areas and what can we do to help the accreditation bodies in meeting those goals that they are working on under their procedures.

It is not to say that we feel that those are inadequate right now, but we do understand that standards are extraordinarily complex and have gotten much more complex over the last 20 years and we still continue to see that direction continue into the future as we looked at some of the challenges that we know are coming down the pike with advancing technologies in the health care sector. Being able to be there and help provide training, answer questions that they have as providing value to the manufacturer who is trying to make sure that their products are meeting the safety marks that we are really hoping to see as we evaluate things that go into the market.

We are now working with looking at how we do conformity assessment, a way to help testing laboratories and accreditation bodies to be a part of that life cycle of a standard in terms of us being engaged with the community and that is helping the manufacturers and have discussions and understanding how their test reports are achieving what they are making in their claims as we move forward.

In closing, I want to really stress the importance of why we have multiple stakeholders here just in this panel and why I am sure many of you that are in the meeting here today are from many different stakeholders and the collaboration that this brings really can help drive best practices, efficient ways for us to work together as a community in the United States, but also drive what we know as always there is that this area, our industry in health care is a global industry. And the more we coordinate together and we know that we have a product that works based upon the process that we have set up, we can share that to the global market and have a much more efficient way to ensure that products are available, not just in the United States, but everywhere that we go because we are a very mobile society and it is important for us to make sure that technologies can be brought into other environments and other economies in a very efficient way. That is one of the core things that we do look at even as a US regulator is how does this in what we do in using standards impact in a positive way our manufacturer's ability to bring products not just to the United States, but also share that information internationally.

That kind of speaks a little bit to what Lane described with ANAB in their role in being at ILAC and other international organizations in the conformity assessment. We, too, are working to try to do this on the regulatory side by sharing our policies and how we look at standards and where can we share on common grounds with our sister FDAs around the world.

I will stop there and pass it back over to Jamie.

Jamie Ferguson: That was great. Thank you so much, Scott. I really appreciate you being able to be here with us today.

And now, without further delay, I will turn the word to Dan Vreeman. And Dan, happy to hear from you about the health standards collaborative.

Dan Vreeman: Thanks Jamie. It is a pleasure to be here. I would like to thank you and the Subcommittee for the opportunity to participate in this important discussion. I have had the privilege of speaking to the Subcommittee a few times before in my prior role as director of LOINC and Health Data Standards at the

Regenstrief Institute. But I am here today on behalf of the members of the Health Standards Collaborative, which we refer to as the HSC, which was launched back at about 2008 against the backdrop of really extensive and excellent standards development work that was happening across the many dimensions of health. But there was an awareness of the ongoing challenges with coordination, alignment, duplication of effort amongst different standards development organizations.

For example, we recognize the challenges of moving structured health information from the many places where it is produced by care organizations to all the other context words needed whether those are payers or PBMs or public health. And across those exchanges, data must flow or be hoisted with a lot of manual effort as the case may be across these interfaces that use specifications developed by different SDOs sometimes simultaneously.

There are, of course, very complex reasons why we do not have interoperability yet across the entire ecosystem. But one challenge is that SDO serve different members have traditionally addressed different but sometimes overlapping scopes.

And against that backdrop that the HSC was formed and really its mission of this Health Standards Collaborative is to provide an environment that facilitates effective collaboration among health IT, health standards development organizations in the US context.

The HSC is not a standards development organization in its own right. Rather it is meant to provide an executive form and a process for the senior leadership of the US health standards development community to be able to have strategic and tactical dialogue planning and action.

Our members work together to support best practices for voluntary consensus standards development in an effort to seek, to minimize overlap and duplication of effort in standards, to we seek to create an open dialogue amongst the community while respecting the unique contributions, policies, and agreements that member organizations may have.

The HSC membership consists of executive leader representatives, primary and alternates, from participating organizations. There are presently about 22 member organizations that fall into three main categories: standards development organizations, SDO-related entities, and official observers.

SDOs or standards development organizations are those that actually develop, maintain, and disseminate standards. This is the category for which we have the most members. Standards development need not be their exclusive focus, but they must actually produce standards to be labeled in this group.

Our members in this category produce a wide variety of standards. For example, those related to data exchange across interfaces, semantic standards such as terminologies, or standards for medical devices or health care products and services.

In addition, there is another category for SDO-related entities, which are organizations that have substantial direct or indirect involvement with SDOs and are active in related areas.

And then the third category is official observers, which are invited or interested organizations who are involved with SDOs, but wish to participate without voting rights. In this category, ANSI is a permanent member with non-voting rights. We find several government entities also participate in this way. The complete list of members is of course available on the website, healthstandardscollaborative.org. I know

that this group has received many comments from our members prior to this meeting. I am pleased that throughout the day they will be sharing in discussions as well.

The focus of the HSC is really on collaboration of standards development organizations. Therefore, we believe it is more appropriate for associations or vendors or implementers to participate directly with relevant SDOs rather than joining the HSC directory.

Throughout its history, HSC has considered a few different potential models for its role in operation. Today, it operates as a very lightweight volunteer forum. We hold a few meetings per year with a purpose of those meetings being really to share, to learn, and to explore opportunities for collaboration. We make it a point to hear from each other from relevant federal agencies about issues and initiatives that need cross SDO coordination but are careful not to duplicate processes that are already well established. In fact, most of the efforts that we embark on take place or sort of actually get done in the context of a particular SDO or the context of existing agreements between SDOs. But the HSC itself is a forum to speak amongst, to share, and to learn from the broader SDO community.

Thank you for the opportunity to share just a little bit about the Health Standards Collaborative and I look forward to the discussion.

Jamie Ferguson: Dan, thank you very much. I, again, really appreciate you being here today.

Now, what I would like to do is – I think we have a little bit of time. I would like to invite all the panelists to go off mute together. We can have a little bit of discussion. The first question I would like to ask – actually, I would like to hear from all of the panelists on this one. We heard at the outset of this meeting that although we have coordination of standardization activities within the HIPAA transaction realm, within the EHR-related realm, within the medical device realm, et cetera, the committee is really focused on broadening the coordination of standardization between and across these different realms, including HIPAA data, non-HIPAA data, social services, public health. My question is if we are trying to focus on coordination of these activities, how could we measure success or specifically, how do you think HHS could measure the success of coordination both of standards' programs as well as conformity assessment across these different parts of the health care sector.

Fran Schrotter: This is Fran if I may just say a couple of words. Certainly, the measures of success. It is always a challenge to try to identify what they are. We have looked at this from the perspective of the things that we undertake in terms of our collaborative efforts. We certainly have a couple of thoughts there.

When we reach out broadly to bring people to the table, one of the measures of success is the number of participants that agree to play a role in the initiative that we undertake. That is one indicator of the success, if you will.

Another potential indicator is the responsiveness of the SDO community. That is particularly important as we look at the gaps that are identified that need to be filled. To what extent do the SDOs come to the table and say yes? We agree this is a gap. We agree that this is needed to be done. We agree we can do it or we will work to do within the defined timeline. Those are just a couple of thoughts. And of course, the ongoing support for any initiative that we may have I think is another potential indicator. Just some thoughts and points for discussion here.

Scott Colburn: I will add to that. I think coordination is absolutely critical in this type of area. When we start talking about coordination, we really want to make sure that we are broadly looking at who needs to be involved so those informed are informed. There are so many areas in which we build standards and standards development organizations will go off and build standards as well. Many of them under the ANSI central requirements, but some of them also under their own areas. It can appear a bit daunting to know what all is going on and how does that all come together. Sometimes coordination sometimes feels like competition rather than coordination. And that is an important thing to make sure that we have a good understanding.

Just look at the Federal Government as well and even in the Department of Health and Human Services to which there is many agencies and even within agencies, many separate centers that have all their different ways of using standards of statutory authorities under which they are asked to use standards.

We want to make sure that even an organization like HHS is coordinating that appropriately. When we, as a stakeholder, come and ask of a particular stakeholder this is what we would like, we have to really make sure too. Do we understand the structure of that stakeholder in a way that we can ask those questions specifically to ensure that we are pulling up ideas from other subgroups of that organization whether it be an agency or a center within an agency to the department or which SDOs underneath the ANSI federation that are accredited in that umbrella, or so forth. I think a council like this, an agency like this is a great start to look at them. But it is one of the biggest challenges as we know as well.

Jamie Ferguson: Any other thoughts?

Lane Hallenbeck: I might jump in and just say while as a conformity assessment guy, it will not surprise you to hear me say I think a good metric of success is compliance with the standards. I would also acknowledge that in lower risk context, suppliers, declaration, other things can work. But in general, when you are talking about health care, that is higher risk issue. I certainly am an unabashed evangelist for third party.

But I would also say realistically that perfection is aspirational like zero defects. It is more about continual improvement and being able to track through metrics like that, but also acknowledging – I mentioned the different objects of conformity assessment, which may come across as belts and suspenders. But most people think about conformity assessment with regards to goods and services.

Increasingly, our partnerships with federal agencies and private scheme owners are across the spectrum of conformity assessment, especially in credentialing. We certainly accredit medical labs to ISO 15189 and most of you are familiar with 9001, we accredit to 17021, all sorts of other health care service companies.

But increasingly, we accredit to credentialing organizations like the NBCOT's occupational therapist programs and electrophysiology specialists for the International Board of Heart Rhythm Examiners, and American Society for Clinical Pathologists especially for scientists and technicians. I will quit before I get too commercial here. That is my story.

Jamie Ferguson: Thank you. I appreciate it.

What I would like to do is I would like to pose if I can one more question. I think we have just a few more minutes for this panel. This one is about how HHS might manage transitions and standards. I am thinking about this in two different ways. One is in the routine or what might be seen as routine version updates

so within a particular family of standards or for what you might consider a minor version update of a standard within the same family or the same technology. How could we better help to manage those kinds of transitions between standards?

But then also the second category really is more in the disruptive category where you have a new family of standards that might align a new technology or require new systems that have some significant benefits, but also some significant costs. How can we manage transitions of standards in both of those sorts of cases?

Scott Colburn: I will take a first swipe at that. Jamie, transition is one of our largest challenges as regulators. We try to be very quick to the mark to try to recognize a newer standard whether it is a newer version or a new standard all together. Now, luckily, in the medical device sector, standards are voluntary by nature and less incorporated by reference, but however, they are also seen as that is what FDA is really pointing to so we should really use that.

When we start looking at transitioning from an older version that has been superseded by another version, there are a number of challenges to that. One is understanding the standard itself and what do those changes mean in terms of if it is a product that would need to have its entire quality system risk management file updated in order to even figure how to test to that standard. What is the timeframe that is needed for that? What are the inputs that are needed from a manufacturing process? Many manufacturers will say it takes sometimes at least 18 months to be able to prep for that from a manufacturing standpoint.

And then there is a conformity assessment side. I think Lane could speak to this as well. We do not just assume that a new standard is published, and all the labs are accredited to it and trained and understand those things especially if there are dynamic differences.

And then I mentioned earlier. We also try to look at what is the global impact to this as well. We get many times where we will see one country or sector start recognizing a standard or utilizing a standard. I think a lot of times that people assume there is coordination around the world on that and that is in many cases not true. But those are things too that we need to look at how can we improve this. It kind of goes back to communication and collaboration aspect.

Jamie Ferguson: Thank you very much. Other thoughts from our panelists on managing transitions between standards?

Dan Vreeman: I might add a few words to that. I think this is a really fascinating topic for consideration. I think the first thing I would mention is just to recognize that there is variation across different kinds of standards and how rapidly they may change. For example, considerations for terminologies may be different than those for exchange standards or process-based standards. We have seen examples where we want to push as fast as possible to get market adoption and use of standards, for example, in situations like the pandemic, which of course have to be balanced from all sorts of other perspectives. Understanding that it is important and maybe pay attention to that.

The second is our focus on or trying to understand better the maturity models that may exist for particular kinds of standards as well, understanding the evolution of those and when is the right time to make the adoption declaration versus to encourage additional use and context that help the standard mature. This is obviously a complicated topic, but I wanted to share those two perspectives.

Jamie Ferguson: Thanks very much. We are actually at time for this panel. I would like to just ask if there are any other thoughts on this particular topic of managing transitions between standards. We can take another minute for that.

Fran Schrotter: Jamie, I think probably one of the most important things in managing transitions is to have the – if you are talking the regulated environment – have them at the table as these documents are evolving, making certain that the newer versions of standards are reflective of the priorities of the federal agencies, one very important aspect of our standardization.

And in some cases, standard developers will have some timelines that they lay down. Certainly, in the code development space in this country, those are done on very routine cycles. That is not an approach necessarily that is used throughout the standardization community, but it is something to be thought about going forward for certain aspects of standardization to enable people to stay abreast and to keep up with all the changes that are ongoing. Just a thought there. Actually, we do not do standards development ourselves, but for those who do, it is a challenge. And Lane mentioned certainly the conformity assessment and implementation, which is so key.

Jamie Ferguson: Thank you very much for that closing thought. I want to thank all of our panelists so Fran, Lane, Scott, and Dan. Thank you all for being here. Thank you for participating. I really appreciate your input and insights for the committee. I am sure we will be following up with all of you.

At this time, I would like to turn it over to the moderator for our next panel, Tammy Banks.

Panel 2: Information Exchange and HIPAA: Present Day Challenges and Future Opportunities

Tammy Banks: Thank you, Jamie. I appreciate that. Again, good morning, everybody. I am very pleased to introduce this next panel, which is titled information exchange and HIPAA, present day challenges and future opportunities. The panel is comprised of standard leaders and subject matter experts who are dedicated to driving standards' work and bringing forward use cases focused on administrative burden reduction. I, along with my fellow committee member, Deb Strickland, have collaborated with many of you who are presenting today and look forward again to hearing your presentation and perspectives.

Our panelists include Dan Kalwa from CMS, the National Standards Group, AMA, Heather McComas, HL7, Chuck Jaffe, Da Vince, Jocelyn Keegan, Cambia, Kirk Anderson, X12, Cathy Sheppard, Blue Cross Blue Shield Association, Gail Kocher, Cooperative Exchange, Crystal Ewing, and WEDI, Nancy Spector.

The purpose of this panel is to obtain your input on opportunities to increase the exchange of data through standards to meet current and future use cases and learn how do the HIPAA-regulated transactions, code sets, and operating rules fit within today's business needs and use cases, understand if there are unmet business needs that could be fulfilled with alternative electronic exchanges, and identify opportunities for new and emerging standards to be adapted that could reduce end user burden, improve timeliness of updates, and mitigate update implementation costs with quantifiable impacts as available.

As you are aware, there are limited participants who are subject matter experts and contribute to the development of the standards that will be discussed today and even fewer who are subject matter experts across the standards. After each of you present your six to seven minutes, we will hold questions during the discussion period. I am really interested in hearing from you after you listen to the

other panelists your ideas for collaboration across participating organizations and those organizations who participate in standard development that may not be in attendance today to successfully drive the interoperability collaboratively and make the best use of those subject matter experts who participate in the standards activities. Just like silos and data exchange will not work any longer. Silos and standard development will not be effective in bringing the vision of interoperability we have for post-pandemic America and really appreciated, Jamie, your panelists really driving that point home.

With that, I just want to thank all the panelists for your willingness to share your organizations' expertise as well as your own. And Mr. Kalwa, would you be willing to kick this conversation off?

Dan Kalwa: Certainly. Thank you. Thank you to the committee for inviting me back again. As Tammy already mentioned, my name is Dan Kalwa. I am the deputy director of the National Standards Group within the Office of Burden Reduction and Health Informatics at CMS. We are the group that is responsible for the adoption, education, and enforcement around the HIPAA Administration Simplification Standards. I am only going to be addressing – I only intended to address the transactions and operating rules briefly today. But I feel like it is worth mentioning that in our purview are the HIPAA transactions, the operating rules, the code sets, including ICD-11. Should that go forward, it would be our group that would be doing the regulatory activities around that as well as the HIPAA unique identifiers. I am pretty sure everybody knows about the provider identifier. But there is also a requirement for still a statutory requirement for health plan identifier as well as a requirement for a patient identifier under HIPAA Administrative Simplification, that is.

I am not talking about the rest of the HIPAA activities today. I know in other cases we have mentioned privacy and security. That is not the purview of our group. Merely the HIPAA Administration Simplification transactions.

I intended these slides to just be a cheat sheet as the committee and others go forward and think about how to interact with HIPAA Administrative Simplification. There is a whole set of transactions that are adopted under HIPAA. They are not necessarily the only transactions that could be adopted under HIPAA. But they are the ones that the secretary is required to adopt.

The way that works in HIPAA is that the secretary is required to adopt implementation specifications for those specific transactions. The way that works for us is, for example, I believe health claims is probably the most understood at this point. We cannot merely adopt a base standard and say build your claims from that. We are required to adopt an implementation guide or specification that describes exactly how that is constructed so how is the data constructed, what codes are required and what is the format for that transaction. If we do not have that then there is not something we can necessarily consider under HIPAA Administrative Simplification.

I will note that this does not mean that there has to be separate guides or logical structures. HIPAA does not comment on that. Only that what is adopted contain the specifications for the transactions that are defined.

I just also wanted to point out that when somebody from my shop or the National Standards group is talking about the transaction. They are talking about how it is defined in regulation. There is eligibility for a health plan. We have adopted in regulation a definition for what eligibility for a health plan means that is a transaction and then the implementation specifications become the standard for that transaction so whatever they look like become the standard for that transaction. I suspect that everyone is aware that there are some different approaches, for example, for pharmacy, NCPDP tends to put out

single large sets of implementation specifications while X12 tends to split those up into sets or individual specifications.

I anted to mention operating rules as well because historically and in the original design of HIPAA, all of those transactions were specifically transport neutral. That is, the transaction definition and then the specifications for that transaction were neutral and did not generally comment on things like what the transport technology on the Internet looked like, what the identity management looked like, what encryption around those transactions might look like. That was not generally included.

To that end, Congress added additional requirements in the Patient Protection and Affordable Care Act that created this concept of operating rules. Wherever the implementation specifications failed to provide business rules that are necessary for the industry to actually utilize those transaction standards that is where operating rules come in. That is generally where you will see things like here is the supported transport protocols. Here is the supported encryption. Here is how you do identity management. Here are the requirements for response times. There is a whole set of things that operating rules cover. But they expand the standards and they expand on the implementation specifications. They cannot overwrite them or change them. That is only the purview of the implementation specifications.

I will also point out that some standards development organizations have developed their own operating rules. Again, I will point out the difference between NCPDP's approach and X12.

I am pretty sure everybody has heard me say this and others from my group many times. The Secretary relies on this committee and the larger committee to make recommendations. But the Secretary also has to rely on the industry to provide sufficient data along with those recommendations to meet the statutory requirements around rule making. Just because the committee recommends it, it does not mean that the Secretary can necessarily act on those recommendations absent more work. I was gratified to hear that we have already mentioned things like return on investment and the cost for training and other sorts of regulatory considerations.

Once a standard is adopted, we then move to the concept of modification. And under HIPAA, if there is already a transaction definition and there is already adopted implementation specification, any further activities around that are referred to as modification. And the method by which we test modifications to standards that already exist is through the exceptions process. I will not go too deep here. But the points I want to make is you do not need to go through the exceptions process if there is not an existing HIPAA-adopted implementation specification. But you do need to go through it if there is one because all entities if you are a covered entity and there is a HIPAA-adopted specification or standard if you would like, you are required to use that.

If you want to test with live data between covered entities so between a health plan and a clearing house and providers, you do need to go through this exceptions process in order to ensure that there are no concerns around HIPAA compliance. And also, it allows you to interface with our group and with HHS to agree on what does that testing need to look like, what does that reporting need to look like and what would actually be useful? These tests are in fact tests. They are not permanent exceptions. They are specifically for the purpose of testing a new standard or an alternative to a standard to presumably if it is successful replace that standard.

Why the exception and why testing? Just very quickly – I know I was not around in the beginning, but it was very easy in the beginning. Anything electronic is probably better than paper. But now we are at

incremental steps. It has to be better than what we have now. That is the purpose of exception and that is the purpose of testing. The goal of HIPAA Administrative Simplification is improving the operation of the administrative health care and reducing administrative costs. In general, reduce cost and improve efficiency. Those are the first two questions that always have to be answered when making a recommendation under the HIPAA Administrative Simplification – I will call it rubric under this concept. All the other considerations come after that at least as far as rule making goes.

I just wanted to mention a couple of things from our perspective that I would like the committee and industry consider. I am not sure if everybody recalls but historically, the implementation specifications are adopted in batches. The biggest lift was 4010 to 5010 and adopting all of those transactions at the same time.

HIPAA does provide for adopting individually the transactions. And strictly speaking, the Affordable Care Act requires us to move to a regular adoption schedule for a whole host of reasons that has not quite come to fruition. And I would also like to point out that, in general, there will not be multiple implementation specifications for the same transaction. I understand that we have split that up often by industry, not industry, line of business. We have one for facilities, one for professional, dental, et cetera. But we would not, for example, have two different implementation specifications for facilities. We would not have two different implementation specifications for dental.

I would also like to point out that the way the regulations are written, it is the health plans as the covered entities that are always required to support all of the standards that fall within their line of business. As we talk about moving to new standards, as we talk about co-mingling or doing updates, I would encourage you to consider what that looks like and to what extent those costs will be supported by the health plans, by the providers, and then eventually it all trickles down to the patients.

If the committee or the industry has any further questions, please feel free to contact my group. I am also at the committee's disposal. If you would like to have more in-depth discussion, this was the quick version. With that, I can conclude. Thank you.

Tammy Banks: Thank you, Mr. Kalwa.

Heather will be next.

Heather McComas: Hi there. Thanks so much. I am Heather McComas from the American Medical Association and I am honored to be the provider representative on this panel. I do urge the subcommittee to carefully consider the written comments submitted by my colleagues and other provider organizations.

Speaking from a provider perspective, we suggest that the subcommittee follow the – three – process in assessing the standards landscape. The first up is to recognize successful transaction code set standards and to preserve and to enforce them.

The next step is then to identify unmet industry business needs. And then after identifying these needs to rigorously evaluate and test any new transaction standards considered for adoption. I will go into some more detailed suggestions on the process on that just in a minute.

But I did want to spend a little bit more time on the rationale for that first critical step. Frankly, it is just a matter of basic economics. Provider organizations have limited resources to devote to technology

build. And for that reason, we urge the subcommittee to first recognize, and I would say, yes, even celebrate the current adopted transaction and code set standards as well as operating rules that are working well.

As we all know, the electronic claims standard and its associated code sets are widely adopted. It should be maintained because they are working well.

Another example is the electronic funds transfer transaction, which is highly efficient. But unfortunately, it shows lower adoption across the industry.

From the provider perspective, we would argue that because there are some questionable business practices that are discouraging and deterring adoption of the EFT standards, we would recommend that NCVHS request that CMS enforce the right of providers to receive free electronic funds transfer without fees and also to strengthen the ASETT complaint and investigation process.

When the subcommittee moves on to consider transaction to address unmet business needs, we suggest a rigorous analysis to address three basic areas of inquiry. The first area is to assess whether or not a potential new transaction is essentially ready for prime time. In other words, is it sufficiently mature? And this is really important. Has it been piloted in real-world settings? And not just with techy folks. We, of course, love the techy folks, but have we involved business teams? Have we involved operation teams? Have we critically involved practicing health care professionals to make sure this standard will meet their needs in real day, everyday practice?

Next, it is really important that we assess whether or not it is going to be feasible to implement the new transaction standards across the entire health care industry. That means organizations of all sizes and all resource level.

We also need to carefully assess the transition costs. We have heard a little bit about that already this morning. Both the direct costs of implementing the new technology, but also the indirect costs of possible workflow disruptions and retraining of staff for these new technologies.

We also need to assess the ROI across all stakeholder groups and make sure that all entities and industry are going to benefit for the new technology.

Finally, we really need to look at if the new transaction standards advance the underlying provisions and purpose of administrative simplification. In other words, are these new technologies going to promote uniformity across industry so that all entities save money? And also, do they ensure the protection of the privacy and security of patient health information?

Here are the physicians' top unmet business needs we would like the subcommittee to consider today. I will highlight the fact that all of these issues impact patients, which is really important.

Prior authorization is at the top of a list of physician's priorities and that is a data-driven priority. In the 2020 AMA – survey, physicians overwhelmingly – to delay patient access to medically necessary care and lead to negative patient clinical outcomes. Most alarmingly, 30 percent of physicians said that prior authorization has led to a serious adverse event for a patient in their care.

The survey also shows that the average weekly prior authorization workload for a single – two business days of clinician and staff time. That is a lot of administrative waste.

What is the status of improving prior authorization with automation? As I am sure most of you are aware of medical services, it is a pretty grim reality as the subcommittee members will know. The adoption of HIPAA-mandated X12 278 transaction is meager. The industry largely agrees that the reason for this poor adoption is that we do not have a transaction standard – supporting clinical documentation prior authorization. And that this lack of an attachment standard for the industry has paralyzed the industry. I am sure they are going to be hearing in a moment from my other panelists today about some newer technologies that have emerged to address these challenges. As you listen today, I would encourage you to refer back to the questions that I have posed in my slide.

For example, has the technology that is being discussed been tested in real-world settings among providers of all sizes – and not just a happy path – results be available for study.

What is the return on investment across stakeholders and how is that being measured? If the technology is going to be recommended – for adoption, will it apply to all health – administrative simplification? Have we accounted for the time and resources needed to digitize the complicated prior authorization payer roles and criteria across many medical services and all health plans?

Finally, again, are we ensuring that we are not jeopardizing the critical privacy and security of patients' health information in the name of expediency of health plan technology build?

For prescription drug prior authorization, the NCPDP ePA transactions are mandated for Part D plans. But the X12 278 – the required transaction for non-Part D plans. Dan flagged earlier. Having multiple implementations – same functionality is very concerning. And it sets a very dangerous precedent under which different standards will be required for different plans.

We urge NCVHS to address this confusion and recommend adoption of the NCPDP ePA transaction for all drug plans –

We also recommend that NCVHS – the ONC EHR certification program require support of the ePA transaction as part of that certification program to ensure access to this technology.

Our other priority needs both address price transparency for patients. Physicians need access to real-time prescription benefit information at the point of care in their EHRs to make informed decisions with their patients regarding treatment selection. Right now, Part D plans are required to support a single real-time benefit tool that integrates with at least one EHR system. I am pretty sure that we can all see the open space around that requirement and how it is deficient for the needs of both patients and physicians.

For that reason, we recommend that – recommend the adoption – integrates with all EHRs and provides information across all drug plans and for all patients.

No Surprises Act passed last year and had provisions related to good faith estimates and advance explanation of benefits. There are currently no transaction standards or operating rules to support these requirements. However, there is a great opportunity for the subcommittee to act now because as you might be aware, CMS did delay enforcement of these provisions until the technology – were figured out. This was a great opportunity – recommendations here.

NCVHS should prioritize this issue and determine what transaction standards and operating rules could be used to support these requirements. We would urge them to take into consideration the underlying

health plan and provider workflows related to this. We feel that they will mirror claims submission, claims adjudication, and remittance processes that might suggest the right – way to go about these standards' development.

I want to underscore the fact that it is critical that both providers and patients receive advanced explanation of benefits.

To wrap up, I want to reiterate the three steps we hope the subcommittee follow in its deliberation. First, we hope that they recognize, maintain, and enforce successful HIPAA transaction and code set standards. That they prioritize the unmet business needs identified by providers and that they carefully evaluate any new technologies according to the principles we have outlined prior to making any recommendations for adoption.

Last, we urge NCVHS to allow all stakeholders to have the opportunity to comment for making recommendations to the Secretary. Thank you very much.

Tammy Banks: Thank you, Heather. I appreciate it.

We will have Dr. Jaffe, Jocelyn, and Kirk in the next order.

Chuck Jaffe: Thanks so much to NCVHS and its staff for providing the opportunity to speak today. I will be brief. I think my message is simple. The time is now. As an ANSI standards development organization, HL7 appreciates the goal and ambition to move standards forward through the regulatory alignment process.

We believe the time is now to bring HL7 FHIR onto the same level as existing HIPAA standards. Specifically, we request that NCVHS formalize the adoption of the now well-established FHIR standards and where applicable, utilize the specific implementation guides to address unsolved, common data exchange challenges amongst all health care stakeholders.

In order to successfully improve data exchange and to reduce clinical and administrative burden, the industry must do several things. It must embrace modern technologies, increase automation, allocate our limited resources to their best use, improve the patient experience and engagement support privacy and security capabilities that underpin trust and transparency, and garner consensus on the best means to support the intersection of clinical and administrative data through a modern standards framework.

As the health care ecosystem embraces the shift to APIs, more real-time discrete data exchange and modern security standards will test our ability to use FHIR's existing and emerging framework and the capabilities it has in advancing the industry in concrete ways.

This has become a reality form the building blocks of the Argonaut project to free patient data from the electronic health records and advancing the work of the senior project to support care teams that are grappling with needed patient information during environmental emergencies and a global pandemic.

This substantiates our progress during the significant shift from a fundamentally flawed business model to one of value-based care and at-risk contracting. FHIR enables the ability to bring together at the right time for all our stakeholders the pertinent clinical information with that of coverage and benefit data. This is accomplished by providing the fundamental requirements of our provider teams with the tools to power the transformation in US health care.

With signals and inputs across all technology industries pointing to the rise of the API economy and the power of this platform, it is imperative that we now point our scarce resources toward long-term solutions.

The growth of the FHIR community is palpable. A CMS connect-a-thon in July attracted over 1200 registrants for three days. In addition, we applaud the recognition and alignment through the profound impact of CMS and ONC for providing a consistent message by regulation and references to FHIR and specific implementation guidelines.

Lastly, NCVHS and HHS have important roles for providing alignment of how FHIR supplements and advances existing HIPAA transactions with both current and future standards.

As NCHS moves forward with the recommendations, we urge you to recognize the core focus and capability of the FHIR standards are to enable long-term, overdue, and necessary resource-specific data exchange. In doing so, it will move us away from the antiquated concept of document-based data exchange and into a modern paradigm of real-time, specific clinical content and thereby solve many of the growing business challenges.

Any recommendations and industry movements toward supportive attachment style models should focus the full breadth of the ecosystem on investments that will advance the entire industry and be accountable to all stakeholders, including providers, patients, community agencies, as well as auxiliary services.

We recognize that many participants are dis-intermediated from data flow, given the complexity and cost associated with adoption of current standards.

We believe that in order to deliver real impact on our patient's outcomes by pairing current security and identity models with FHIR-based APIs, every stakeholder can enjoy success through transparency, continuity, and actionable data.

The message is simple. The time is now. Thank you.

Jocelyn Keegan: Thank you, Chuck. Jocelyn here. I would like to thank NCVHS for the opportunity to share the real-world progress of Da Vinci. Founded in 2019, Da Vinci has grown to over 55 committed members and funding members and a growing community of hundreds of organizations that are defining, building, testing, and deploying the outputs from the project in earnest. There are now 14 active implementation guides. I do not think that we ever could have imagined when we started four years ago that that is where we would be. They lay out about four - five core focus areas.

As Chuck mentioned, in addition to the full speed of IGs, there are full seven of the guides that have been referenced as resources for implementers in existing CMS final or proposed regulation and the industry adoption is underway across all of the focus areas. The momentum is amazing.

But let me clear. Da Vinci members in the industry are driving this change. This is really the party of the willing, moving ahead of the rest of the industry to really set the path forward. The Da Vinci use cases are actively selected by the membership and the entire community understands the power and the alignment that regulation can have to fuel the necessary real-world adoption beyond just this core community of the willing.

I think that that was one of the points that was made earlier this morning is really this idea of industry starting to drive. I think that the work that is happening inside of the accelerators is really amazing.

We will not have time to get into all of the details, all of the use cases today. But it would really be helpful for this audience to focus on two areas: burden reduction and clinical data exchange.

First, on the clinical data exchange side, we have – as Chuck was referring to, we have a need for modern, specific data exchange standards. Da Vinci has created a framework, which is the health record exchange framework, HRex, and has underlying implementation guides for specific use cases and specific business challenges. Underneath that, we have clinical data exchange. It is created specifically to enable providers to be able to share information with a partner, either a payer or another provider.

The implementation community is actively discussing the ability to further define various agreed-upon scenarios and the required data sets for those scenarios. Providers, payers, and vendors are adding CDex into their data exchange models. There is a complementary guide, which is payer data exchange, which I am reflecting here in the slides, which was developed initially for us to be able to get payer data to providers. But one of the things that is important about it is that it really constrains the data and the resources within FHIR to a payer's perspective so if we really think about that semantic interoperability.

It is broadly an active production, given the 7/1 deadline this past July for payers for CMS' 9115 Final Rule for patient access API. And there is a vocal community of adopters. That is actually where this slide comes from. Really advocating that for the one one payer-to-payer data exchange deadline that is coming up at the beginning of January that the industry uses the PDex API as the default way.

Take a step over to burden reduction. We really started thinking about how to rethink about prior authorization from the get-go in Da Vinci in our early days. It has really been since the very first conversations that prior authorization I would say has gotten most attention of all of these cases that we have discussed.

The promise of reducing the need for prior authorization by either increasing transparency that of patient-specific coverage or automating what does require prior authorization has of course gotten much support in active engagement from the industry. With membership of virtually all national payers, CMS, leading national EHRs, the major utilization management companies and leading provider organizations, Da Vince is redefining how we think about the process of PA. The work was recognized in last year's NCVHS ONC's Intersection of Clinical and Administrative Data transactions Task Force. The final report covered the continued progress of the HL7 Da Vinci coverage burden reduction implementation guide development and the general industry momentum really with the focus on our goal to create new ways to reduce efforts and waste for all parties involved with prior authorization.

The quote from the take-a-way, the final report from the NCVHS report was we would encourage NCVHS to take a more holistic approach to the entire topic of prior authorization instead of evaluating the move forward on a siloed approach for the existing HIPAA transactions.

HL7 welcomes the opportunity to talk further about the work that we are doing around FHIR authorization. We would love to bring our early implementers together to share their progress about the real concrete adoption and benefits that people are seeing by putting these prior authorization workflows into production.

As we know, providers routinely must determine whether prior authorization is required for diagnostic or interventional orders and that this can be incredibly wasteful. Heather does a great job of describing that. The AMA studied this significantly. Given the variety of health insurance plans, it is really – today, there are so many different ways that people have to solve this problem.

What we are doing with coverage requirement discovery is simply allowing the EHR or the provider's preferred workflow to request information just asking whether or not documentation is required or prior authorization is required. Being able to get that simple answer is game changing for folks sitting in the provider seat. And then documentation templates and roles in payer rules basically leverages smart on FHIR emerging technology coming out of the HL7 FHIR community in production in many places to be able to allow an interactive session with the provider or the provider team member to understand what the requirements are for that particular patient at a given point in time and prior authorization support. We have worked very closely with our colleagues over at X12 to be able to ensure that if and when a prior authorization is actually needed that that process can be as automated as possible. And behind the scenes, we have worked with X12 to be able to mappings between the X12 standards and the Da Vinci implementation guide and the FHIR resources. It has been really, I think, groundbreaking work that we have been doing.

We are also starting to look at this around some of the patient cost transparency work. I am really excited about our ability to be able to treat our work here around FHIR authorization. It is not an "or" but an "and", how are we taking both sides of the world and leveraging people's existing investments in prior authorization while meeting people that are able to do more advanced technology with cleaner solutions.

With that note, since last year, we had pursued and received in the spring of this year with the support of the payer members of Da Vinci an official exception to the name HIPAA standards for prior authorization. And we are actively working towards creating the demonstration project to prove out the use of Da Vinci prior authorization support implementation guide without the use of the X12 278 and when only using the coverage requirements piece upfront and exception from folks needing to use the X12 270-271 for coverage.

The progress and the pace of the work – if I can get it across to folks today, the engagement from industry showing an openness to really try and unlock this longstanding challenge between payers and providers, the demand for alternative tools from the provider community and the vendor community and the payers is really overwhelming.

When we go to a connect-a-thon, the PA table or our workflows around PA are always the largest, biggest group with the most eager participants and people are really starting to put in code into production throughout this year and as I mentioned, will be working on some demonstration projects for the FHIR only piece.

Since last year, Da Vinci – we are continuing to move forward. I think the ability for the industry leaders like yourself and the other committees involved to be able to synthesize the existing state and its checks that draw that line to what future state is and will be crucial so that we can ensure the coordination that we have maintained thus far and sustain the momentum that we have underway.

We are all here, dedicated to fixing the longstanding challenges in health care. We appreciate the deep current investments, the functioning systems that are in place and the tools and the workflow. I look

forward to supporting NCVHS to help advise and create a clear path for our implementer community here.

I want to say that I am personally thankful to work with this community daily. It has drawn out really our best and brightest change agents I think to their highest purpose work.

You will get to hear from Kirk Anderson next. His team at Cambia and Regence and their partners that they are working with on the provider side really has set the tone and the pace for our industry peers I think with humility, humor, and they have given us gobs of factual advice and give back to the community every step of the way as really our change agents getting this stuff into production first. Thanks.

Kirk Anderson: Thank you, Jocelyn. Good morning or good afternoon, everybody, depending on where you are. I am Kirk Anderson. I am the chief technology officer at Cambia Health Solutions and very grateful for the opportunity to join you today.

Following the comments of Chuck and Jocelyn, I wanted to say a few words from a payer's perspective on the value of FHIR-based interoperability and on the experiences of our health plan Regence in implementing FHIR-powered Da Vinci use cases with our provider partners.

As Jocelyn and Chuck mentioned, Cambia has been an active supporter of FHIR for several years now as implementers of FHIR-based solutions and as member of accelerator groups like Da Vinci and the CARIN Alliance.

We have invested our energy in FHIR because we believe that secure, scalable, open standard APIs are critical to creating a person-focused economically sustainable health care system. We have been fortunate to have great provider partners here in the Pacific Northwest, who feel the same way we do about the promise of FHIR.

And working together under the context of Da Vince with those providers and the EHR vendors used by those providers, we have delivered Da Vinci use cases into production, supporting clinical data exchange for quality measures and risk-based member identification.

In these two use cases, which are really foundational for accelerating the move to value-based care, have successfully demonstrated for us and our provider partners the value of FHIR-based automation. After implementing these Da Vinci use cases, our provider partner was able to immediately realize a 40 percent improvement in quality measure compliance and a 40 percent reduction in manual, i.e., burdensome resource-intensive chart cases. And these benefits were directly attributable to the automation benefits of having provider systems, talking directly to payer systems via FHIR APIs and removing the burden of sending Excel spreadsheets back and forth and the inevitable challenges that the complexity that is inherent to those sort of ad hoc data exchanges will bring.

What is most exciting for us and our provider partners is not the benefits and the improvements we realize on a one-off basis, but the opportunity for these improvements to be scalable across all of our partners. This is the build it once-leverage repeatedly mindset. It is how we can maximize the return on innovation for health care. For this, we need API standards.

As an industry, we have benefitted by data and format, conformance standards like X12, the standardized way we structure data. And we will continue to benefit from that moving forward.

But to move to the future or some might say to catch up to the present, we need to complement X12 with standardization at the API layer, using FHIR so that our systems can talk to each other directly and securely in real time regardless of what EHR vendor is in use by the provider, regardless of what claims management system is in use by the payer.

One of the areas that we are most existed to apply the power of FHIR-based APIs to is in the area of reducing burdens related to the prior auth process. My fellow panelist, Heather, just spoke about the burden of prior auth on providers. For us, as a payer, who works with hundreds of different providers, the extent to which our process is in support of helping individuals pay for their care is burdensome for providers is a big deal in itself and it is something that we are always striving to improve upon.

Like many insurance plans, we have invested a lot of energy in recent years in improving the prior auth process. But prior to the introduction of FHIR and our Da Vinci work, these initial efforts were primarily focused on bringing more efficiency and automation to the prior auth process inside our four walls, speeding up the data collection process, automating determination, et cetera.

And then like a lot of payers, we then surfaced a lot of that automation into a provider portal for providers to interact with. That is certainly an improvement in some ways, definitely a step in the right direction.

But one of the most fundamental objectives that I hear over and over whether it is from the provider partners here in the Pacific Northwest that I work with directly or others who are part of Da Vinci and we heard it again here from Heather today is that any process or any innovation that we implement that takes the provider out of their native EHR workflow is ultimately missing the mark. Providers work with many different payers of course and they do not want their staff to hop between all those different portals, manage all those authentication credentials, et cetera.

Similarly, as payers, we work with hundreds of different providers and we receive prior auth requests from them in every way imaginable. Some of them are using the portal. Many still send us faxes and emails and phone calls, which are costly and burdensome for us to support as well. While we do not talk a lot about payer abrasion or payer burden, it is a real thing too and it is expensive and it exists any time we, as an industry, lack the ability to standardized and automate our work in coordination with providers.

Finally, and really most importantly, we know that the prior auth process is a primary pain point for patients. Our number one call into customer service at Regence is from our membership, making an inquiry into the status of their prior auth. In our prior auth work in flight with Da Vinci, we are not only focused on automating the process to allow the provider to reduce their burden, but we can now piggy-back on that real-time standardization to keep the member, the patient in the loop as to the status of the prior auth request.

For all those reasons, we are very excited to participate in the CMS exception process that Chuck mentioned, to test FHIR-based options, to further automated prior authorization.

Once, again, I want to thank the subcommittee for the opportunity to join the conversation today and for the important work that NCVHS does to help all stakeholders build a better health care system.

With that, I will turn it back to Jocelyn or someone else. Thank you.

Tammy Banks: Thank you, all. Jocelyn, did you have any more points or should we move on to Cathy Sheppard? Okay. Cathy.

Cathy Sheppard: Thanks everyone for allowing X12 this opportunity to speak today. I know that people who have heard me speak over the last four or five years will not be surprised to hear that X12 firmly agrees that health care stakeholders need access to complementary, administrative, and clinical information. That means that we need standardized and well-understood metadata to be the foundation that establishes interoperability between various syntaxes and delivery systems.

X12 has been recognized as the authority of administrative health care for more than 30 years. But we clearly understand that that has to be a symbiotic relationship with the clinical data. At the provider side of the industry, no one cares whether data is administrative or clinical. They just need access to the data that they need to use when they need to use it.

X12 and Da Vinci leaders have been actively working together to align the administrative and clinical data across our areas of focus so that we can consistently translate between X12 EDI transactions and FHIR transactions across the industry and we do not end up with hundreds of different crosswalks so that the data cannot be clearly interpreted or understood on either end of the transaction.

We know that many organizations have invested heavily in their stable and successful X12 EDI infrastructures and that those are necessary for financial stability. We know that pairing and emerging in existing technologies in new ways presents opportunities for entities to better leverage the technology investments they have already made. And the best way to foster innovation is to standardize the data content while supporting various transmission syntaxes.

I think you may have heard me say if we get the right data to the right people in the way they can consume it at the right time, we have all done our job.

We were asked to give information about any upcoming recommendations to NCVHS today. We want to point out that X12 recently conducted a health care industry survey, not just of our members, but an open survey to better understand the perspectives of the industry stakeholders related to the mandates.

Based on the input that we gathered from that survey and other industry feedback that we have gotten through other venues, we are finalizing recommendations for advancing the version on many of our mandated standards.

The move to more updated versions will allow the industry to take advantage of enhancements that they have been waiting for such as UDI, improved reporting of adjustments, and more detailed balancing instructions. Those are just samples, not intended to be a full statement, of course, of the benefits of moving forward.

I would like to make a point that X12's recommendations will include the value of adopting of additional EDI standards that work with the current mandated standards to provide more robust information exchange. For example, we have had a lot of interest in mandating our inquiry and response implementation guide that supports provider inquiries related to existing authorization and certifications as a way to close some of the missing pieces that are on the mandate right now.

We have also been receiving tremendous amount of encouragement to move forward our 838 provider enrollment for EDI service transactions so that there can be more consistent automation in provider enrollments. And this, to add to what several speakers have said so far today, does replace what is still often a paper-based enrollment system. There is a lot of gains to be had there.

We intend to put forward recommendations that will provide implementers with compliant options for meeting emergent federal mandates in a way that takes advantage of their existing trading partner endpoints and their significant investments in mature and effective EDI infrastructures, but also gives them a compliant option for meeting federal mandates with emerging technologies or syntaxes that are based on the same data requirements and that include detailed guidance describing instructions that ensure consistent use.

We do not want to go back to the days where there are 250 different ways to do every health care transaction electronically. That is not a benefit to any portion of our industry.

I wanted to say one more thing about recommendations. That is, earlier today, Dan talked about batching recommendations. We think it is important. X12 thinks it is important for NCVHS to recognize that at some level, industry stakeholders are nervous about the federal rulemaking process timeliness in a way that encourages them to encourage the SDOs to group things together in large batches so that they are sure that work can move forward in a more timely manner than the attachments. Let us just say that.

X12 is going to put forward the recommendations in a way that are not dependent on each other, but with the caveat that if they are implemented sequentially, the timeline for improvements to the industry is probably too long.

We were also asked today to talk a little bit about what barriers we have for collecting ROI data that can accompany our recommendations. You heard Dan say earlier that that is really important to the rulemaking process. We know that it can be difficult to get return on investment data from live testing because organizations are already spending so much of their thin resources on upgrading current implementations or implementing new transactions as test cases that they do not know whether they will move forward or not. That is a big ask for organizations in today's tightly constrained situation when everyone is focusing their resources on pandemic solutions and health equity.

Also, many organizations that would normally work with SDOs to test and prove out different concepts related to return on investment and cost of implementation are fairly overwhelmed with a stream of federal and state mandates that they have to support, which gives them little appetite for proof-of-concept implementations and these challenges will continue to be a hindrance for us collecting valid, defensible ROI data in the future.

With the SDOs, we understand this problem and I will say again as you heard me say earlier, Da Vinci and X12 leadership are working on ways that we can work together to reduce the load on individual organizations that are willing to help us collect this data by having consolidated plans instead of having repetitively plans for showing interoperability and showing how data moves between the transactions.

We were asked to also clarify today what kind of policy opportunities there are for improvements. I think that we all know that SDOs have made significant improvements across all of us to support more efficient publication and approval process, to make new and enhanced standards available on a

predictable schedule and to answer the call that has been issued to us from NCVHS roadmap work or recommendation work over the past number of years.

At this point, X12 has a predictable annual schedule that we can commit to so that we know that we can move things forward for rule making or for consideration on a regular basis. Like was said earlier, we think it is more palatable to the industry if those are small-bite increases and not change for change's sake. We intend to bring forward recommendations when there is value to be gained, not just to check a box or to move forward a set of transactions in a block.

Over the years, we have identified through NCVHS' information-gathering listening and collaboration sessions a number of opportunities that condense the federal rulemaking process. Those opportunities still fit on the table and do reflect a wide variety of ways that policy could change to foster innovation and also to foster the implementation of additional functionality that the industry needs.

We also think that a policy opportunity that exists is for better coordination on the federal side so that there are fewer overlapping federal requirements. This will free up the resources for the industry players that are trying to support all of the well-intentioned and very understandable mandates. We just cannot do them all at once. It would be helpful if the federal requirements could be coordinated in a way that assisted the rest of the industry with accommodating them.

That is all I have. I was trying to stay quickly within my six minutes. I would, again, like to thank the committee for having us. I apologize for my somewhat raspy voice this morning. X12 is ready to continue to work with the partners that we have been working with to provide the industry with what it needs and we are also ready to assist NCVHS in any way that is helpful as you form your recommendations and your plans. Thank you, Tammy.

Tammy Banks: Thank you, Cathy. And now, we will move on to Gail Kocher, Blue Cross Blue Shield Association.

Gail Kocher: Thank you, Tammy. Good morning to members of the subcommittee. Thank you so much for the opportunity to present to you this morning. Blue Cross Blue Shield Association is a national federation of 35 independent, community-based and locally operated Blue Cross and Blue Shield companies or plans that collectively provide health care coverage for one in three Americans.

We supplied some more detailed remarks through a comment letter. But I wanted to highlight a few things. First of all, we think it is very essential that any evaluation of new standards and technology takes several factors into consideration. First, we really need to look at whether the current infrastructure is sufficiently meeting business needs of the industry or whether there are gaps or additional business needs that are currently using work arounds.

Just moving to a new version or a different standard when there is no added business value does nothing more than divert resources from other implementation efforts. As several others have mentioned this morning, the industry is facing some significant implementations right now from other federal statutory and regulatory requirements. I think we can all appreciate that while as we are still in a pandemic situation, resources continue to be either limited or need to be diverted to other efforts. We need to make sure that as we move forward with other things that we really are achieving a business value from doing so.

We also want to look at when we find gaps, what is the use case and how well does any existing standard if it is in place work and how broadly is that implemented. Not all the use cases really necessitate moving to a different standard. I would suggest claims, claim payment remittance advice. Those are fairly well integrated within our industry and moving to something more – a completely new standard would actually likely take much more effort than upgrading to a newer version if there is a need or a gap analysis finds that there is additional business need.

We also want to make sure that we are looking at the complexity of the underlying business processes that are at either end of the data, that is, what do provider systems have to do to get data into a transaction and then what do payer systems need to do with that data or vice versa.

We also want to look at what the maturity of these standards are especially when considering newer technologies. Are they completed? Are they published? Are they in initial development? The ability to pilot these newer standards especially when the underlying technology is not yet implemented widely for specific business use case is critical to successfully enabling these other technologies. Pilots allow for that real-world testing, which can then identify the potential gaps in data or implementation barriers, which then can be modified in the standard prior to broader industry adoption.

I would also comment that providers rely heavily in many cases on vendors who are not covered entities under HIPAA. And changes to the underlying standard can result in significant changes to provider systems. Heather mentioned this earlier. Smaller providers often do not have the resources to implement either at all or as quickly as the other stakeholders. Any new standards whether they are newer versions or newer technologies really must consider the impact to all the stakeholders with respect to costs and other non-monetary resources.

Regardless of the standards that would be named, aligning them with HIPAA allows covered entities to more seamlessly share data without the need for data segmentation that is tied to different privacy or security standards. This alignment is especially valuable when facilitating information exchange with third-party applications.

The HIPAA FHIR standard should be considered for HIPAA transactions where such a standard exists that is fully developed, published, and ready for pilot testing and specifically for transaction where there is industry appetite to consider this option. Identifying the opportunities where file standard will enable use and provide a pathway to increase adoption rather than the approach that everything should be moved solely for the sake of moving to a different technology.

One of the other questions that was asked was around what the significant barriers to use of standards and implementation guides are. First of all, it is simply the access to the standards. There continues to be lack of broad participation in the development process and there is often a lack of broader knowledge of the business impacts form the technical aspects of the standards. Standards need to be readily available to stakeholders to increase engagement and adoption and engagement in the development processes.

We support pilot testing of new voluntary and innovative standards, but caution that the wholesale encouragement of these voluntary and innovative standards may undermine the goals of interoperability, transparency of data use, or the enforcement of data transaction standards implementation in support of data exchange and consumer access.

We do support HHS continuing to publish a universal dictionary of clinical administrative and financial standards that are or will be available for use. For example, the ONC's Interoperability Standards Advisory.

We suggest that such an existing dictionary with ongoing maintenance in lieu of creating a new and separate dictionary for administrative transactions and operating rules is the best use of all stakeholders' resources that we again know can be somewhat limited depending upon the particular stakeholder segment.

I also wanted to just comment slightly around the barriers to collecting documentation for return on investment. It is always difficult to provide estimates for implementation without thorough and detailed gap analyses and then requirements development. I think we found this when we talked about going into 4010. I know it came up when we talked about 4010 to 5010. This analysis is in and of itself a project and it is often difficult to assign resources to complete when it is – I will use the word hypothetical as opposed to actual implementation planning. We need to look at additional ways that we can look at where that return on investment and I think that is where pilot testing can come into play – can pilot it in a smaller segment and then you can look at what was the return on investment for that sector and then that is much easier to extrapolate as opposed to, again, I will use the term hypothetical where you are simply looking at your systems without any direct information or calculation across true practice.

That is the scaled down remarks from our letter that I had for us this morning. I, again, want to thank the subcommittee for allowing us the opportunity to comment. We will be available for questions later if needed. Thank you, Tammy.

Tammy Banks: Thank you, Gail. I appreciate it.

Crystal.

Crystal Ewing: Thanks Tammy. I would like to thank the subcommittee for this opportunity. My name is Crystal Ewing. I am the Chair of the Board for the Cooperative Exchange. Many of you know what the Cooperative Exchange is. I am not going to spend a lot of time there, but we are the National Clearinghouse Association. We represent the United States health EDI highway system. We are a lot of times agnostic and take a step back and listen and support.

I want to take a bit of a different approach here, as I have sat and listened to the panel here. I am going to talk slower because I want you to listen to what I am saying. I want you to digest what I am saying. I want you to process what I am saying because I think we have a fundamental problem. I feel like we are a bit in a ground hog day situation here. We have been talking about these same things for years and years. We have executed on pilot programs. Attachments is a great example. Many of us have invested in an ROI analysis of that transaction. We have shown and proven ROI results. We have shown best practices for implementation. We had all the major stakeholders involved, including providers, vendors, clearinghouses, payers and yet we still do not have a regulation even though it has been recommended in multiple letters to HHS.

I think we really need to take a look at the process and figure out what we need to do to execute on these things that we have recommended and proven to have value, have proven the ROI, and figure out what we need to do to have this stakeholder accountability.

I am being asked questions. We, in the industry, are being asked questions. When are attachments coming? Where are we with acknowledgments? Where are we with ICD-11? When is the next version of X12 coming out? We cannot answer any of these questions. We do not have a roadmap. We cannot get through the things that we have been asking for years.

As I am sitting here and I am listening to this today – I had a great slide that I wanted to talk to. Honestly, I have to take this opportunity to really put a voice of reason to this that we are going to have to – our first priority should be trying to figure out how we fix the process and how we can get things through. Because as we look at all the opportunities here, do we use X12? Do we use FHIR? Do we use something else to solve these critical business processes and the technical workflow inefficiencies where we have to break that workflow and go back to manual processes where we have said this over and over again and have provided business justification for it? What do we need to do? What do we need to do to solve this problem?

I would challenge coming out here this organization to take a focused view on how to do that. I am looking for help from Dan and from these other very smart people in this room to help us understand how to do that. Until we can solve that problem, are we still going to be talking about the things we are talking about today in ten years because that cannot continue to happen? It seems to be getting worse.

We have these health care regulations. Look at the latest one that came out with the No Surprises Act. We have had multiple stakeholders that we have heard from today where we had a very complicated regulation, a lot of requirements, no solutions available, and just on Friday, we have feedback on questions that should have been answered months ago and probably should have been answered before the regulation even came out. And how much of an investment has the industry made over the last few months, scrambling to try to figure out a solution? That is not an efficient way to implement health care regulations.

We have heard several times over the years. We are missing key stakeholder participation. Practice management systems and vendors. They are not at the table. They do not have to follow the same requirements. They are not covered entities. How can you have administrative simplification if everyone is not required to follow the same rules? You cannot. And now, we have more stakeholders coming in. We have consumers, which we all are, that we have not had to think about before. We have to be careful to protect the burden. We cannot shift burden from providers to patients or patients back to providers or burden back to vendors or payers or clearing houses. There has to be a neutral solution here.

I will just say we do not understand why there is a lack of HHS response. Dan, we opened feedback to understand how we can help. What can we do? I am a problem solver. Do we need a template? Do we need a business case template? Very familiar with how to get funding here in the private sector. What do we need to do? What do we need to do? We have got to do something.

We need more guidance. We need more guidance upfront. We should look at opportunities to not only put out something that says this is what has to be done and this is when it has to be done. A lot of times it does not have a realistic timeline associated with it. We need to have the what as well as the how. That analysis has to be done upfront. We cannot continue to scramble.

Do we need to have a better liaison process? I do not know. We do not know the answers to these questions. All we know is we see letters going out. We see responses coming back from 2016, from 2019, from 2020. We still do not understand why. What are we missing? What do we need?

We have a couple of opportunities here that we would like to mention. We support the HIPAA exception process. We support the testing process and are open to those opportunities. I would caution us as an industry though. Heather mentioned this. Gail mentioned this. We have to be careful to protect those mature processes. We do not want to break something that is working.

Dan in Panel 1 – I thoroughly listened to a lot of things that was being said in that panel. Two things resonated with me. The first one was understanding the maturity of when to invest in the immature products and solutions. When do we need to enhance something that is working? I would consider attachments and acknowledgements to be in that category. It is working. It is a mature process. We have defined ROI. When do we invest in something new? How do we make those decisions?

The second thing that resonated with me was the competition rather than coordination. It kind of taking a step back. It kind of feels like that is a bit where we are. And the industry is confused. What do we use? If we are going to invest in a pilot of something, how do we know that is not going to be a sunk cost? When we go to our board rooms and ask for investments on that and we look at something like attachments that had not gotten through the process even though we have invested in it, what confidence do we have that something is going to be different the next time? But yet we are continuing to say throughout this process that we need to pilot. We need to test. We have to fund those things.

We talked a little bit today about the Advanced Explanation of Benefits on the No Surprises Act. My goodness. That is a challenge. But a great thing, as Heather mentioned, is we have a little bit more time. We have a little bit more time now to go figure out how to do this right. We should execute on that opportunity. We need to band together to make sure that we are not working in silos and everybody is trying to solve the same problem. We need a clear playbook. I know members of the Cooperative Exchange have looked at opportunities to use the next version of X12 for predetermination opportunities there.

I will just end here. I know I took a little bit of a different approach here, but I think it was absolutely necessary. I will just end with we have to fix this process. I do not want to be talking about attachments or prior authorization or acknowledgements two years from now, five years from now. We absolutely have to have a regulatory roadmap. We are being asked these questions. When? When? If we are still in discovery, that is okay. But having something that is predictable that we know what we need to focus on and what we do not need to focus on and where we are with the process is absolutely critical. We have to plan. We need predictability.

I thank you for your time today and appreciate the opportunity.

Tammy Banks: Thank you, Crystal.

And then we will hand it over to our last panelist and we still would like a few questions. I know it is nearing one. But Nancy, could you close it up with WEDI's perspective?

Nancy Spector: Thank you. I am Nancy Spector with the American Medical Association, but I am speaking to you today as the current chair of WEDI. Again, I just want to like others appreciate – thank you for the opportunity to participate in this panel today.

Before I get into talking about the challenges that we see with standards, we did want to take a minute to acknowledge that there are successes with some of the standards that are in place today. As an industry, we need to focus on what is not working and make it a priority to solve those problems. We

have heard several people – Heather definitely spoke to this about what is working and others talked about this as well.

These are the challenges that we chose to highlight here. But this is by means a complete list. We need to have broader stakeholder involvement in standards development, and we specifically need people who understand the business requirements in order to develop solutions to meet those needs.

We have talked about – Crystal just talked about the standards adoption process being excessively long. I do not need to say anything else about that.

The current format for standard adoption has not allowed for flexibility to adopt standards among the versions or within the suite of transactions. That is something that we should look at.

There is an overall lack of trust between providers and health plans and that results in added administrative burden on both sides.

We have heard mentioned too of the fact that vendors are not covered entities under HIPAA. That continues to present challenges. Health plans and providers rely on their vendors for their compliance with regulations and an equal commitment of HIPAA compliance from the vendors is necessary.

We have also seen recent regulations apply to only certain heath plans, which means that different workflows will have to be maintained by providers and payers.

We continue to have insufficient testing and piloting of standards. We do agree that there is a path for expediting standards for adoption, but only when there has been sufficient industry experience with it. When the industry experience has been minimal, then piloting and testing is critical because we need to know that the standards are going to function as expected when they are adopted.

And then last of course, there is a lack of federal funding for the development and testing of standards.

Moving on to talk about barriers to automation. At WEDI, we have been talking about improving administrative automation and not just thinking about simplification. We have heard others talking about that here today as well.

Again, the focus should not just be on simplifying a process. Sometimes you cannot simplify. Sometimes it is a matter of automating so that we do not have those manual drop downs.

Return on investment and the stakeholder implementation cost. These two are linked. Although ROI is not just about dollars so we are not just talking about dollars and cost here. We are not going to be able to convince organizations to change unless they really see value, which can also be about time or improve patient experience. And then without ROI, what we see is inertia. It is really this combination of lack of ROI, implementation costs, and inertia that results in standards becoming outdated. And workarounds are developed to keep up with business needs. But then those workarounds start to vary from organization to organization, which then causes a breakdown in standardization and more manual processes, which we all agree is not the direction we want to be going in.

We do believe that there are significant opportunities to improve the current standards processes.

We need to focus on the current gaps and data exchange and what is not working. We have critical transactions that are still missing. We should consider adopting transactions as needed and not necessarily wait for the full set. Not every transaction is going to have the ROI necessary to adopt it, but that should not hold up adopting the ones that do have ROI. And then we do support administrative automation wherever it can bring value and especially with prior authorization.

We do see a role for and a value with the FHIR and API standards. But we believe that they also need to fit within the provider and payer workflows. They need to be easily integrated. We suggest that NCVHS further explore through broad industry participation how FHIR and API standards can augment current data exchange processes.

Our past experience with ROI makes us skeptical about new standards and whether or not they will deliver as promised. This is why we do need that real-world testing and pilots that are going to give us that real proof.

We also need to continue doing analysis of standards after they are implemented to know that they are continuing to meet the business needs.

And we need to be able to meet new mandates like the No Surprises Act. And we do have the HIPAA waiver process, but it is not well used at this point. Of course, it would benefit from additional government funding to help with those waiver programs.

We need to work together to improve data flow and create a functional knowledge supply chain. This will give the lower cost and improve care delivery that we are looking for. We need to create a positive environment that is going to deliver a win for providers, payers, and patients. These three key stakeholders need to have equal participation in the win because progress is not going to happen unless all three are seeing value in what they are doing.

We do see that change can happen through voluntary consensus solutions within the industry. It can also come through regulations and we see value in both, but it has to be the right combination of voluntary and regulations. WEDI is more than willing to offer assistance in convening and facilitating any efforts that will lead to positive change in the data exchange processes.

I just want to say thank you for including us in today's discussion.

Tammy Banks: Thank you, Nancy. I appreciate you wrapping this up. I know we had a wealth of information and this is all going to be extremely helpful as we put together that environmental scan and work on recommendations or other next steps in order to move the needle forward.

If I may, I know we are at the end of our time, but if I could just get two questions in and I will try and target them, but would really love to hear everybody's feedback at some point. I know we do not have time today.

I really appreciate the opportunities mentioned and the potential next steps. The two questions I want to ask is first, adding on to Cathy Sheppard's mention of metadata, Heather McComas' comment on need for adoption within workflow for all size practices and also the need for both administrative and clinical data to solve for administrative use cases. I would like to address this question to Dr. Jaffe and Jocelyn. With HL7 FHIR API solutions, are both the practice management system and the EMR divisions within the five vendors participate in Da Vinci working together to solve for these use cases you are

mentioning. We know that both the PMS and EMR software solutions are typically under different budgets, using different standards, and just would like to confirm how that is working to pull both administrative and clinical data out of those systems collaboratively within those EMR vendors.

Jocelyn Keegan: Do you want me to talk from a Da Vinci first and then you can talk more broadly about we are seeing in the FHIR community overall with the vendors? Okay.

One of the things that is great about the way the accelerators work is that we have as part of each accelerator basically sort of a hands-on operating committee member that helps us navigate those organizations. What we are able to do is from a workflow to a workflow perspective depending on the API implementation guide that we are building is get the right people from the right organization involved in the discussion about how it is going to fit into workflow.

What is interesting because everybody is configured differently. Every company sort of works in different ways is often we will have somebody that is from maybe the core EHR team on a call but will also have somebody that is from a different vendor on the practice management side. And we may have somebody else that is in the population health side of the business because they are the person that is owning that particular suite of workflows and how that data is going to get exposed and how that data is going to get collected. It really varies across the board.

We constantly work on the membership side to make sure we have the right coverage of all the stakeholders in our work that we are doing and bringing things to connect-a-thons to test them and make sure that we are getting good representation from folks in the wider industry and getting folks if we feel like we are missing a representation from a particular stakeholder group, recruiting those groups to come into and participate in the actual standards build process.

I feel like we are canvassing the different parts of these organizations, but there are large complex – when we get into sort of having dozens of organizations involved like we do now. I think we sort of hit all of those different functional areas. Because we all appreciate that these APIs are going to be put into place in different parts of workflows so by different personas and different end users inside those orgs.

Tammy Banks: The answer is yes from both practice management system and EMRs depending on the vendor and its workflow.

Chuck Jaffe: I could say briefly, Tammy, that we pride in the openness and transparency of our processes. We encourage a diverse group of stakeholders to participate and the 1200 attendees at the July CMS connect-a-thon were evidence of the complexity of the problems we deal with and the energy that people apply to solving.

Jocelyn Keegan: In my resources, I actually have a link to the event that Chuck is referring to. It is actually available for free for anyone to be able to log onto HL7 and get access to.

Tammy Banks: Cathy, you had a comment to add as well.

Cathy Sheppard: I did. I just wanted to make sure that everybody understands that at the level of communication that Da Vinci and X12 are having also means that practice management systems and vendors that are on the X12 side are getting exposure. We are feeding back to them things that we think might have been overlooked or things that need further consideration and they are feeding back to us things that may be in our transactions that are not necessary anymore. It is not just the people who are

actively in Da Vinci that get a chance to weigh on those things anymore. We are spreading that across the cooperating organizations.

Tammy Banks: Thank you, Cathy. And that is where I was going next. The collaboration between HL7, X12, and other standard organizations as well as the other stakeholders on the call. Are we or how can we better collaborate to get a consistent message out to Crystal on where things are and understanding? Unfortunately, we are mandate-driven versus voluntary-driven in some of our administrative standards, which we know when there is incentive like a claim. If you do not submit a claim, you are not going to get paid. If you do not receive a claim, you do not know what services are rendered. We have a very high implementation.

What type of collaboration messaging or carrots do we to collectively as standard SDOs, operating rule bodies, and heath care stakeholders need to be thinking about? Anybody want to venture on that one? I know we do not have much time. I would always love to have your comments after the fact as well.

Debra Strickland: Just a reminder, Tammy, Denise has her hand up.

Denise Love: I can ask it during our discussion. I heard a lot about ROI and I am just sitting here and I totally agree for the necessity. I like Crystal's comments about a business case template perhaps. But how deep on ROI? Are we expecting the perfect to be the enemy of okay because I do not think we ever could get a complete ROI through the whole industry in every stakeholder and every player in real time? I guess I would ask X12 and AMA what their thoughts are in a nutshell.

Chuck Jaffe: I think I can answer part of that question. I am often asked to address the ROI. We forget that we are doing this to benefit our patients. And sometimes we need to make investments that do not return – because – will benefit and we should not lose sight of that.

Cathy Sheppard: I think that ROI includes more than just money from most of our perspectives and that there needs to be some new advantage. That might be a tangible dollar amount. We can quantify more readily what people expect to be included in ROI. It is easier for us to answer the questions.

Also, the more that the SDOs are working together, the more the supporting organizations are working with the SDOs in the same cooperative manner, that is a big carrot. If people do not feel like they have to be everywhere all the time to be represented then that reduces resource burdens on the industry and gives them more time to be beta testers or to do some of the testing that needs to be allowed. It is the fear of missing out. I think that is the right trendy phrase right now that causes people to have a lot of resource stress.

Tammy Banks: Heather, I think you had your hand up next.

Heather McComas: Thanks so much. I think this was alluded to. I think we definitely need to put the ROI in human costs, again, looking at the care delays associated with prior authorization. Is this technology actually getting patients the care they need more quickly? Are we reducing the unintended adverse health outcomes for these patients? I think it is really important.

One thing I would like to point out that I thought was really interesting when I was listening to my colleague, Gail, talk – remember, I am representing physicians. She is representing health plans. Oh my goodness. We were seeing a lot of the same things, which is a little surprising, but we have a lot of the same points. I think that is really important.

First of all, are these potential new transactions we are talking about mature? Let us remember that some of these Da Vinci guides are still standards for trial use. They are really exciting. They are really promising. But they are not normative standards yet. And before we really consider adopting them, we really think there should be some more testing to make sure they work for practices of all sizes that do not necessarily have a lot of resources.

To the point about the connect-a-thon, they are exciting. I have participated in them. My staff has participated in them. They are so fun to watch. But that is not the real world. They are kind of the happy path. They are seeing things that are set up in a certain way. What happens when something falls out and we have an error? Those need to be managed and we need to be confident they are going to be managed before we deploy this across all providers.

We also need to make sure that these technologies are protecting the privacy and security of health information. Remember, we are talking about the technology. The help is going into the electronic health record. We are talking about you are my personal health information possibly being seen by the – we need to control and put guardrails around that to make sure that is not being done inappropriately.

A lot of important things to think about here today. Thanks.

Tammy Banks: We are going to go to Jocelyn and Nancy, but I would like Dan to speak first if I may.

Dan Kalwa: Thank you, Tammy. I just wanted to point out that in the context of ROI from our point of view, what we are asking for is support in meeting all of our legislative mandates when working through the regulatory process so things like the Administrative Procedure Act, Freedom of Information Act, as well as various executive orders require us to go through steps and if we do not have that information at hand where we begin the regulatory process, it very often stops it. If the expectation is that the government will go out and procure that information, that may also stop it for even longer.

When our ask is to the committee and to the industry, when we talk about return on investment, we are talking about give us enough information that we can refer to publicly and could be utilized publicly in, for example, a proposed rule or in a final rule and used to justify the adoption of the updating of a standard.

I can say very often we hear back we have tested this, but that is proprietary or this is business information that we choose not to share with CMS. That applies to all of these tests.

If the industry is unwilling or unable to share it with us and to allow us to share it publicly then that is a very big steppingstone that becomes a blocker for adopting regulations.

Tammy Banks: Jocelyn.

Jocelyn Keegan: -- the conversation is great. I think the approach that we are taking in the FHIR community in the – standard approach is the way that we sort of get the proof points and make sure that we chase everything down to make sure that is works for real.

But on the ROI question specifically, Cambia Grove actually – which is a nonprofit, funded by Cambia Health in the Northwest part of the country actually did a pilot program with us earlier this year to explore whether or not we could create a common framework for understanding what ROI is for adopting these APIs because I think that not even from should we make it a standard perspective, but

can I get buy-in of what am I going to get out of moving to this API conversation that happens between provider and payer partners is an important step in this adoption implementation process.

After some positive feedback of a three-month survey of some of the Da Vinci use cases, we have expanded that work. And Cambia Grove actually has a number of fellows that are interviewing everyone for a subset of all of the accelerator implementation guides to really figure out are there common ROI models that we can say what is the value, not necessarily just monetary – what does the value get from shifting to this API? I am more than happy to share information or steer folks, Tammy, to that group to learn more about it.

But I think that this type of thinking about testing, thinking about validation, thinking about proof going into these projects is critically important. Any of us that have been doing software development for 20 or 30 years understands if you do not measure it then you really have no way to know if it is working or not. I think it is critical that we come up with these common vocabularies and constructs around ROI.

Tammy Banks: Thank you, Jocelyn.

Nancy.

Nancy Spector: I just wanted to make three quick points. The first is that we understand that collecting ROI, quantifying it is difficult. It is not an easy task to do across a large industry and get really the widespread participation that is really needed to have true cost.

WEDI did participate a little bit in gathering some of that data back when we were looking at going from 4010 to 5010. WEDI has a little bit of experience in trying to do the surveys.

I think one of the aspects that could be helpful is even just trying to get together and convene a large group, a multi-stakeholder to understand what the measures we should even be looking at to say what is ROI, what is not, how do we measure it, how do we go about doing that. That is a need.

And then just a final point that I wanted to make, going back to what Chuck had said too, we agree that – we can agree that you might not always have the quantifiable ROI that you can show to the stakeholders who are going to have to do this implementation. But let us be honest about some of that going into it.

It helps the organization that is going to have to do this work to really know honestly, am I going to get a return on investment or am I investing on this because there is a greater good that is to be had by doing this. I will leave it at that. Thank you.

Tammy Banks: Thank you, Nancy.

Crystal wanted to make one point first. And then we can wrap up.

Crystal Ewing: I just want to thank you, Tammy, for having Dan respond because I was actually hoping that he was going to. I just want to hone in on something that he said, which I think is an important action item coming out of this. There is a process, which honestly, I did not understand the process. I still do not understand the process. There is a process. There is a checklist of things that have to be done. As we are looking at whatever our own organizations are doing – we have to align with whatever this checklist is if that is the way that we are going to get things through the process. I think we should take a

look at that and understand how we can enhance our own processes to be able to answer the questions that needs to be answered. I will just leave it at that. Thank you, Dan for that transparency.

Tammy Banks: Thank you, Crystal. I did not cut anybody off because I knew the content was going to be very valuable for us moving forward. I know we had a shorter Q&A, which believe me I would love a longer Q&A with all of you folks. Again, thank you for your participation on the panel.

Denise, I will pass it back to you. Thank you for the extra time.

Denise Love: I am going to have to work with Rebecca here. Do we have a shorter break or extend the break a little bit and come back instead of 1:45 or 2 o'clock? What do you recommend, Rebecca? You are the MC here.

Rebecca Hines: It is really up to the members. We have two really important panels this afternoon. But if you want to just move everything 15 minutes forward that is totally fine so people have enough time to catch up on email. It is really up to the members at this point.

Tammy Banks: Rebecca, didn't we cushion in 15 minutes? Should we just add ten minutes --

Rebecca Hines: It is fine. We can close at 5:30. There is room here. If you all want a break until 2 p.m. and resume at 2, that would be just fine.

Tammy Banks: Is everybody agreeable to that so we do not lose more valuable content?

Denise Love: I am fine with the 45 minutes, but I will go with whatever the group --

Rich Landen: I think we should resume at 2 and then try and make up some time this afternoon as we go. Maybe shorten the afternoon break.

Rebecca Hines: We will see you all back promptly at 1:59.

(Luncheon recess 12:45 p.m.)

Rebecca Hines: I would say we are ready to resume. Thank you.

Denise Love: Do we need anything to go right into Panel 3? Do we need any adjustments like public comments?

Rebecca Hines: That is a good point. The website agenda, the HTML version that is posted, has slid everything 15 minutes forward. For members of the public, you check out the HTML front page of the meeting site. We have slide everything 15 minutes forward. We hope to stick to that and be done by 5:30. That would mean the public comments will probably going to fall somewhere between 5:10 and 5:20. Thanks Denise.

Jim Cimino: Are any of our panelists stuck in attendee mode?

Rebecca Hines: I do not believe so. We are good to go, Jim.

Panel 3: Semantic Harmonization of Standards

Jim Cimino: I had a few slides to start this off. The topic for this panel is semantic harmonization of standards. I just wanted to start off with maybe definitions that we could all agree on. Everybody probably has different ideas about semantic harmonizations. I have at least two.

Let me start off with next slide and take a definition from Wikipedia. Semantic interoperability, not semantic harmonization, but semantic interoperability, which many people have been talking about, is the ability of computer systems to exchange data with unambiguous, shared meaning so that the sender basically knows what the receiver is going to get. We can do that a number of different ways with lots of different standards, standard information model, data model for organizing the actual data, the data themselves represented typically with controlled terminology and/or controlled structure.

But a lot of times what we do is we end up with some kind of standard terminology that we choose. We force the sender of the information to translate their data into the standard terminology for the receive. It might work. It certainly allows for semantic interoperability if the sender agrees with the term that he or she is sending.

But sometimes we run into problems. If the standard terminology does not capture the true meaning, the semantics of what we want to say then that gets lost in the translation. For instance, hypovolemic shock in ICD-9 at least would have been translated to shock, not elsewhere classified and then that is all the receiver gets. It does not really know anything about that. I use that example for a reason as you will see.

These are data that I took from the NIH clinical centers biomedical translational research information system. The years do not matter and the codes do not matter. But what I was looking for is an example where there were some codes that were changed in ICD-9 that caused a change in what might be send and received by people trying to achieve semantic interoperability. 2007. The various forms of non-traumatic shock. There were three codes: 51 for cardiogenic, 59 – sorry, two codes, 51 for cardiogenic shock and then 59 for everything else. If you had septicemic shock, hypovolemic shock, you crammed those into 59 and you would see a graph like that.

In 2008, actually, it was earlier than that. Somebody just pointed this out to me. But the clinical center started using this new ICD code, 785.52, in 2008. Now, septicemic shock could be broken out from 785.59 and you could code it differently.

You can see that we are winning the war on 785.59. The incidence of that disease dropped dramatically. But of course, that is not what really happened. What really happened is that now we had a new way to code septicemic shock or septic shock, which was actually the majority of those codes.

When we translate using these standard tables, we give up something that becomes problematic. The semantic interoperability that I am talking about is a way of maintaining the actual meaning of things in the interoperability step.

Here is semantic harmonization. The process of combining multiple sources and representations of data into a form where items of data share meaning. The meaning is shared, not just this is the best I could do and you will have to go with it.

I am just going to use some terminology examples here because that is where I come from. But LOINC, RxNorm, and SNOMED all use a semantic model for representing their terms, some more formal than others. SNOMED – maybe Clem is not on yet. Or LOINC rather. They just kind of cram these things together. But that is actually a semantic definition of the sodium test. Sodium substance concentration point in time urine quantitative tells you pretty much exactly what that test is. If somebody on the receiving end who might have a test that measures sodium in the urine will understand whether or not what you are sending is comparable to what they have.

RxNorm uses something based on work that I did with HL7 back in the day, building a model for clinical drugs. Of course, you do not need to see the detail there, but understand that a drug is modeled by its form and its ingredients and who provides and who labels it. All those kinds of things are modeled in semantics.

And SNOMED in 1998 or 1999 adopted a semantic model for their terms. They have models for everything. It is hard to do that, but they really made a lot of strides in modeling this through representing one term through other meaningful relationships to other controlled terms that express the semantics. That is my little pass on semantic harmonization and it works.

I did some work back in the early days at UMLS where I took all the cardiac procedures in MeSH ICD-9 CPT and I think SNOMED and was able to create meaningful representations in each terminology that then allowed automated translation. This is just one example from MD Computing. It was not a lexical thing. It was a semantic thing.

UMLS was looking at semantic modeling. I am pretty convinced that if Alexa McCray had been named Samantha McCray, maybe they would have done semantic modeling, but they chose the lexical modeling instead and that is what we have in UMLS today.

Enough of my stuff. I am just trying to set up the questions. Here are panel members. We will try to go in this order, top to bottom. I will let everybody introduce themselves to save time.

I asked the panel to address these questions. And, of course, everybody has their own agenda, which is fine. This is a listening session. These were just suggestions. They may answer these questions. They may answer other questions and we may come back to these later on. When we talk about semantic

harmonization, what does that mean? What is its current state from your perspective? Are you working on solutions and should we be working on solutions? What is worth doing? Should we just give up because it is impossible and we should just settle for translation tables and that sort of thing?

With that, we can move on to our first speaker, Jeff Swanson, from Kaiser Permanente.

Jeff Swanson: Hi. Thanks everybody. Thanks so much for having us and for NCVHS for bringing us in. I say us. It is a team effort. You heard from Jamie Ferguson earlier today as one of the moderators. The director of CMT, Rita Barsoum, is on with us. And I do not know if you are going to be able to chat with her or not, but she is certainly integral to this process. We have great business partners as we go through this from the business and coding perspective like Erica Eastham of The Permanente Federation, if she is on.

This has been great, learning about how to share the information. I really appreciate Jim kicking us off, trying to talk about what information we should be sharing. I am going to do my absolute best to limit this to a few small topics and points. There is so much we want to share. We are very passionate about this. Kaiser Permanente is all in for harmonization.

I practice in the Kaiser Northwest Region as an internal medicine doc. If we can go to the next slide, you will see that there are actually eight regions for Kaiser Permanente. KP Washington just joined a few years ago. They are not yet on our CMT or convergent medical terminology standard yet, but they are coming. I say we have eight regions because on the next slide you can see that our 12.5 million members are divided up into – they are divided up into these eight regions. Surprisingly, each of the regions has their own instance or iteration of the electronic health record. We are all on the same platform, but we all have different content and that was initially a scalability issue, but now we rely on it for innovation. Someday we may join. Who knows? But a Kaiser member traveling to another region looks like a new member to that region. It looks like a new patient. We need to do this discovery and reconciliation on our own KP members. To get good at it, KP's CMT, that convergent medical terminology, works to use the same terms in all regions.

You can see that we have over 100,000 people using the CMT terms. When KP Washington joins, it will be even more. That standard is great. Monday, Tuesday, yesterday, I was in clinic seeing our members. We have patients from outside. I had a visiting member. The visiting member feels just like it is a KP member. I do very fast reconciliation. In my region, we actually reconcile diagnosis, the problem list. We will do medications, immunizations, and even allergies. For this talk, if you can, let us focus on diagnoses because that seems to fit most people's view of the easiest.

When I have someone new who is from the outside, it is incredibly challenging. We are not able to pull the information directly across or if we pull it directly across, sometimes it is wrong or sometimes it is just plain confusing. On Monday, I had a patient, who had a diagnosis from an outside organization of hyperglycideridemia. I do not know if I missed that in medical school or if it is hypertriglyceridemia, or the years I have been out of medical school. I actually googled it and the first things I found for it were scholarly articles from the 1960s. I dug through the chart on their side. I could see some notes. And the clinician put hypertriglyceridemia. That was a lost to me. It took time. It took effort. I could have been with the patient. I could have been documenting better rather than chasing this down. Either the map got it wrong or it is a one to many or many to one or one of those things. It was extra work. Having the terms go straight across with a good one-to-one mapping is crucial. It is a personal thing too.

We were down in Legoland a few years ago and my daughter was not enjoying it. She had a headache. We went to a Kaiser facility down there. We just googled it and walked in the door. They created a record in their system. Their doc knew everything about my daughter, and she got great treatment for sinusitis. It was a great translation.

These things are just so challenging. Some of the mapping that comes across when it is not the same set can be wrong side. It can be a laterality issue, right versus left. You can also find wrong body part. And a couple of times I found some instances where it was not the right term, concept, medical entity, or anything. And computers do what computers do. We just need to give them better content.

You can also imagine that a physician sitting in front of a computer is more willing to do better chart discovery and reconciliation if there is some accuracy involved and it is well presented and it is fast.

You can see that this is our daily work. This is not something uncommon for Kaiser Permanente or really any medical organization. We have our members back after receiving care outside. You have new patients. We see them all the time. So 165 million times we exchange records, inbound and outbound in 2020. That is a quite a bit.

We can really talk about Kaiser Permanente really trying to do this well. We are all in. We have leadership at all levels. We have a dedicated department. You can imagine the resource spend for all the technical folks. We have dedicated physician modelers. We pay physicians to help our modeling to make it as good as possible. We also help with mapping. We have dedicated coding teams. That is a lot to ask for, but that buy-in investment really offers us quite a bit.

We are so invested that we have actually partnered directly with SNOMED International and IHTSDO. We have contributed over 25,000 concepts that have made it into the SNOMED core or into the US extension. For us, this is key work. We are down with it and we want to work with you.

The ask is really everyone to work toward either adopting or mapping to that one-to-one standard. I think it is great for all of our patients whether they are your members, somebody floating passed, whether it is you getting care. A doctor or other clinician or provider who can see exactly the case that was on the other side of that wall with the other organization means the best care for you. This is a huge challenge. For every record or term that is put into one system, it may be unmapped. It may be unmappable. It may be mapped one term to many on our side or many to one or you can imagine many terms to many terms as we work through these mapping things.

I started this off to really talk about the generation of the data as a frontline doc sitting in clinic the last couple of days. I am generating a lot of data that I hope carries through efficiently, effectively and accurately to the next person who cares for this person whether it is here or across the world.

I will hand it off to the next presenter. I just wanted to say thanks again and contact me with anything. Thank you much.

Jim Cimino: Jeff, thank you very much. Before you go, a quick point that I think is worth hammering home and that is you are mapping to a single terminology, but that terminology – the purpose of that terminology is to represent the original data for its original purpose. It is not mapping through for billing or pre-approval or research or any of these other secondary uses so that the intent is actually to convey the original meaning at the level of granularity that the original clinician wanted. That is why you have to 25,000 terms because you cannot settle for something that the read codes put in 30 years ago. You need

what your clinicians want to see. You can just nod if that is true. But I think that is a difference. That is a harmonization. It is a tough one, but you can pull it off because you are a single organization. But it definitely qualifies as semantic harmonization.

Jeff Swanson: Jim, I will just say that as a frontline clinician, what I put in the chart I want the next person touching that chart to have that exact same information. That is my clinical standpoint. Along the way, we try to do a good job to mapping so other people can use it as well. These standards for coding – we do not do much preauthorization in Kaiser. But yes, it is a follow-on attribute of all that. Thank you.

Jim Cimino: Thank you. Next up we have Matthew Rahn from Health and Human Services, Office of National Coordinator for Health IT.

Matthew Rahn: Thanks for having me. I really appreciate the opportunity to present on this panel today. As Jim said, my name is Matthew Rahn. I am the deputy director for the Standards Division in the Office of Technology at ONC. I have been at ONC for about ten years now and I have worked on many different interoperability projects along the way. Most of my work has focused in the CCDA landscape. But I have been coming to speed on some of the FHIR-related work. I will speak to a little bit about that. I know Wayne later will probably speak a little bit about those as well.

For those that may or may not know, ONC is the federal office charged with coordinating nationwide efforts to implement and use the most advanced health IT in exchange of health information.

I am going to talk a little bit about a few different projects that are being coordinated by ONC that have been with the purpose of driving towards the semantic harmonization of the standards that we have put in our regulations and working with industry on those things.

This is just a little bit about ONC with our vision, mission, and our strategic goals.

One of the key things I wanted to touch base on today was our United States Core Data for Interoperability. Formerly, we referred to this as the common clinical data set and the 2015 edition of one of our regulations. We have created this as a standard and more of a concept. Moving forward in our Cures Act Final Rule, we did include this. By the end of 2022, all certified health IT modules will be able to capture USCDI data for exchange, using, for example, C-CDA or FHIR.

What is USCDI? It is a defined set of health data that must be expressed in certified health IT in the United States and made available for exchange using like I mentioned FHIR or C-CDA. If focuses on the core data for patients' data access and care related to exchanges. It is represented in individual concepts. There are different data, medications, allergies, procedures, and so on. In particular, some of these data elements are expressed in specific health IT vocabulary standards such as SNOMED CT or RxNorm. For example, our medication data element is captured with RxNorm.

It is content exchange standard agnostic. It does not specify how and to what extent they should be captured. But he will follow the FHIR or C-CDA standard to help template those specific data.

As I mentioned, these are our core principles and this is what we are working towards as we continue to update and receive feedback on USCDI. It comprises a core set of structured and unstructured data to support patient care and facilitate patient access.

It establishes a consistent baseline of harmonized data elements and it will expand over time via predictable, transparent, and collaborative process. This is one key thing I wanted to harp on is we are currently in a comment period for the next version of USCDI Version 3. This is an opportunity to help us update our standards and improve with industry in any way if we need to specify a specific terminology for a specific data class or element. There is opportunity to comment on that. As I mentioned, it will expand over time. But we want to do that in a way that does not burden the industry.

I will just mentioned that the USCDI Version 1 is our current requirement even though we have released Version 2. You can follow that, but our regulation program is specific to Version 1.

This is just an example that I wanted folks to be able to see. This is what data is included in the USCDI. This is not much different than the common clinical data set. Most health IT systems should be able to capture this information as of this time.

This is Version 2. This particular version – we decided it was a good opportunity to focus on addressing some health inequities that have been highlighted based on the pandemic, specifically adding the sexual determinants of health and the sexual orientation and gender identity data elements. Work is underway to kind of update the ability to capture this information in standards so far.

This is just an overview of what our update process looks like. It could be updated at any time. But the plan is we put out every July a new version, a new USCDI. We receive public feedback. There is a HITAC committee that is focusing on the different versions and how we should improve our product. And then the hope is eventually it gets considered for a standard – advancement process that could then be part of our certification program.

Now, I am going to talk a little bit about direct investments in industry to kind of help drive interoperability. ONC has created some partnerships with direct funding streams to organizations that can help with semantic interoperability. For example, we have cooperative agreements with HL7, Regenstrief, and IHE. On the LOINC side, the goal is to develop and release LOINC codes that accurately describe the test results and procedures, provide services and infrastructure to ensure correct LOINC code is applied and that steps and procedures are performed and the results are obtained.

The IHE one focuses on the ability for the IHE profiles to essentially be FHIR-ized if and when it is a good solution to support the use of FHIR as an alternative for those IHE profiles. But I wanted to focus more on the HL7 side. We have many direct – essentially, with the FHIR US Core and C-CDA update cycle, we have partnered and tried to mimic our USCDI update cycle to meet these updates so that there could be specific timing around when those standards are updated to address the USCDI version we release.

We have FHIR connect-a-thons, C-CDA implementation-a-thons to kind of help build the consistent implementation of these standards. That is most key. We consistently implement standards. We have created test tools to help with that that are either part of our certification program or part of above and beyond like our C-CDA Scorecard where you can get a score based on consistently implementing certain rubric, for example, like lab results shall contain recommended UCUM codes.

And then we offer FHIR terminology support. We have been providing a lot of different options to work directly with industry and the SDOs to help improve the interoperability of these standards and the consistent implementation that can lead to that.

On the next slide, I have a bunch of different links. But I will say just to end that we are here to help and these are just initial projects we have been working on. There is a lot more going on, but in the interest of time, I will turn it back to Jim.

Jim Cimino: Thank you. I put all the links in the – hopefully, everybody can see them in the chat. If not, we will make them available afterwards, I am sure.

Next, we have Wayne Kubick from HL7.

Wayne Kubick: Thank you, Jim, and thanks to the committee for inviting me to join you today. I expect most of you know what HL7 is all about. Chuck Jaffe, our CEO, was on the previous panel. I think most of us on this call probably share something similar to the HL7 vision of making information widely available and useful. My focus is principally on the mission, HL7's goal. To provide standards that empower health data interoperability. We focus on semantic interoperability more than semantic harmonization. But we will talk a little bit about how that fits with HL7 with reference to the questions that Jim posed.

The map is on the right by the way. We are a global organization. The blue indicates HL7-affiliate countries around the world. The bottom indicates pockets of significant activity around HL7 FHIR, which also spreads across six continents.

This is my FHIR in a nutshell slide. I am not going to go through this in detail because I am sure most of you are familiar with FHIR as well. Again, the focus on interoperability. FHIR was designed as a platform standard to utilize the technologies of the Worldwide Web to address interoperability in particular. Our V2 standard was based on messaging, very useful within organizational entities to exchange information and to run the internal operations. Our V3 CDA standard is a document-based standard that is widely used within the US as well.

FHIR is really determined to use multiple output formats, using the capabilities of the Worldwide Web and this concept of resources as building blocks. FHIR can be expressed as web services like web pages like V2, documents like CDA as well as bulk trials that can be used to populate a database. I think there is probably a build – I think the best way to describe it is what Grahame Grieve, the founder of FHIR, calls FHIR with the just the web for health care.

The way this is expressed within the FHIR standard is by using terminologies that are expressed particularly within resources. And FHIR has – and I am using resources in the sense of how it is used within the FHIR standard itself, these building blocks. And these building blocks are used to specify coding systems and codes and are fairly agnostic. Basically, FHIR is meant to be a platform standard to meet the global needs of interoperability. The way to address it is specifically through additional capabilities of FHIR. There are a robust set of terminology services about the core spec and these capabilities of expressing it in coding content.

In order to support this, we built a system within called terminology.hl7.org. This capability lists all the code systems that we use and all the HL7 standards, V2 CDA and FHIR. There is more than 1050 – over 1000 code systems that are written. Many of those are internal specifications itself sort of codeless associated with particular attributes. More than 2200 value sets. I think it is actually more than 25,000 terms. 10,000 or so come from actually a free set offered by SNOMED that was used for our international patients summary term. The 200,000 web pages are really what express all the various different drill down views and visions. It is a pretty important resource. Accessible to APIs. Terminology.hl7.org.

Now, when we talk about using FHIR to support, again, I will say semantic interoperability at this point, it is a base global standard that really has to be tailored to address the various different needs in health care.

Terminologies are applied basically at the implementation guide level. Implementation guides take the capabilities of FHIR and basically tailor them in order to solve a particular use case or meet a particular context. They consist of profiles. Within profiles, we specify terminology findings. We specify extensions and constraints.

Here is an example to segue from MAT. The US core patient profile expresses several of the concepts that are in the USCDI. And what you would see, if you look at it closely, in some cases, it takes an URL. In the first case, there are particular extensions in the US core profile to deal with race and ethnicity, which is treated in the US differently as it is in other countries. In some cases, we may have a particular terminology binding as in this case with the third element that is listed down here, birth sex. And in other cases, we have particular constraints like the statement at the bottom. It would be conformance statements, for example.

We also have an initiative within HL7 called CIMI. I am sure many of you know Stan Huff. This is his life's work, working on detailed clinical models, which try to express a combination of attributes associated with, for example, an observation. A lot of the CIMI work has been about modeling lab observations. They will do things like specifying an addition to a specific LOINC or SNOMED code. They will specify some units in magnitude and other extensions that will have a deeper level of precision associated with the clinical observation.

In pulling all these things together, what semantic harmonization means within the context of HL7 is first of all our vision and mission focuses on achieving semantic interoperability. And FHIR is the means for achieving this. As Chuck said, the time is now for this. And the FHIR platform and the FHIR global community are completely dedicated to this activity.

Semantic interoperability is based on conformance with FHIR profiles, which are in standard FHIR implementation guides. In our previous session, Jocelyn was talking about the Da Vinci initiative, which is – a dozen or so implementation guides to dealing with things like prior authorization and so specifically how to tailor the specification with the terminologies that are used and additional constraints or extensions that may not be in the core standard.

But in terms of the notion of semantic harmonization within the context of FHIR resourced transfer of information, you would expect that to occur either before or during the translation from an EHR database to the set of FHIR resources that may be transmitted as a web page or a message or a document or afterwards when these are pulled into some internal data repository, instantiated data repository and then there would be some degree of harmonization to address trying to put consistency, particularly when you are dealing with merging multiple data sources, for example, public health or research use cases. It still means that there is a need to convert individual code values between systems in order to achieve harmonization.

I think one of the powerful notions of the global FHIR community is that FHIR as an open source standard. There are lots of tools and resources that are being developed around the world from entrepreneurial small companies to large, big tech providers like Amazon and Google and Microsoft. What FHIR provides is an avenue for achieving these things and a method to be able to make it possible.

That is my eight minutes. Thank you very much.

Jim Cimino: Thank you.

Next, we have Clem McDonald from NIH National Library of Medicine.

Clem McDonald: I am going to give you some real quick brief tour of NIH's current work related to standards. We do a lot of things, and I am not going to read through them. We support either funding or build a number of different vocabularies and systems. I have emphasized – there is also a "genetic standard" activities in NCBI, SNPs, et cetera. Anybody interested can click on those.

I want to emphasize – that first slide was about vocabularies or coding systems. This one is about structures. NLM is also involved in the Fast Healthcare Interoperability, FHIR. It has implemented FHIR's questionnaire or the SDC. It has implemented FHIRpath. It has built something called the Research Data Finder. It is trying to convert the five billion records in dbGaP into FHIR. That is uphill though.

NIH itself has gotten on board with standards for the first time. I 2018, there was a Guide Notice encouraging researchers to explore the use of FHIR, that is on the structured side. And in 2020, there was a Guide Notice encouraging researchers to adopt and use USCDI that is on the semantic side, the federal ONC specifications. There is some funding for such efforts as well.

The underpinnings of NIH's interest in FHIR and other data standards is that they have had this long running goal since 2003 of making research data interoperable. This goal has been difficult to reach because there was no accepted framework to standardize around what had encouraged researchers to adhere to.

FHIR has been embraced by federal agencies, health insurance industry, EMR developers, and all the health IT companies. It provides the needed framework. It is probably the last and best great hope for NIH's ambition. But a committee of NIH-funded investigators called NCPI is already working toward these goals.

Semantic interoperability is only part of the answer – take one swing at the fact – I do not think physician's diagnoses are so perfect and precious that they have to be – the exact. I am always going to check on the EKG and the lab tests before I believe that this guy has an acute myocardial infarction.

Some early developers thought semantics were everything. They built systems that flowed from one word or phrase to another, stringing them together with code. At least five companies took this tactic. Recording a note to these was impossibly slow for care providers who then clocked it over 200 words per minute when they are dictating. All five failed. Weed's problem-oriented record really was an analogous system. You click on everything, and you build up from codes. It did work in obstetrics, which has a narrow scope. But it failed miserably on the internal medicine ward and it took six plus hours to write a single admission note. The result was residents revolved and the University of Vermont deinstalled the system.

Semantic and structure are like love and marriage, horse and carriage. As the song says, you cannot have one without the other. They are quite dependent, interdependent. Databases have structures made up of fields or slots. Think of them as questions that take answers. But you cannot decide on the answers until you know the question and you cannot decide with questions often without knowing the

answers. If you do not anchor and standardize the structure, there is no hope for semantic interoperability. I realize I am oversimplifying. I apologize in advance.

The US has made big progress on standardizing data structure. V2, CDA, and FHIR all have defined structures. FHIR is the most elegant and advanced. But all three really are quite analogous in respect to their primary tables like observations or the OBX segment.

Observations have a field for the identifier, the relevant time, the abnormal flag, the value in all of them. We are closing in on a common structure. Semantic interoperability occurs when everybody uses the same coding system and structures. I do not like the idea of harmonization because it is often fraudulent and it is really messy. Why don't we just use the same codes for the same field? That is just a wild proposal.

More standardized of semantics are also in progress. We are making progress. USCDI has specified specific code systems/semantics for specific fields. LOINC for laboratory tests and other observations, SNOMED CT for problems, coded observation answers, and others, RxNorm for medicines, UCUM for units of measure and so on.

This round, the second round standardize codes for a variety of clinical notes and reports. In the next round, we are optimistic. We will get standardized codes for many physical measurements and in the USCDI 12-lead EKGs, tonometry, nerve conductions, endoscopies, and wall motion echo studies, et cetera.

But lots of clean-up work. With all the standardization or theory of standardization, we still see tons of idiosyncratic local codes running around in little messages. That is something that we have to beat down because for all of our good work and its theory, the practice may not work out right.

The big problem is the codes and structure for history and physical and progress notes, things physicians say. I am an internist. I have to confess. I love looking at the discharge summary. But after that, I went and looked at the labs and x-ray reports and the other ones because they gave you solid stuff. This is important. But I am not sure we are going to master this in my lifetime anyway.

Entering this data would require scarce provider time if they did it with fair amount of structures. I would say let providers write their notes in free text, but identify limited set of key variables or questions for each problem. I do not have this list. But say, for example, for heart failure, are they better or worse? What is their body weight? See if they are going to go into failure or bubble into their lungs, ejection fraction. Many problems could have a handful of specific questions that physicians could assert their views on. That would go a long way.

And then depend on natural language processing to pick off anything else of interest from the free text. This may go against some other theories here, but I think we are going to have a tough time getting the physicians' output. It is free language. Language is a really deep problem, which we do not fully understand. I think eventually what they do with this – their judgments is they order something, which often then settles what it is.

I think we are done. I hope we are on tie.

Jim Cimino: Clem, thank you very much.

Next is Jay Ahlman from the American Medical Association.

Jay Ahlman: Good afternoon, everybody. I am Jay Ahlman. I am from the American Medical Association. My role is as the lead staff in support of CPT, including the CPT Editorial Panel, who maintains the CPT code set. Thank you all for this opportunity. I admit. I feel like I am coming from a bit of a different perspective. But it is actually interesting with that different perspective of how many places I agree with what has been said so appreciate the opportunity this afternoon.

Just upfront, I am a CPT person, which means I am very into rules. Jim, I am actually going to go question by question and try to answer those as you laid them out in your initial slides. Absolutely.

Jim's first question is what does semantic harmonization mean to you and maybe mean to us as an organization, AMA? We really think about it from the patient and the provider perspective so what is best for the patient, what is best for the clinician. We are thinking about what is ultimately going to enable that true coordination of care. As we go forward and think about semantic harmonization, we are thinking both pragmatically from a patient point of view, but also from a physician point of view.

We are thinking also about taking into account the different points of view from the provider's perspective, meaning the places they are coming from so these different care settings. And also, we at least feel very strongly that there is not a one size that fits all approach so getting all of these stakeholders together is really critical.

At the higher level, when we are talk interoperability from the AMA perspective, we are talking about enabling clinicians to coordinate care across the continuum. We have done a lot of work in CPT on the care coordination side, but it really takes a whole team and a whole group like this to bring it together to fruition.

We view this as critical to patient ownership and patient engagement in their care. Individual ownership of their health data is truly critical to interoperability. It is critical in this time especially of a public health emergency to truly support the needs of those that are on the frontline of public health. We, as the AMA, view this as truly fulfilling the promise of the quadruple aim. I can say to you also from the mission side of things, we view this as the AMA's – critical to the AMA's ability to fulfill the mission of promoting the art and science of medicine and the betterment of public health.

Your next question, Jim, was where are we now. I think there has been a lot of great dialogue and actual evidence in terms of the great strides that have been made on what I would say the technical capability side. But for the AMA, I think we look at functional interoperability as truly on the horizon and still needing some work. I think I would agree with a lot of the comments that have been made both from Jim and Jeff that in the areas of trust and consistency and data, there is work to be done there. From the perspective of the AMA and from my perspective as well, we feel like we have a great head start with the terminologies and the people around the table of foundational terminologies that can really advise and help this work.

Ultimately, we are thinking about this, not just from the physician and clinician perspective, but ultimately the patient perspective, making sure that they get the right care at the right time. I know this group has mentioned the triple need in various meetings and that is critical to this work as we go forward as well.

I am actually continuing down this path of where are we. I was really encouraged, Jim, to see when you put up a definition around thinking about – I do not know if you had under semantic harmonization or interoperability, but it was so close to my first bullet here. I will not read that, but I was at least thrilled to see that we were actually from different points of view coming at this from a very similar definitional side.

I will tell you from the AMA point of view and from me as a CPT person, I feel like there are evidence-based standards that can really advise this work and advise this committee in going forward. There are many medical terminologies out there. As Clem just mentioned, there are certainly local codes that are in play out there that can lead us in confusion. We feel like there really is not the need for true – to achieve semantic harmonization does not require the design of new approaches or new vocabularies but leveraging all of those that are in play that we have been talking about. That does not mean that there are not new perspectives that need to be brought to bear.

From the CPT side, a lot of the folks think about us as just codes and descriptions. CPT has guidelines that are embedded that are actually mapped to and I will say have explicit relationships to codes and provide meaning around the use of those codes. We feel that it is important that content like that that is in CPT and not only in other terminologies be fully utilized for this work.

My point here is to recognize the value of foundational terminologies in this work. I am coming at it from the CPT point of view. We mentioned CPT a few times today. In this world, millions of transactions and millions of patients and millions of physicians accessing this content over its 50 years. It is maintained by the CPT editorial panel. The panel has just recently expanded to 21 members. They are clinicians on the frontlines. The panel is advised by medical specialties that are coming at this, not just from a standpoint of maintaining CPT, but as clinicians on the front lines. When we think about CPT, we really do think about it being fit for purpose because we are not just thinking about it making codes and descriptions. We are thinking about it in terms of the care as being delivering by those clinicians on the frontline and making sure the terminology meets their needs.

We do feel like there are foundational elements with CPT and other terminologies to really build on and to create a trusted and well-integrated semantic interoperability work within the framework. We suggest start with what is working and then begin to expand.

What we want to stress and this has been mentioned a couple of times is that ultimately, while we work and while we make our progress, we do no harm to what is working right now. When it comes to issues of patient care and issues of clinicians interacting with their patients, we want to make sure that whatever we do is the right thing for these interactions and ultimately that we do no harm.

Jim had asked of things that are underway. I will not go through each one of these because some of these have already been talked about in terms of the implementation guide. And we are going to talk about the Gravity Project a little bit later on in the meeting.

A couple of points that I want to bring out. Work that has been underway in CPT is to start providing frameworks around technologies that are emerging and so we have seen in the public health emergency. The role of telehealth, as some have referred to it, has really expanded.

We have been thinking about digital medicine on the AMA and the CPT side for some time. We actually convened a digital medicine payment advisory group, which brings together subject matter experts to advise on building standards and common terms associated with these technologies. They have brought

forward to CPT a digital medicine taxonomy, which builds upon that work and creates a framework for these services both within CPT and beyond.

We also have an AI taxonomy that a CPT editorial panel will be considering at their October meeting, which again puts some structure around these technologies as we consider terms like what is assistive versus what is augmented versus what is truly autonomous AI. These are frameworks that we have been putting in CPT that can be utilized elsewhere.

I just want to mention mapping. I know Jim Case is going to talk some about the SNOMED and CPT mapping. We actually have been doing bidirectional mapping for some time. The SNOMED, the CPT mapping, and the work we are going to do with SNOMED is really going to bring that to a whole new level. We feel like there are other use cases both at CPT and other terminologies. We, as the AMA, really do encourage stakeholders to come forward. We are really interested in gaining perspective on where we should be thinking about mapping in other places. Much of that mapping has already been mentioned.

I want to make sure that we at least bring the patient perspective to bear here. CPT, as I mentioned, is supported by the clinicians in the frontlines. We have advisors, over 200 clinicians form medical specialties from throughout the specialty arena.

They are coming at this not only from the physician's voice and physician's point of view, but they are also coming to us with the patient's point of view. What we hear over and over again is that we need and patients need information that is accessible and consumable. They need tools so that they can actively participate in their health care and when they are being treated – coordination of care continuum, they understand what is actually taking place so that they are better informed as patients and consumers of this health care.

The AMA and CPT has been maintaining CPT consumer descriptors for some time that really empower patients with plain language descriptions, again, ultimately to play a proactive role in their personal health and understand the services that are being provided.

I would be remiss if I did not at least mention a little bit about what has been happening even today on the CPT front related to the public health emergency. Obviously, with a group like this, a lot of folks think about the use of case of CPT as being purely with administrative billing perspective. But the COVID-19 crisis has really demonstrated the need for CPT and other use cases and this is one of those. We have been actively working with the CDC and CMS to develop codes and very specific codes that not only address the billing requirements of those of the health care ecosystem, but also the long-term tracking and research requirements, which are going to be critical, not just for the next year or two, but for the coming years so that we hopefully do not see another public health emergency like this again.

We have also created educational resources that we again intent to provide true meaning around and a framework around what these codes are actually intended to do both now and into the future.

Finally, Jim, you had asked what the NCVHS might focus on for the next five to ten years. I think based on what Crystal said this morning, we might not have that much time. Maybe we will boil that timeline down just a little bit.

I think just a couple of quick highlights here. First, I will focus on the bolded items there. Prioritize work based on high-impact use cases addressing unmet needs. Essentially, there is low-hanging fruit that we

could certainly focus on and we feel like that we can make progress quickly if we focus on that low-hanging fruit.

Focus on patient empowerment. The consumer descriptors that I mentioned and I know that others have mentioned and other terminologies we believe are critical to empowering patients and allowing them to be part of their care.

Standardize rules for data submission. Again, this is around the subject of reducing burden, which we have heard quite a bit about and ultimately again leveraging those standard code sets that are out there to achieve true semantic harmonization.

I am hoping I am within my eight minutes and I really thank you. Jim, I will turn it back to you.

Jim Cimino: Thank you.

Our last speaker is Jim Case from SNOMED.

Jim Case: Thank you, Jim, and thank you for the subcommittee for giving me the opportunity to speak. One of the advantages of going last is that most of the other people on the panel have said many of the things that I already wanted to say. But I am going to be addressing this from a clinical terminology standpoint and try to go through some of the questions that you asked in a little bit different way than you asked them, but hopefully to address some of the things that you are looking for.

Within the SNOMED community, what we talk about in terms of semantic harmonization is that in the context of health care, we are talking about clinical terminology standards here. In the context of health care terminology standards, we are looking at as the maintenance of fidelity of meaning throughout the life cycle of a piece of data that is unaffected by mappings or by translations and that we want to be able to capture the clinical meaning as specifically and explicitly as possible, which requires that a terminology have the appropriate granularity that there is no implied meaning in the terminology and that there are computable definitions associated with this so not only the words, but also the ability to reason automatically on the terminology is important.

As many people have said that there is a lossless transfer between systems. Oftentimes this requires bidirectional equivalence maps. And some of the issues around mapping have been already mentioned. But it is this bidirectional aspect of maps that really retain the semantic interoperability between terminologies.

The other thing about terminologies is they need to be compatible with multiple information models. The robustness of particular information models varies significantly. The ability of a terminology to support all levels of information models is very important. And then finally that the meaning is maintained when we translate it to another language.

One of the questions that we are looking for is what are some of the opportunities for harmonizing terminology standards? It has already been alluded to. Clem mentioned it a little bit. Let us pick one standard or let us pick a few standards. The greatest opportunity is to limit the landscape and identify a subset of high priority, robust, and fit-for-purpose standards, which brought to mind Andrew Tanenbaum's quote about the nice things about standards is there are so many to choose from. We want to try and limit that. And some of the qualifications for this high priority, robust, fit-for-purpose is that those terminology standards be reliably maintained and have frequent releases.

Many times one of the concerns about terminologies is they do not have sufficient coverage. But rather than creating a new standard, the focus should be to enhance the existing standards to meet the particular gaps that have been identified as opposed to creating a new standard to cover those areas.

USCDI has been mentioned quite a few times. We think that is a very good start in terms of limiting the number of standards that are being recommended. But it is in limited scope. There is a lot more within the health care environment that needs to be supported by standards that is currently covered by USCDI.

And one of the ways that we can enhance this is through collaboration among the standards development organizations by creating formal agreements. The Joint Initiative Council for Global Health Informatics Standardization is one such organization that strives to come to agreement on how standardization should be handled.

Some of the barriers. I do not think anybody is going to be surprised by some of the barriers that exist out there now. Clem mentioned the extensive use of local code systems or idiosyncratic code systems. We have already seen that there are different underlying models and editorial policies and how to manage the terminologies that are out there and the fact that many terminologies have different primary focuses such as clinical administrative reimbursement or classification.

It was mentioned earlier this morning. There are deeply entrenched implementations. Implementing standards is a costly and time-consuming undertaking. The ability to make substantial changes in implementation is restricted by the fact that oftentimes there is reluctance to change and that the cost of the change is prohibitive to an organization. In some cases, there are intellectual property constraints.

How do we remove these barriers or move these barriers a little bit? One way is to try to leverage experiences that have occurred in other countries that do not have necessarily such a discontinuous health care system as we have in the United States and see if there are things that we can learn from countries that have national health care systems.

As also been alluded to is that we really need a national strategic plan that is being developed in collaboration with all of the stakeholders that are involved in semantic interoperability or heath care in general. That includes the vendors, health care enterprises, payers, the government, and standard development organizations. One of the ways to remove a barrier is to demonstrate the real-world benefits of adoption and implementation of standards.

Another question is what types of crosswalks are necessary to achieve semantic interoperability or semantic harmonization. SNOMED is actively involved in integrating other terminologies and maintaining clinical cross maps to other terminologies.

This is just an example of some of the collaborations and partnerships that we have. In the content improvement and addition area, we have agreements to actually incorporate content from other standards such as the nutrition content from the Association of Nutrition and Dietetics, the nursing content from ICNP and NANDA. We work with the ADA to integrate the SNODENT terminology. And then we are also working with other organizations to incorporate structured determinants of health.

We also provide a number of focused sets of things all derived from SNOMED, the SNOMED core, as either reference sets or free sets. And then we have a number of other products and services such as

the COVID-19 Coding Guide, which was produced in support of the pandemic response. And then we have a number of other things that are listed on this slide. I am happy to talk to people individually on this.

Another question is what additional kinds of crosswalks would be beneficial for nationally standardized cross maps. As I mentioned in the first slide, the health care industry really should identify a few relevant and comprehensive interoperable clinical standards, driven by common information models to potentially reduce the need for extensive maps. And the FHIR information model, the FHIR resource model maybe a foundation upon which those types of interoperable standards could be based.

We feel that the cost of creating and maintaining large numbers of maps can be significant and it gross geometrically as new standards appear. And as was also mentioned earlier from a quality perspective, any map poses an opportunity for error. As much as you can in reducing the number of maps that you need to maintain or create would improve semantic interoperability.

The costs and burdens and resource constraints that might impede the adoption or harmonization of standards is, again, as has been mentioned, the idiosyncratic implementation of standards. And there are oftentimes technical limitations in terms of implementing terminology standards as well because of the proprietary nature of EHRs and the fact that there is no common information model.

Again, FHIR is a way to begin translating these proprietary information models into a common representation. But that is going to require that all systems that are going to exchange information adopt the FHIR model.

The other burden is just the cost of implementation and the maintenance of standards over time. One of the biggest issues is legacy data migration. If a system has a substantial investment in data and then decides to adopt a standard, migrating that data to a common structure and a common meaning is again very costly and time consuming. Because of that, there is oftentimes a lack of perceived benefit or motivation to move to a common standard.

What are some of the mitigation steps? First of all, I think that the health care community as a whole needs education on the benefit and appropriate uses of terminology standards. There will also be some benefit – and these are aspirational, of course, that the development of a common ontology for clinical terminology would be very helpful in achieving semantic interoperability and semantic harmonization of standards.

The creation of focused terminology subsets such as subontologies I think would also be something that would really benefit specific domain areas within health care.

And then encouraging all of our partners to a staged implementation strategy in order to minimize the pain that there is in adopting and using these standard terminologies.

Thank you for the opportunity and the time. I hope I made it within my timeframe.

Jim Cimino: Okay. I think we got in under an hour and a half altogether. I am counting that as a success. Thank you all.

How are we going to handle questions and answers? Is somebody reading those?

Rebecca Hines: You have about ten minutes. Jim, if you want to continue to moderate for committee members or if you want to ask the panelist members, any member of the subcommittee is welcome to do so, including you.

Jim Cimino: Okay. I do not have any questions for them. I am just monitoring the Q&A here to see if any attendees have anything. How about other subcommittee members?

Clem McDonald: Can I just make a comment? I want to give some credit to ONC, a lot of credit to ONC because I have labored in this vineyard for more decades than I want to admit. We may progress over that time, but it was an inch at a time. In the last round or the current round of ONC, the speed has been relatively blazing compared to the past. I think they deserve a lot of credit for having happened.

Jim Cimino: Okay. If there are no questions --

Rebecca Hines: Tammy has her hands up.

Tammy Banks: I just have an edification question. I am not sure who is the best to answer, but to bring this to an administrative perspective with coding, the procedures and services that are performed. Can anybody walk me through because with the USCDI, the elements that are needed to be – in that conversion from the documentation and Clem, I think you said using free text to put in what actually happened, what work has been performed as we look at AI, as we look at natural language processing to convert that into the billing side and respond to some of those billing administrative use cases? Can anybody just educate me a little bit more on the work that has been done across CPT, SNOMED?

Clem McDonald: I think there are two categories. One of them is if it is a simple thing today, they grab a CPT code and put it in. And physicians – they have memorized – the surgeons have memorized their codes. They know what those codes are.

Now, when you get into the deeper problems of how big a procedure is, are they cheating and all that sort of thing. Then I think you have to go to the Op note. I do not know of any work besides a human reading them over. But others might – that would automate that process.

I am sure you could find key words and find things that would be better to review when you know there are certain kinds of problems that others --

Wayne Kubick: There is a project that ONC has been funding through HL7 with Boston Children's Hospital. It is not dealing with billing information, but it is surveying clinical notes, particularly with reference to identifying COVID-19 symptoms and indications that can be used for public health analysis data bases. The technology that is being used to just look at unstructured clinical notes data and trying to translate that into structured information that is more suitable for systematic research and analytical tools I think would certainly be applied. It is moving along quickly. I think they have done some preliminary work already. I think that is something to keep you eye on. I am sure there are lots of other activities. That is the only one I have been directly involved with. Again, I think it would be easily adaptable for billing information.

Jim Cimino: We did get some questions about whether the slides and recordings will be available.

Rebecca Hines: I answered that. All the meeting materials are on the website and a transcript will be made available in the next couple of weeks and at the end of September, there will also be a meeting summary. And the slides are being put up as we get them.

Clem McDonald: Do we have any idea how many people listened?

Rebecca Hines: Right at this moment, we have 122 external, not here in this open session, but attendees. We have had as many as 160. It has ranged between 120 and 160 today.

Clem McDonald: Who won of the Academy Award with the highest points?

Rebecca Hines: I think Panel 2.

Jim Cimino: Other questions?

Denise Love: Thank you for this session. I feel kind of lost. I feel like it is a whole world, a future world. I have been embedded in more of the administrative and data research world.

With all this advancement and the terminologies and structures, when are we going to really see an enrichment of the administrative data with the clinical data for research and public health?

When I presented data over many years to policymakers, we relied on administrative data to make our case for variation or various policies and for research. But we were missing clinical data. But when people presented just clinical information, we did not get their attention unless a – was attached. Thus the billing data is so valuable when you are marrying clinical variation presentations and how much the cost is and the burden. When is that true marriage of administrative and clinical for aggregation and widespread research and use on the horizon?

Clem McDonald: It is on the horizon almost. In the next round of ONC stuff are clinical notes in total. You get the diagnostic report as being required to be submitted.

One little loophole is they have not really explicitly said surgical operative notes. But I think we can still wiggle it in because I think that would be the most interest because you could then do some playing around with the words and those things. I do not think you are going to find things for sure, but you can find things that should be looked at. And of course, you can also look at volumes. If someone is doing 10,000 heart surgeries a year, you know there is something wrong.

Wayne Kubick: In terms of timing, I think a lot of it is when the ONC and CMS rules going into effect over the next couple of years and we will begin to see that. It is a process. The standards have gone pretty far in terms of the actual use and availability of data within the standards. That is really still just getting going.

But I think over the next couple of years, I think you are going to see a lot of stuff forward as the requirements are going into place from government, which is really is a widespread option.

Clem McDonald: The C-CDA already includes Op note, doesn't it? The C-CDA?

Wayne Kubick: Includes the what, Clem? I am sorry. I did not hear it.

Clem McDonald: Operative note, and it actually has discrete --

Wayne Kubick: I think that is one of the C-CDA templates. The C-CDA has some limitations for interoperability, which I think FHIR has tried to address. I think you have to look at it as an incremental improvement over time. I think we are in a period of very rapid developments that are happening, and it is becoming to really be much more widely adopted within the health care environment now. Watch that space. But really, within the next 24 months, I think we are going to see dramatic changes and improvements.

Matthew Rahn: I was just going to add that one of the criterions in our certification program is the electronic health information export. That actually is a little bit more delayed than some of our other new criterion that would go into effect at the end of December of 2020. The EHI export would go into effect the end of 2023. Part of it is patient population export. I think as that picks up and people start adopting that, I think that will help, plus the refinement of the bulk data IG that is being updated right now, the FHIR bulk data IG, being updated now, the next version of that should be published eminently. Maybe Wayne knows. But I think once people start adopting that more that can help in the research aspect.

Denise Love: We look forward to that day when we can enrich our administrative data with key clinical data elements.

With that, I will maybe close the Q&A, Rebecca. Are we out of time? Are there any final remarks?

Rebecca Hines: Any final remarks and then we take a break and then move to Panel 4 at 3:30 so in less than 15 minutes.

Tammy, do you have your hand up?

Tammy Banks: I will just ask one more. I know that as we talk about terminology, we also want to talk about accuracy especially as we use it in – I am going to use CPT, but there are a lot of different languages. But Jay, since you are here, I will use CPT. That coders have to code differently for different entities. Is there anything that you would recommend in order to create more consistency with coding especially as we use – Denise, you always bring up the all-payer claims databases. In order to use the codes in there and again they are not just CPT, but I am using you as an example. In order to get that increased accuracy that can become more and more important as those get relied on for perspective review.

Jay Ahlman: A couple of things just to note. We put practices in place. I think Jim Case mentioned some similar practices within SNOMED, but to actually get to that kind of what I would call consistency in our data.

Now, when you talk about coding for different types of or thinking about coding from different points of view based on somebody's personal point of view, that is a lot of times where the other data that I am talking about when you are talk about guidelines comes into play. We put meaning around those codes to try to actually get away from a lot of those personal points of view.

I think, Tammy, one of the things that we are really focused on is putting processes and standards in place so that we do get to that level of consistency. We hold here in the next couple of months a meeting of a thousand coders, which is called the CPT symposium where they bring forward ideas in

terms of where we have a few gaps that we should address either in new codes or in existing codes. I am encouraging folks to come to that. I am happy to provide the output of that meeting because it is always interesting to get the coders' perspective on where we can actually close some gaps in CPT.

Tammy Banks: And the genesis for that question --I know with ICD-10, the codes and the convention or guidelines or whatever words you want to use are mandated under HIPAA and CPT, unfortunately, or HCPCS does not have that same thing. Is that a reason for some of this deviation in the reporting?

Jay Ahlman: It can be.

Tammy Banks: By – or by other entities.

Jay Ahlman: We do definitely see interpretation sometimes within the codes themselves in isolation without considering those guidelines that sit around them. Yes, I would say that is absolutely a factor.

Matthew Rahn: I will just add that in our certification program, we do have test tools that would test whether someone has implemented a specific code system. For example, for procedures, you can – you HCPC CPT for SNOMED. We would test, but actually, you would use one of those codes from one of those code systems.

I think working alongside with industry whether it is HL7 on C-CDA and FHIR, there are opportunities like the C-CDA implementation-a-thon where the industry is working on specific examples on how you should code a specific type of section like medications or something and which codes you should be using.

And then to add, we created some rubric around best practices. And the more that we get people to implement those practices, the better chance we can get at consistent implementation of the standard.

Tammy Banks: That is really helpful and again coming from a coder perspective, Jay, like you know. If you are trying to report a bilateral modifier, there are three different ways depending on what payer you are reporting it to and what claim platform you are sending it to, which just adds complexity. I did not know if that could be avoided. You are saying through the guidelines conventions that could be a helpful element.

Denise Love: Rebecca, I think we will have to cut this one off and have a short break.

Rebecca Hines: A short break and have Panel 4 and then just to remind all of our panelists that if you want to hang on, we are having a discussion as well with the subcommittee after Panel 4. You are welcome to stay. Public comment at 5:15. Thank you. See you all in ten minutes.

(Break.)

Panel 4: Update on National and HHS Initiatives on Public Health Data Systems and Social Determinants of Health

Denise Love: I will say a few words before we get started. Thank you everybody, for hanging in here. And to the panelists for joining us. This session is going to highlight the insights about the exchange of public health vital statistics, social service data, as a part of a national standards strategy. And after listening to

earlier sessions, I want to emphasize that this is not a point to point or one to one exchange necessarily, but one to many.

So we have data that is captured and going out to the world so to speak for research and policy. The issue of race, ethnicity, social determinants data to me feels like Groundhog Day, because since the 1990s working in data policy, the collectors and the users have struggled to balance the burden of capturing non-claims data and then figuring out how to responsibly use it, compel the reporting of it, and then deal with all the missing data.

It has been a huge challenge and left many holes as we found out during this recent pandemic. Many policy makers, researchers are relying on data linkage to fill some of these key gaps. But times are changing as we've heard today, but the urgent need for such information may also be overriding the burden issue that has stalled some of the collection of social data. We have new technology and new business needs.

So the discussion today is not a debate about whether we collect social determinant and other non-claims data, and not whether it should be distributed and shared, but how we can do this with consistency and trust, with a focus on administrative and vital record systems data. These originate in payer and provider systems, which makes industry a key partner to the data that we use for all of our downstream uses, research, public health, and policy.

And standards are critical, but without a national coordinating system that incorporates workforce training, enforcement, validation, methods for imputation and disaggregation of the data, and purposeful use of the data, standards alone are not going to lead to actionable information. I'd like to open it up to Denise Chrysler, my co-moderator, for a few remarks, and then I'll introduce the panel.

Denise Chrysler: Hi everybody. It is hard for me to add more to what Denise Love aptly said. We've all known the importance of social determinants for years, this was simply confirmed by our experience with COVID, and as Denise said it's not a debate about whether social determinants should be collected and shared, but how we do it with consistency. And I would add in compliance with the patchwork of laws that govern data collection and exchange. This is including the state laws which vary from state to state, and then also from system to system. So looking forward to hearing all of our panelists.

Denise Love: And today, we will start with Vickie Mays from UCLA and a National Committee on Vital and Health Statistics member. Then we'll go to LaShawn McIver, CMS. Then we'll hear from Janet Hamilton from the Council of State and Territorial Epidemiologists, but also recently a cochair of the Public Health Data Standards Task Force that OMC supported.

Then a critical data system, NAPHSIS, Shawna Webster will talk from the vital statistics perspective, and then key partners again, industry, and what is happening in this realm with the industry, Evelyn Gallego with the Gravity Project. So I will just turn it right now over to Vickie Mays to start out from a research perspective.

Vickie Mays: Thank you Denise. I'm totally in agreement with your introductory remarks about it isn't whether we should collect this, but I think I'm going to do who/what/where in terms of collecting it. What I want to do today is to really make some distinctions between structural versus social determinants of health, and social risk versus social needs.

Part of what you're going to see is precision does matter. And throughout this talk, which I've got about ten minutes, this is really a much longer talk, I'm going to leave you with materials which you can follow up. You can see here in this health affairs blog by Green and Zook what really matters is the precision to really know what is the focus when.

So for example one of the public health concerns currently is feeling that what we're doing is overmedicalizing individuals' social needs, rather than taking ourselves up to the kind of upstream community health interventions level.

Really what Zook talks about is the difference between determinants versus risk, and part of what we're talking about with patients is whether they have a risk sometimes for the development of the disease or disorder, or a risk to get worse. And what are the sectors of engagement that should be at the table, versus the focus totally being on the needs of individuals. And part of this work has been done by a group that is composed of payers, purchasers, patients, really looking at value-based payment models.

So here you'll see this is the work of Alder and Laura in 2019. These are all the things I'm using today so that you can follow in terms of more information. Crear-Perry which just came out. And of course, the basis of this really is the WHO report.

So when we're trying to make distinctions between structural determinants of health, there are very distinct differences from the social determinants of health. So basically, what we're looking at is are the social and political mechanisms that operate are really the things that are at the helm of being structural determinants of health. So structural determinants really are things that are the governing process, they're the economic and social policy.

So it's everything from talking about sick leave policy to housing first when for example you're trying to take care of mental health. What you're looking at also is that structural determinants are the things that push us over to the social determinants of health, and structural determinants, you have this unequal distribution of power, prestige, and resources, and those are things about whether you have a job, whether you're educated, et cetera.

So structural determinant interventions often are marked by the ability to actually be transformative, to actually have the agency to do that, to intervene in ways that alter the course of events. We usually think of the Federal Government, Supreme Court and others having the capacity to do that.

So here again what we're kind of looking at is the sense of it's the context that we're looking at. And in this context what happens is that those structural determinants also end up creating the social determinants of health. And so you then have the problems that we're looking at. The question is do we need to do everything that we're talking about within the context of health and healthcare, or should we be in social services, or should we be at the level of policy changes.

So here is just, again I use some slides of others so that you would really get a sense of it, in terms of structural competency it really is understanding what the policies, systems, and social hierarchies are, and how those end up creating the social determinants of health, which then create our health disparities.

So here what I want to do is just quickly talk about social risk versus social needs. So when we're talking about what a social risk is, what you're really talking about now is how that social determinant of health is managed at an individual level. So you have to really think about social determinants are often

collected not at an individual level, but sometimes they're collected at a group and a population level, or we know their veracity by group and population. The social risk should be at the individual level.

Some people like to use the term social vulnerability, and you saw this in COVID where social vulnerability was to be a part of the formula in terms of rolling out who was going to get the vaccine. So when you start to talk about social risk, these are things that we know with certainty that people have them, it becomes worse, they end up getting sick. So not having enough to eat, having housing instability, transportation problems, financial stresses. Those are all things that are risks. But they then kick this into social need.

So what you see here when we talk about social risk versus social need is screening by healthcare practices to try and prevent rather than to focus on just curative approaches, and create some kind of innovation within the context of value-based payment models, is really I think where we should be thinking about efforts to collect data.

So the data, what you want to say is what are the social risks, and are we collecting social risk data, and then the social risk data tells us what we need to do in terms of social needs. Social needs can vary, this is some of the complexity, but we know very clearly that if social needs are met that people's health can be better.

If you want to get a sense of, I think really good work in social risk, the department of ASPE in particular has been doing that, Rachael Zuckerman is the person who has been doing this for a while. I think it's very helpful to understand about value-based purchasing programs.

Here I'm just going to give you kind of the visuals about moving from structural determinants to social determinants in terms of particular diseases. And these are actual studies that have been out there. Again, what I want you to pay attention to is what's on the left, that's the structural determinants, what you begin to see as we move towards the right is the way in which they operate, this is in asthma.

Here you see social determinants of health in epilepsy, and what you can see here are these structural determinants, public policy is very important here, thinking about cultural and societal values is important. Now we begin to move into the social determinants, and you begin to see that people's status is the populations that they're in, how those end up being translated into social risks, and those social risks you can see then what happens in terms of diseases and disorders.

This again, the next slide is on the social determinants in epilepsy. What you see is this is ten years later. Built this model back in I guess it was 2004, a little longer than that, 16 years, and they just refined it. We have seen that as we talk about social determinants that the structural side is important for us to think about.

So at the federal level, what are some of these structural interventions? Again, I think that there are several people in the department who are great at being able to inform this. Medicare advantage, I don't know where you live, but where I live, you're always hearing on TV about people in Medicare can now get transportation, they can get gym memberships, they can get home improvements. This was an issue in which a policy intervention actually went out as far as also taking care of people's social needs.

The Social Determinants Accelerator Act in 2019 in which you see the feds really particularly for high need Medicaid patients, homeless, nursing home residents, we saw this as being very important within COVID, of how it is to come up with these partnerships. Now of course this one has been around for a

long time, including the Medicare Post-Acute Care Transformation Act, and this is some of the work we see with Rachael Zuckerman, where you're trying to understand social risk and value-based payment programs.

Again, this is just a quick reminder. Using community-based data does not give you a granular enough social risk, but individuals' social determinants of health screens do, which is why we encourage them. Last slide, some of these issues around the patient's social needs, you might find that there is a debate, because some patients don't want health entities in the middle of their social needs.

So again, the presentation of this framework was to really make sure that we're all talking the same language, and that there is a public health aspect to this, and that in terms of the healthcare and health status that we understand where it is that those interventions should be, and when to bring the other sectors, particularly the social service sector, into play. I'll stop there.

Denise Love: Thanks. In the interest of time, we'll have Q&A afterwards. We'll move on to LaShawn McIver. LaShawn has to leave early, but CMS plays a critical role obviously, so we'll hear from LaShawn now.

LaShawn McIver: Thank you. My name is Dr. LaShawn McIver. I'm the Director of the Office of Minority Health at CMS. It's a pleasure to be joining you today as a member of this distinguished panel. And in the next few moments I've been asked to share with you an overview of how CMS and particularly the Office of Minority Health is approaching and seeking to address the social determinants of health within our programs and policies, and a lot of what the previous speaker talked about around how do we think about the definitions of the social determinants of health, et cetera, those things are very important to us being aligned across federal programs as we think about this work. So I will be coming off camera now, but I just wanted to again brief the group as I proceed.

And here are the topics that I'll be covering as I go through my slides today. I'm going to start with just a brief overview of our office, and some of CMS's current health equity efforts that are underway. And then I'm going to briefly discuss how we're working to define the Social Determinants of Health within CMS, how we're working to strengthen our data collection, reporting, and analysis related to the Social Determinants of Health, and then finally I'll touch upon how we're working to leverage the data that we have to embed SDoH within CMS policies and programs.

The mission of our office involves leading the advancement and integration of health equity in the development, evaluation, and implementation of CMS' policies, programs, and partnerships. And our overall vision is that all of the nearly 150 million served by CMS have achieved their highest level of health and wellbeing, and that we have eliminated disparities in healthcare quality and access.

Within CMS our office serves as the principal advisor and coordinator to the agency for the special needs of minorities and underserved populations. And this includes providing leadership, vision, and direction to address CMS minority health and health disparities goals, as well as participating in the formulation of CMS' goals, polices, and strategies, implementing activities to monitor CMS health equity programs and consulting with federal agencies and external organizations to address health equity, such as the panel today.

One thing of note that I wanted to start with is talking a little bit about the recent executive order. So the President has signed several executive orders over the last several months that have had a direct impact on the current health equity work underway at CMS.

And here is a summary of what I really call one of the primary executive orders that's entitled Executive Order 13985, and it's entitled Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.

And this executive order lays out a systematic approach to addressing equities, and it includes embedding fairness within the decision-making part of all federal government agencies, and it takes a very comprehensive approach to doing so. It also explains or describes underserved communities as those adversely affected by persistent poverty and inequality. It talks about tribal communities, people of color and those otherwise historically marginalized populations.

Listed here are some of the key sections that speak again to our current work at CMS. So for example the executive order talks about establishing the implementation of policies across the federal government that address racial equity and issues faced by persons in underserved communities, offering methods to assess equity through data, barriers to benefits, and increasing stakeholder communication and engagement, just to name a few.

But some of the key activities within CMS include we are looking across the agency to fully understand more holistically our approach to equity. CMS plays a major role in the healthcare system of setting many types of standards. We have a very significant role in helping to be proactive in the work of equity.

And so we're looking within the agency to ensure we're approaching this from a more holistic approach, and we're working very closely with our stakeholders from the many different sectors that touch the healthcare system, as well as working intentionally with leaders within CMS on how we approach equity for our programs.

And lastly, I will say panels like the one today are very timely, and that there is an increased focus on data as outlined in this executive order as well, as we look to collect more comprehensive data to better understand our populations and their specific needs.

Our CMS data, our CMS OMH, so within our Office we have a group that focuses on data and policy analysis, and they are working on several projects to help address many of these critical issues of data completeness and continue to work in collaboration with other internal and external stakeholders on this issue.

So in summary, these executive orders really are directing us to take a whole government approach to equity, and they provide a unique opportunity for our agency to impact underserved populations and to leverage the key tools we have within CMS, but also tools that can help drive work within the healthcare system.

So now I'll shift to describing one aspect of this work, which is the focus today around SDoH. Our office is working to ground the agency in the common understanding of the SDoH as established in the Healthy People 2030 framework. So we just heard in the previous presentation that words matter, and how we think about these terms during this time are critically important as we're thinking about programmatic and policy implications of things like the Social Determinants of Health.

So we're working across the agency to drive a shared understanding of these distinctions between the demographic data elements that we're focused on and social determinants of health information, as well as what was noted before around social risk factors and some of those other pieces. And at a more granular level we're working to understand how the differences between these terms, and as I said

terms like social risk factors and health related social needs, what some of those differences are in their implications.

For CMS, as noted, our definitions are rooted in Healthy People 2030, and we consider each of the five domains of the SDoH and what levers we have within CMS programs and policies to ensure healthcare coverage and the delivery of services are informed and tailored to provide the best care to the millions of individuals the agency serves based on each individual's lived experience.

And to meet this mandate and charge we must build the shared agency understanding of what the SDoH are, and why this information is important in the context of CMS informing our benefit design, service delivery, coverage, quality access, and outcomes.

One of the biggest challenged with understanding the drivers of disparity is the lack of SDoH data, and we know that demographics matter, but disparities can be caused or exacerbated by SDoH, so it's critically important to have data to help us understand more about the populations we serve and the barriers they face in accessing healthcare and achieving their optimal health.

So CMS has a role in helping to align and increase the collection of SDoH data, and some of our efforts are noted here. Our work in this area again aligns with Healthy People 2030's objective around healthcare access and quality, particularly related to health IT, healthcare, and health communication.

So for example, we work with our federal partners and other sister agencies as well as within the private-public partnerships such as the Gravity Project to support the standardization of demographic and social determinants of health data elements across federal programs and the healthcare system.

As data is more standardized, we also work across CMS to increase the collection of standardized demographic and SDoH data elements. A few examples of CMS work include strengthening standardized demographic and SDoH data collection in the Medicare Current Beneficiary Survey, in the SPADE assessments in the post-acute care setting, and in the ICD-10 Z codes. We also support analysis and reporting related to demographic and SDoH data in several ways.

For example, our annual stratified report and our Mapping Medicare Disparities Tool have Medicare fee-for-service and Medicare Advantage data stratified by race and ethnicity and geography. We also analyzed claims data and published reports and snapshots to increase understanding around the social determinants of health that are commonly coded in claims, breaking out where social determinants of health data is available and where that information differs across the populations we serve.

And finally, across the agency we collaborate to provide tools, outreach, and education to care teams and healthcare organizations around how to collect and use standardized demographic and SDoH data to drive improvements in care and health outcomes. The graphic on the right here is an infographic we have on our website to help increase the uptake of ICD-10's social determinants of health Z codes, and to help providers understand how to use SDoH data they have to improve care.

So on this final slide, this is just an example. So as we collect more granular and higher quality demographic and SDoH data, CMS has a charge to use our levers and authorities to better tailor our design of services and coverage and benefits to meet the needs of those we serve.

Also, it gives us a greater understanding of individuals and the communities' needs we have the opportunity to create and support linkages across healthcare and social service providers to help those

we serve get the best care for them at the right time and at the right place, and that they can afford. Without understanding and addressing these barriers communities may not realize the full benefits of their health coverage or may not get the care they need to age healthy and well.

So you'll see here on the right side some of the ways CMS is advancing Healthy People 2030 objectives related to healthcare access, insurance coverage, and communication. The left side of the slide shows a selection of some of the data CMS published or has published that is stratified by sociodemographic characteristics to illustrate what I mean when I say we work to expand how we bring data across the agency to advance our program and policies.

In this case this data is from the preliminary Medicare, COVID-19 data snapshot related to COVID-19 hospitalizations. This data is available publicly on the CMS website at the link below, and is stratified by race and ethnicity as well as age, disability status, and ESRD status. It's then stratified again as you can see by dual eligibility status, and this shows us the difference among demographic characteristics between those who are enrolled in Medicare and Medicaid plans versus those in Medicare only.

By putting this data together with the agency's policy and program experts, we're looking to tailor services, coverage, and interventions and messages about how to get the right care in place and time to enrollees across healthcare settings.

We can also help to educate providers on effective ways to culturally and linguistically tailor their communication and services to ensure they're reaching the patients who are most likely to experience adverse health outcomes and most likely to face barriers accessing the care they need when and where they need it.

Just a last few points here, we've paired this work with models and demonstration projects like the Accountable Health Communities model. This model tests ways in which healthcare providers and community partnerships can effectively screen for social risk factors and health related social needs, and then link individuals with social services and supports where need is identified.

In closing, at CMS we are committed to working across the agency and with our federal partners and external stakeholders to drive the health equity movement forward for our nation and for each individual in every community that we serve, particularly as we all age to be healthy and well. Our intentional focus is always members of the minority underserved community, and we strive each day to make sure their voices are heard within CMS.

So thank you for the opportunity to speak with you all today, I hope this provided a useful overview of some of the health equity work underway at CMS. I've included all of the different ways that you can contact our office, and again thank you so much for the opportunity to present today. Thank you.

Denise Love: Thank you. You will be leaving early before the Q&A, is that correct?

LaShawn McIver: Yes, unfortunately I have a hard stop at 4:45.

Denise Love: Can I take advantage of your presence and break protocol here? Are you seeing at CMS an improvement in data quality of the race/ethnicity fields that you are capturing, from current to past, are you seeing an upward trend?

LaShawn McIver: So what I am seeing a positive trajectory within CMS is the pathway to get there. I think we still have many challenges within, there are certain barriers that we have in terms of authority to collect certain data, but also working as an agency on a unified way in which we get there to better data collection, we're on that pathway, and I'm very excited for the work ahead.

I do think we've had some great opportunities to expand that collection, some of which in the post-acute care setting will go into effect in 2022, but I'm very excited about the conversations that we're having within the agency of how do we get to collecting better data over time. I think somebody mentioned in a previous panel some of these things will require a little bit more time to get there from a policy perspective, but the work internal to the agency is really moving in a very positive direction.

Denise Love: I want to thank you for the work you're doing, it's really important. With that, we will move on to Janet Hamilton for her comments. Thank you, Janet.

Janet Hamilton: Thank you so much. It's wonderful to be part of this panel. For those of you who did not join at the very beginning, I don't have slides but I'm really looking forward to this discussion with you all today. And I have posted some links for your reference, which I actually think are more robust than slides that I could put together for our brief time together today.

So I am Janet Hamilton, I'm the executive director of CSTE, the Council of State and Territorial Epidemiologists, and I want to talk to you about two different things. One, more under my hat as CSTE executive director, and the other, which is the topic that I'll start with first, is under a role that I helped support where I helped to cochair the public health data systems task force that was convened by ONC under the HITECH and completed its work over a few short months earlier this year.

So the task force itself, for those of you who are new to hearing that it existed, was to inform HHS's response to President Biden's executive order on ensuring a data driven response to COVID-19 and future high consequence public health threats. And the focus of the group itself was to focus on bidirectional data exchange between public health data systems and primarily clinical data sources, but really the exchange of data and information between systems.

So you can see in the first link that I posted, it will provide you a link to the actual presentation to the HITECH as well as to the full report, and the second link that is in there is the presentation itself, if you just want to look at the slides. But the full report and the slides are available on that first link.

There were a total of 52 recommendations that the group put forward. So in 10 minutes I'm going to go through all 52, no, I'm just going to highlight a couple of them that are pertinent to the discussion today. So the first one that I really wanted to highlight and I think pairs nicely with the discussion that we just heard from CMS, is the need to really envision public health and the contributions of public health and its alignment with healthcare in new ways.

So one of the overarching cross-cutting recommendations is for ONC to work with federal partners to create a health data ecosystem that fully supports public health during a response to high consequence public health threats, and that the plan should create a healthcare paradigm shift where public health is a full and integral partner and part of the healthcare ecosystem. So often there are decisions made within healthcare that don't necessarily incorporate the data needs from a public health perspective or how that data should be shared across the ecosystem.

And so one of those cross-cutting recommendations was to really challenge us all for a new paradigm shift where we're not viewing healthcare and public health as separate, but viewing them in a much more holistic way so that we can work on standards and so many other things in this collaborative fashion.

The other couple of recommendations that I wanted to highlight, the next one being about the need for funding and support and infrastructure, so a specific ask within the document was for ONC to collaborate with CDC to educate Congress on the need to support a robust sustained consistent funding of CDC's Data Modernization Initiative to support the enterprise five key pillars in scalability during a response, and I'll talk a little bit about those five key pillars at the end, but specifically they are electronic case reporting, the National Notifiable Disease Surveillance System, lab data, specifically electronic laboratory reporting, the LIM system, the process for orders, vital record systems, the public health workforce. And then the couple that I wanted to highlight that are specific to this panel include two health equity recommendations.

So one of those recommendations was for ONC to collaborate with CDC, CSTE, state, local, tribal, territorial health departments, to ensure consistent collection of agreed upon standards for health equity data elements, including race, ethnicity, disability, condition, and resulting impacts, gender identity and sexual orientation, preferred language, as well as data needed for social determinants of health.

And within that recommendation there was recognition for the need for advancement of development of national standards describing more fully disability, and that those standards should encompass the physical, the sensory, and the intellectual component of disability. Additionally, there was a recommendation to ensure collection of language of choice or preferred language to ensure effective communication during the response.

And the last recommendation that I really want to highlight was for ONC to support the development for technology for patient use, such as while waiting in treatment rooms or other private areas or access, where those patients themselves could review and update their own soda data and the data collected in that manner that was patient provided should be available to all entities in the health ecosystem serving the individual and of course as permitted by applicable laws.

My apologies, there was one other that I wanted to highlight, and this was specific about address information and the need to require additional standardization of address information and collection to facilitate interoperability, geolocation, and merging with census data. So those were the highlights from the public health data systems task force that I wanted to cover.

Now I'm going to shift gears, and I want to talk with you about one other topic, and this is related to the last link that I posted, and certainly does also relate to one of the recommendations by the task force, and this is CSTE's work under the Data Elements of Health Campaign, and you will hear about this, as well from my wonderful colleague Shawna Webster, who is the next panelist.

I wanted this group to recognize that CSTE, as well as critical partners, NAPHSIS, HIMSS, APHL, as well as ASPO, NACCHO and the Big Cities Health Coalition and HIMSS, have joined together to really emphasize the need for data modernization. And this activity started pre-pandemic, but I think we can all appreciate how critical and important it is, and there were five key pillars that were identified in that.

And I did briefly mention those in the recommendation that the task force put together about the need to support those five key pillars. So again, electronic case reporting, the National Notifiable Lead Surveillance System, lab, data, syndromic surveillance data, as well as the vital record system and in particular death certificates.

And I will say under the efforts of this campaign, one of our overarching and guiding principles is that support of these activities need to be enterprise activities, and these data systems need to ensure interoperability, and I'll highlight as I close that there is a very high degree of interest for interoperability to support this pandemic between the vital records system and other systems, in particular of importance for our members is the interoperability between those death registration systems and the case management systems that are within the state and local, tribal territorial health departments.

So with that Denise I will pass it back to you for our next speaker.

Denise Love: Shawna, take it away.

Shawna Webster: Good afternoon, everyone. Thank you for the opportunity to add the State Vital Records Agency perspective to today's discussion. A little bit on the data provider side. I'm Shawna Webster, Executive Director of NAPHSIS, we are the nonprofit membership association representing the nation's 57 vital records jurisdictions, which includes all 50 states, New York City, Washington DC, and five territories.

I'm going to take you a little far afield, you're going to wonder where I'm going with all of this, but I promise I'm going to tie it up with a nice little bow at the end, so stay with me. So vital records are the very bedrock of all public health reporting, and even a lot of health reporting. The origin of individual identity is also within vital records. As such it is an essential component of the Data Modernization Initiatives Janet just mentioned.

When our states and territories collect birth and death data it's not just the fields you see presented on the certified copy, as this body I'm sure well knows, but for the benefit of folks at home, the standard birth certificate contains at least 58 fields, and for death it's 55.

Those fields are based on the 2003 standard certificates produced by NCHS, though most jurisdictions add a few of their own fields as well. So that's what makes up the backbone of all public health reporting. Well over 100 data fields for each individual, filled with a goldmine of health and demographic information.

But it's the mortality data that's been in the news lately because of COVID. And now there should be no question that timely, accurate death data reporting is absolutely necessary to promptly assess and respond to outbreaks or natural disasters or anything with a high mortality rate. Any improvements or additions to this reporting or really just to sustain where we are right now requires a more modern vital records infrastructure that supports real-time surveillance.

And one that is interoperable with other surveillance systems and other case reporting systems as Janet just mentioned as well. Those advances require sustainable and coordinated investment to upgrade legacy systems that are now five, ten, or even 15 years old. And vitals are just one of the four pillars of the data elemental to health campaign that supports CDC's Data Modernization Initiatives.

And even though I describe vital records as the backbone, that doesn't necessarily mean that they are easily accessible, or that they're able to be easily linked with other important datasets on the fly. And that's for a variety of reasons, but one of them is the legal issues, the legal barriers that vary state to state as Denise mentioned at the top of our panel.

Recently through the Data Modernization Initiative CDC funded vital records through the epi and lab capacity grant to move towards implementing FHIR in the electronic death registration systems. But the majority of our jurisdictions describe themselves as not being ready for this.

This two-year funding, which is just over a million dollars for each jurisdiction, which is fantastic, don't get me wrong, should move us forward, but it's going to take time. We're going to need additional time and funding to fuel basic infrastructure improvement, workforce, and to implement all of these new standards that you've all been talking about all day. So I would strongly encourage the committee to weigh in on the Data Modernization Initiatives, and recommend that HHS support every effort they can to make vitals more of a priority across CDC and other federal agencies who rely on vitals data.

Because every part of every level of government needs access to vital records data, whether it's for statistical and research purposes, fraud and identity theft prevention, or for real-time health surveillance. Each use case requires vastly different skillsets, technology, timing, and accessibility.

And the data saves them billions of dollars every year on the administrative side. Shouldn't those use cases help support the public health use cases? But also I think the committee could encourage HHS to advocate for other federal agencies who use vital records data for those administrative purposes, and have them pay their fair share of systems cost.

In 2015, SSA testified, this is the Social Security Administration, testified that the state death data that they receive saved them over $50 million per month in stopping improper payments. Back in 2015 they paid all of the states combined less than $10 million. And that figure hasn't really changed over the past six years. SSA already has the authority to share state death data with other benefits paying agencies like the VA, the IRS, CMS, and others. And how much money are those agencies saving per year in improper payments? Hundreds of billions of dollars. And they don't pay the states at all for that data.

Recent legislation has set a timeline to expand SSA's authority to share state data with any other federal agency or state agency within a three-year timeframe. That means their contracts with the states need to be renegotiated right now. And NAPHSIS will need all the help it can get to convince SSA that it should pay the full price of the data if it's going to become the broker of death data for the entire government system.

SSA needs to reimburse the states at a rate that actually supports them, otherwise this legislation will end up gutting their ability to sustain their revenue and their services. It won't take long, and that will have a devastating effect on the quality and timeliness of the data and all of the work that all of you do when you receive this data or get access to it.

So why do I bring this up? Aside from the fact that while the Data Modernization Initiatives at CDC are crucially important and must be supported, public health shouldn't be the only entity to have to bear the burden of supporting services like vital records. It can't. We've seen that proven over the last two years in the pandemic.

But if SSA were to pay something like a full price for states data, that would really go a long way to build those foundations for data modernization, all of the infrastructure that goes into it. The legislation that expanded SSA's data sharing authority also commissioned a study of death data conducted by the National Academy for Public Administration.

It might be useful for this committee to weigh in on this subject, to shed light on the issues surrounding security, standards development, interoperability. You have a unique perspective and a unique set of expertise that could really help them in their role in providing a report to Congress. Also, SSA has recently approached NAPHSIS about the possibility of including race and ethnicity data along with birth and death notification.

So theoretically, with expanded reimbursement to the states, and expanded data sharing between federal agencies, NAPHSIS could facilitate possibly an expansion of the data fields that are shared as well. Nothing has really come of this discussion yet, but I thought it would be a useful idea for this group to discuss. Lots of possibilities.

And I think we're really at a crucial opportunity moment to affect the way that vital records are funded across the federal government so that CDC and health don't have to support the entire operation when really vital records is about both the health, public health, statistics data that they produce, and also in the individual identity that is used for all of those administrative purposes. I know that's a lot to process, so I'll stop there for the moment and turn it over to our next speaker, Evelyn. Thank you so much.

Denise Love: Thank you Shawna. Evelyn.

Evelyn Gallego: Thank you so much to the NCVHS team for the opportunity to speak to you today about the Gravity Project. I also appreciate hearing from the other panelists throughout the day mentioning the Gravity Project. For those still curious about what we are and what we do, I'm delighted to speak about it today. I'm Evelyn Gallego, I currently serve as the Program Manager for the Gravity Project, I'm also one of the cofounders.

Also, delighted to have heard from Vickie, who mentioned Dr. Laura Gottlieb from SIREN. SIREN is the original founder, we cofounded it together with funding from the Robert Wood Johnson Foundation, very much building on the significant work that SIREN does under Dr. Laura Gottlieb's leadership to gather evidence on integrating social care in clinical settings. I'm also the CEO of EMI Advisors, we're a small consulting firm outside of the Washington DC area.

So a quick agenda for what I'll go through today in the ten minutes we have together. It's really, again for those who don't know what Gravity is, telling you the why of our work, which has already been emphasized through this panel, the what of our work, and then I've given our topic is really how can we scale our work within public health, so I'll spend some time there.

So again, borrowing from Dr. Laura Gottlieb, this visual, if you haven't seen it already, and she uses it for her presentation, really the context of the why of our work. We want to emphasize the existing challenge healthcare providers face today in treating patients when they often focus on the acute or health related issues without considering the underlying social determinants.

And we've talked about what we mean by social determinants, completely agree, words and language are important. What I want to emphasize through this image is why we focus on this is because

healthcare systems today are poorly equipped, and also not fully accountable for addressing these determinants as they would with regular acute problems.

So we see today a growing interest from health industry stakeholders around addressing SDoH in clinical settings, and we've heard today of course as more healthcare organizations are increasingly being pressured to shift from fee for service models to value-based payment models, we have clear business case for doing this from both health systems and payers, however we still face challenges around SDoH data capture and exchange. And this slide highlights key areas outlined in the National Association of Social Determinants of Health Data Interoperability Report they published last year, and today I'll focus on two of these, which are the standards and data sharing between ecosystems.

So this brings us to the Gravity Project. The goal of the Gravity Project is to develop consensus driven data standards to support the use and exchange of SDoH data within the healthcare sectors and between healthcare sectors and other sectors. We focus on developing data standards for multiple SDoH domains as listed here. We initially started with food insecurity, housing, and transportation, and have evolved since then and continue to do so. The domains are grounded by those listed in the National Academy of Medicine or NAM 2014 report, the link there is at the bottom.

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 data captured across the four clinical activities of screening, diagnosis, goal setting, and interventions.

The Gravity Project is not an entity. We are a project funded by multiple organizations through existing funding mechanisms. Here is a snapshot of the various organizations that sponsor, provide in kind support, including the federal agencies, and most recently we've added CMS to our executive committee, so very excited to have CMS involved.

Here is our roadmap that we're actually in the process of updating for 2022. But this is to highlight our trajectory for our two active workstreams, which is the terminology workstream where we work ion the SDoH dataset, and the technical workstream where we have primarily been focused on developing the FHIR implementation guide and reference implementations.

I'm in the process of standing up our new pilot workstream, which will focus on testing the new terminologies and the FHIR implementation guide. The green line is where we are in our timeline. In 2020 we completed the domains of housing instability and homelessness.

In January of this year, we completed the domains of inadequate housing, transportation insecurity, financial insecurity and demographic status, including education, employment, and veteran status. We recently completed material hardship, and are working through completing stress, intimate partner violence, elder abuse, and social isolation.

So we've broken them up between the activities we work on. On the technical workstream lane we just completed, so early this month, HL7 formally published the FHIR Implementation Guide as a standard for trial use, and we've also completed development of reference implementation that will be used for upcoming testing events.

So focus on terminology. When We talk about the terminology domain, we really speak about defining these data concepts for SDoH, and many of these that have not been, I would say consensus driven defined. And there are different interpretations again, language, words matter. So we ask ourselves

when we kick off any new domain we say what concepts need to be documented for that domain within these four activities you see there on the left-hand side, screening, diagnosis, goal setting, and interventions.

And after we define these concepts, we create language for them, then we ask what codes exist, or what new codes need to be developed. And when we talk about codes, they're very specific to the activity. So what you see here is LOINC, primarily to code for screening question-answer pairs, and for goals, ICD-10 primarily for diagnosis, and SNOWMED cuts across observations that tie to the ICD-10, and then for goals and primarily for interventions.

Last year the Gravity Project made a formal submission to the ICD-10 coordination committee for new SDoH diagnosis or Z-codes for the domains we've worked on to date. In June of this year we were very excited and pleased to hear from the ICD-10 committee that they approved the publication of the codes submitted for education, food insecurity, and housing, and those are ready for release October 1st of this year.

So how we accelerate the adoption of these nationally recognized standards is by incorporating the standards we use to define the data, the semantics, into the standards we use for syntax, for structure, and transport. So what we use to move the data from one system to another or to expose it. Each of the coded data concepts across those four activities I mentioned are represented for exchange in the HL7 FHIR specification, and I mentioned we just completed the FHIR IG. As noted in this visual, the goal is to integrate these standards into existing and evolving standards being developed by other projects.

Also I'll spend more time on USCDI, and we are, I failed to mention, the Gravity Project became an HL7 FHIR accelerator in August of 2019. So we are very much focused on advancing the FHIR specification, and it's really important for our work to integrate with other FHIR accelerators, including the Argonaut, Project Da Vinci, CARIN work, CodeX, and Vulcan. And I will speak more on the regulatory side in the next slide.

So I mentioned the Gravity FHIR IG was published as a standard for trial use, version one in August. The IG itself, for those not familiar with FHIR, they are published as an HTML site or webpages. The IG supports all those clinical activities I mentioned around screening or gathering assessment data.

It also incorporated health concerns, problems to inform the diagnoses, goals, interventions which include referrals or closed loop referrals from a clinical setting to a community-based organization. It also has two overarching use cases, the ability to capture consent and across these activities, and aggregating the data for upstream and downstream use, including research and public health reporting.

We've accomplished a lot since we kicked off our initiative in 2019, but we say our success really ends or is based on the ability to integrate these data standards into other areas. So really important, we'll talk about policy next, including the data standards and payment model. So as we heard from LaShawn earlier, that we work very closely, the Gravity Project does work very closely with the Office of Minority Health, and also with the CMS Innovation Center, and how we can integrate the standards in new innovation models.

Working across programs, I'll talk about Medicaid next. Other standards I mentioned, grants, practice. This is where we still need to do more work around creating a repeatable process for adopting, using, incorporating the capture and the use of this data into workflow, and then innovations, we want to

encourage the development of new tools and technologies that support the aggregation and analytics and use of the data.

Our success factor number one was achieved on July 9th of this year, when ONC officially announced the inclusion of the SDoH data class in USCDI version two. With this addition health IT stakeholders nationwide will have a clear direction toward standardized electronic exchange of SDoH. This lays the foundation for the provider community to start systematizing the capture and use of this data in clinical settings, and adopt technologies or these new innovations, with the capabilities to perform this work.

In January, CMS published guidance for states on opportunities under the Medicaid and CHIP programs to address SDoH. The guidance clarifies how states can use federal funding to support the implementation of a technical infrastructure that integrates health and human service programs. The letter directly encourages states to incorporate SDoH standards as published by the Gravity Project.

In addition to policy integration, Gravity standards have been incorporated in two existing grant programs. The first one is administered by the Administration for Community Living or ACL. They have an active social care challenge program right now, there are 12 awardees or winners, and they're all incorporating the Gravity standards.

And then last week, ONC announced the award for the Leading Edge Acceleration or LEAP Project for referral management to address social determinants of health aligned with clinical care, and this was awarded to the University of Texas at Austin, and we will be working with them, they are integrating Gravity Project use cases.

So how can we scale this to public health? So I'd like to leave you today to think about how we can build on this work to promote interoperability of SDoH data in public health programs. So in addition to the CMS guidance, I just talked through, public health agencies have several levers as well as the government in that they can use to encourage, consent, and require the use of the standards.

So for one, you can start now to incorporate the standards and public health reporting requirements, to set the expectation for data sharing, security, and compliance to the standards. We're starting to see some of this already again tied to COVID where there are some requirements to collect structured data for COVID based interventions.

So hopefully we can see a lot more of that. That's also why the ICD-10 CM information, the coordination maintenance committee was very much interested in education, housing, and food, because of its relation to COVID based interventions. Federal and state agencies can also provide specific technical guidance for public health providers to use in the procurement specifications.

So for example if they're going into, they can incorporate the standards in functional and technical requirements for a new EHR system or the development of a public health registry. Agents can also strategically embed incentives for adopting technology capable of sharing standards based SDoH information.

And then finally agencies can finance testing and piloting of the terminology and data exchange standards with data sharing partners. And all of this comes from a report released in 2014, another NAM report on procuring interoperability. I love to tie it with different levers across different stakeholders, but it does do a nice job of highlighting opportunities for standards adoptions.

So I conclude with questions, and the next slide is just how you can reach me. And that's how you can join us. We meet publicly on the domain work every other Thursday and every week on Wednesdays for the FHIR IG. Thank you.

Denise Love: So we will open it up now for questions, I think. Can I start? I have so many. And Denise, maybe this is better directed to you, but I'm sitting here thinking about, first I'm going to start with Evelyn.

We have 50 states or more that have statewide hospital reporting systems. We have over 20 states with all payers claims database systems. These are often reporting requirements that are embedded in either legislation or regulation.

The practice has been to go to the lowest common denominator, which means if you have race/ethnicity we'll take it, but the providers and payers say they don't collect it, and it's a huge burden, so we end up in some states with 40 percent missing, or more. So how do we, with your excellent work, it's obvious that providers have a little, maybe more capacity for reporting these things. And so how do we move these into some statewide mandates and regulations to raise the bar for everybody.

Evelyn Gallego: I think the inclusion in US CDI is a significant first step. That can also inform future rulemaking. So there's an opportunity there from levers. The states themselves, I've seen some states already embedding, again not all standards based, but have requirements for capturing SDoH data and reporting it, very much many of them tie to the Medicaid program. I think there is significant opportunity to do it from a public health perspective, that is ongoing. I think also the ability to capture COVID data, I know there are other projects on standardizing that, it can be embedded.

Part of your collecting data regarding COVID can incorporate social risk and social needs data, and our work within the Gravity project is to define those concepts and have those standards available so that they can be plug and play. For us we say we're just creating the footprint that can be adopted and integrated into different areas.

Denise Love: Your work is important, so I applaud what you're doing, because I think it will move the industry, and if the industry moves then our downstream reporting will improve. But one other quick question.

Rebecca Hines: Denise, Vickie Mays is short on time, and she has her hand up.

Vickie Mays: I wanted to ask about this issue of standardization, because it bothers me when it comes to this issue of race and ethnicity. It's not as if we don't have a set of standards, but what happens is we get ourselves down to the lowest common denominator, and for the State of California standards have been put into place sometimes where it doesn't help us, we have to collect data more broadly. In Michigan they might have a different group, and they want to have the African Black group in greater detail.

So I'd actually like to ask Janet Hamilton in terms of the thinking with CMS for the collection data on race and ethnicity where they stand, you did use the word standardization, I'm trying to figure out whether this standardization would allow this to be by the diversity that we need.

Janet Hamilton: Thanks Vickie for your question. I would just offer too, if CMS wants to comment more fully, if our colleague is with us, on exactly how they are implementing that, because I do think one of

the things that we have really realized in public health is that we have used for many years at least on a communicable disease side categories that were set forth many years ago by OMB, the Office of Budget and Management, and they really don't fully represent the way people see themselves now.

So it is a limited number of race categories, and particularly when we're asking people to self-report how they see themselves rather than maybe a clinician assigning race based on someone who comes in and/or only giving people the five race categories, it doesn't really allow them to fully describe themselves, and I think it does also really present challenges for us in public health when now we want to make data publicly available, and people want to see themselves and find themselves and understand their risks as compared to others, and we have these much larger categories that we can't really separate people well with.

Vickie Mays: Maybe I'm not clear enough. The capacity, and this is what I'm trying to understand in terms of states and territories and others, the capacity exists. OMB does not require that you not do it. But what has happened is that people are drilling to larger categories, and I have yet to hear the support for states or the requirement for the states to actually do this, in a public health context, to actually collect the data that would be useful. I mean I've heard a lot of recommendations, I'm trying to understand that as a potential one, because we can collect data to the Nth degree, but we don't, and it has to do often with cost, it has to do often with time. So I'm trying to see as these other things are being asked if that's not something that would be a recommendation.

Janet Hamilton: Let me make a couple of comments, and LaShawn maybe has to leave, so I'll let her go first, Dr. McIver, and then I do want to respond to that because I think there are a couple of critical things to comment on. But please go ahead.

LaShawn McIver: I would answer your question Vickie by saying that we are looking at very expansive strategies on how to collect the best data for our populations. In the past we have been thinking about, some of our work has centered around those OMB standards that Janet mentioned.

However, I think we're at a point where we are looking more broadly at what this opportunity, given these directives from the President on getting it right in this moment, and how do we propel this forward. We are looking very closely, that's essentially what I can say at this moment, but I'm excited for what's ahead because I do think we will see some positive steps taken by CMS in our role and being able to contribute to this.

Janet Hamilton: I would just add from a public health perspective and from a disease perspective, states and jurisdictions consistently have a law that asks for, I'm just going to say without going into the refined categories, race and ethnicity to be reported, and specifically in the context of COVID it's a requirement. What's not happening is the data is never making it to public health. And now in this resource constrained environment, trying to close that gap is very hard. So it's often been done through an interview process or other types of ways to fill in the gaps and what we would really like to see is when reports are made initially the information for race and ethnicity is complete.

And we have a space for it right now, so I don't think we need support for another space to collect it, but if we could get the provider community to give it in the same way that they've maybe collected it when a patient goes in and attests to their race and ethnicity when they're in that encounter, we could like it to flow to public health, and right now that's not happening, and it's leading to huge data gaps and problems.

So I think as we work in this space, and it's wonderful to hear the work with CMS, my hope is that we can also have that information actually seamlessly, electronically be transferred or provided to public health so that we don't continue to have these major gaps. I don't know Vickie if I'm fully addressing your concerns.

Vickie Mays: It's fine. I just think that the flow for me is the other way, it's not trying to put it on the provider and the healthcare system, but public health has a much broader set of records in which the linkage could actually provide the information. We have a birth certificate. I don't always think of the provider, that's why I'm asking in the sense of public health, but I know we're short on time, so I want to make sure that --

Janet Hamilton: I would love to think through this with you too. Many times, public health will only get a name. And so even though maybe we have a birth certificate, if we can't get enough information about the individual to do the matching, we also can't fill in the gaps.

So if you get Janet Hamilton and that's it that's reported to you on a COVID case, am I going to match you with that right information even if you had my birth certificate? So I think we also need, this was included in those public health data system reports, at least a minimum amount of information that goes with a person so that we can do the right matching.

Obviously if we had individual patient numbers potentially, I know that's been talked about for many years, some type of national medical number, that would be different. But in a space where we don't have it, if we don't have enough minimum information, including race and ethnicity about a person, we can't fill in the gap even if we have 1000 data sources where maybe it exists.

Denise Love: As we collect more information, and Janet, I really hope that public health enforces some of these data fields and collections, because they are becoming available, and they are critical for linking and others, but another thing I worry about, especially as we get into SOGIE and the gender splits and refined categories, are we, and maybe this is Denise Chrysler, the more we collect, if we're fortunate enough to be able to collect what we need, does that mean the less we can release, because we get into the fun of disaggregation and patient identity on the backend when we release it publicly.

Denise Chrysler: I'll just mention collection is a lot easier than releasing in the sense of collection there's often a lot of authority to collect very granular data, but when you release, the more granular, the more characteristics, the greater the risk of identifiability, and that's where you need to use your masking techniques and your aggregation of data and all those sorts of things, if that's what you're referring to, Denise.

Denise Love: Yes. For decades, collection is one thing, but releasing is quite another, and when I worked at NAHDO, the number one frustrating call that I got was there's all these data out there, these states maintain, but I can't get it. I can't get it for research. Or it takes a year of data oversight, board review, to get the data, and in a crisis that didn't work very well, when we had third parties trying to look at the data from a research perspective.

Denise Chrysler: Denise, let me just throw out to our panel, one of the challenges and why things can take so long is not only do laws vary with each state, they often vary with each data set. Do you see any potential for some sort of resolution, we think of like a master data collection and protection law, or something to deal with all the variability, so we seem to have to develop solutions for each jurisdiction.

Denise Love: Like an uniform code.

Denise Chrysler: Uniform code could be one possibility. We have a uniform commercial code, why not?

Denise Love: Shawna?

Shawna Webster: I think from the vital records perspective obviously I think the states are sort of in between a rock and a hard place. They want the data that they collect to be useful, they want it to be used, but they do not have the bandwidth or the political ability to fight the fight in state government to get those laws changed easily.

So I think there are opportunities for federal pressure that can help loosen some of those things up, especially in the case of a pandemic, but I haven't seen anything yet come down that would sort of tie those things together or get rid of those hurdles, because the hurdles are a little bit different in every state, unless there's sort of a federal mandate level issuance then it's tough going, it's really tough.

Janet Hamilton: I think the space is getting more complicated instead of less complicated, because it's also true as more and more data is available and different types of datasets, the opportunities for discovery are there, and I think state and local health departments take their job of stewardship to protect privacy very seriously.

And so as you make datasets available, and now people are interested for many reasons, and rightly so, in finer and finer detail into those, it does allow other opportunities, especially in this digital world, for maybe linkages to occur in ways that when you're looking at a dataset individually you're not necessarily thinking of some of those triangulations.

So I don't have an answer in terms of solutions, but I do think it's something that needs to be carefully and critically addressed so that we can make improvements, and maybe there's opportunities to look at how we can distinguish making certain things available for research versus public datasets and what that could look like.

Shawna Webster: That is one of the reasons I brought up the whole SSA use case. There are going to be many cases. Vital records was not onboard with this. We are 100 percent behind stopping improper payments and fraud prevention and all of those good things, but we have real problems with SSA being the arbiter of death data for the entire federal government, because those state laws, they're not going to flow through SSA.

SSA doesn't have the capacity to take every customer that comes knocking on their door for death data and say well how are you going to protect the security of that data, how are you going to keep it from being reproduced, all of the security issues, all of the legal issues. It's going to put SSA and other federal agencies in conflict with state law. But it's going to happen. So regardless of the conflict with state law, SSA is going to do this.

Denise Love: Do they have a governance in place for that?

Shawna Webster: No.

Denise Love: It could work with the right governance structure, but it also could just lock it up for just friends of SSA.

Shawna Webster: We will see. Like I said it's going to happen, so why not make the most of this opportunity and have the data be accessible through the federal government agencies, and have the data be more robust than perhaps it is now? Maybe that's how we get around 57 different vital records laws creating hurdles for research and data use and all of those things.

Denise Love: How do we make it more robust?

Shawna Webster: I think that's a conversation the feds have to have with SSA. If SSA is going to be the agency that has the authority to do this, and share it with all the other agencies, then the entities should have a say in what they collect maybe.

Rebecca Hines: Denise, I just can't help but wonder where the evidence act comes in here, because a big part of the Evidence Act, you said the feds Shawna, well they are all feds. SSA is federal, HHS is federal, CMS and CDC are federal, and the Evidence Act is about how federal agencies share data.

So it seems to me there is an opportunity to take what's relatively recent, and it's not fully implemented, the Evidence Act, and work towards a rational approach, given that now there's an act in place that actually would support what you're laying out. I don't know how familiar you all are with the Evidence Act, but it's all about federal agencies sharing data. It's a little different than what you're saying, it's sharing data among, within, but it is related.

Denise Love: I think what I understand, it would be helpful to have other people at the table when these decisions are made, and not just SSA and their customers. And so I think that will be important to monitor and to advocate for. Are there any other questions on this topic?

NCVHS Standards Subcommittee Discussion

Rebecca Hines: So we are in the part of the agenda actually now for discussion for the day writ large, just go beyond panel four to include all the panels, didn't know whether we wanted to reengage all of the subcommittee members now Denise?

Denise Love: Sure.

Rebecca Hines: Rich, maybe you want to lead us until we hit public comment at 5:15?

Rich Landen: I'd be happy to do that. I think it was just an overwhelmingly informative day, and my thanks to all the panelists, and certainly then to the subcommittee members and staff who helped put this together. I think this gives us a lot to think about in terms of a diverse set of needs and what we as NCVHS might be able to bring, some organization to some of the chaos, and some future thinking, potentially some recommendations that will help coordinate and focus and address some of the opportunities and the issues that were generated today.

I've been keeping some notes, and I think there are a number of themes we heard particularly early on in the day about what's not working with the current system, I think we heard compelling argument for the need to look at how the HIPAA transaction and code set regulatory process needs to work with the emergence of the APIs and FHIR and all the work going on there. I think it will be challenging to us as we heard from the Division of National Standards, there's a whole set of requirements that the regulator must comply with in order to get a proposed rule out the door.

So there's a lot of moving parts to the puzzle, but I think the primary benefit as I see it today is trying to get ourselves looking at the larger picture, not just the HIPAA transactions, but how the data flows, work among the different terminologies and vocabularies, crossing the sectors of the industry, moving into new sectors as we talked about with the social determinants and structural determinants, SOGIE, and then bringing a little bit of order to the chaos while protecting some of the critical aspects of the system, and I heard a number of players reiterate the need for the basic approach that this country takes, which essentially is voluntary consensus standards, but then implemented in such a way as we get policy decisions are supportable, return on investment is demonstrable, and that we manage the system a little bit better than we have over the previous years.

So that's kind of the big picture, let me open it, well before I open it to the subcommittee members, looking at the slide on the screen now, as we mentioned this morning, we had over 30 letters, written letters with comments, recommendations, thoughts, concerns, and they're all available on the website. Some of the themes here, and thanks to Denise Love and Loraine Doo for pulling these out. You see some of the common threads that we gleaned from an early reading of the submitted comments. You can read those for yourselves.

But there's a lot of food for thought there, and in the subcommittee deliberations as we go forward and kind of feeling our way toward potential recommendations we will read these letters carefully, go back and read them again for the detail, and then as I mentioned this morning, we intend to do some reach out to those panelists and those submitters of the written comments to follow up in some more detail.

Again, I want to reiterate that we only had one day for this, there are a lot more organizations we would have loved to have heard from, who could have contributed significantly to the conversation, but again thank you to the panelists who did for sharing your time, your perspective, we do appreciate the effort that you put in to organizing your thoughts. And so clearly articulating the state of the art in your neck of the woods. So now I'll open it to the subcommittee members for observations, questions, discussion.

Denise Love: I think this going to take us a long time to digest, 200 pages plus of comments, and today's content. But it's clear that both industry and experts are seeking change. And I hope we can find the right messaging and engage with the appropriate parts of HHS to hear that messaging, and pinpoint where the change needs to be led from.

Rich Landen: Subcommittee members, last opportunity.

Jamie Ferguson: One thing, I was just reviewing my notes from the different panels today and looking at connecting the dots across the different subjects that we talked about. I really thought it was noticeable that one of the best ways to have consistent SDoH data and to converge administrative and clinical data, and it was said that the best way to achieve semantic harmonization is actually to capture data in just one way, with one content standard at the point of origin. And so this will require different standards for different purposes, but then assess compliance with the content standards.

And I also heard that standardized cross maps have value, but adherence to the original content standards has more value. And so that leads me to think that one of the things we should focus on would be a roadmap to achieve more consistent implementation and compliance with the content standards from the point of origin.

Rich Landen: Good observation. I just can't resist to point out that in this ecosystem, across all the different sectors of healthcare and wellness, there are for many things more than one point of origin. So

figuring out is there wone source of truth, if not how do we manage that, and what happens when they conflict, but that's just part of our challenge.

Jamie Ferguson: Exactly. That is where we get into there are different content standards for different purposes that are used at the different points of origin, and that's where we may need to look at standardized cross maps where it's appropriate. But we're not necessarily currently assessing the conformance or compliance with those content standards at the different points of origin.

Rich Landen: I think that came out from the first panel, that there are things that we could be doing differently than under HIPAA for that conformance assessment, and whether we call that enforcement or conformance assessment, semantics, it's the thought of it's not just enough to write a standard, but for the transaction as well as we heard about CPT and some of the other terminology vocabularies and code sets, that they're designed for specific purposes, and while they may well work for that purposes, when we try and use them elsewhere we run into the semantic interoperability issues that we talked about with Jim Cimino's panel.

Denise Love: I will bring this up, and we may have to finish this after the public hearing, how much possibility or authority or probability is there to expand HIPAA? Because expand covered entities for instance. We heard that today too, and I've heard this before, how does that happen, and how does the committee address that?

Rich Landen: That will be part of our ongoing dilemma about what is within our scope to recommend because our charter sets us up as an advisor to the secretary, and we've had discussions historically for decades preceding all of us current members about how far outside that we can go.

If we touch legislation, if we touch the role of the federal role versus the state role, there are certain things we can do, but then there are certain boundaries that we cannot cross by the structure of our charter. So within the structure of the charter, can we get creative? Do we have a bully pulpit? Yes, we do. But it depends a lot on ourselves and a lot on the support mechanism we get from our structure within ASPE.

Denise Love: Thank you.

Maya Bernstein: I put it in the chat, but the committee is free to make recommendations to the Secretary suggesting that he propose legislative changes to the Congress if that's required. And the committee has done so in the past. You can make a recommendation that HIPAA needs to be expanded, either by the kind of materials that it covers or the kind of covered entities, that's fair game for the kind of recommendations you could make. And in fact, I think back in 2006 the committee recommended that all health information wherever it be found should be covered by some base level of protection, whether or not HIPAA was the right model.

So those kinds of things, you can make recommendations as long as you're making them to the Secretary, but of course the Secretary has the power to promote legislation through its normal channels, it has to be cleared and so forth. But the secretary has the power to promote legislation, and you can recommend that. I don't want you to feel too constrained about being creative about the kind of recommendations you can make.

Denise Love: That is helpful. I am mindful of the public comment period. Is it now?

Rich Landen: And then the subcommittee will take up the deliberations at our regular biweekly meetings, and we will give a preliminary report out to the full committee at our upcoming meeting in September.

Public Comment

Rebecca Hines: Thank you Rich. If we could pull up the instructions for the public comment, and you can have live audio or type it into the Q&A or send email. Greg, if you could review the instructions for public comment.

Greg Richards: Sure thing. If you would like to submit public comment, please click the raise your hand button at the bottom of your screen to indicate that you would like to do a verbal comment. If you are on the phone, you can indicate that you would like to speak by raising your hand by pressing the star nine key. If called on, it is star six to toggle mute and unmute.

Otherwise, if you would like to submit a text comment, please feel free to use the Q&A box at the bottom of the screen, if you're doing a verbal comment when called on please provide your name and organization. And I see a public comment from Isabella Chu.

Isabella Chu: So first of all, I want to thank Dr. Webster so much for her presentation. I think it was a very lucid and comprehensive overview of some of the challenges and opportunities with vital records data. I in my professional life manage a data core for an academic medical center, population health sciences data core.

And one of our biggest challenges has been being able to get death data at a price researchers can afford. The pricing models were set prior to the widespread digitization of data, and so for many of our cohorts the purchase of the death data would subsume the budget of the entire lab for a decade. And so it's just become sort of a non-starter.

And so as you think through how to enable access to vital records data for public health, my only request would be to really think about how that same data can be made available for research, and certainly research is able to pay something, but it's not resourced to sort of robustly support Offices of Vital Records. Thank you.

Rebecca Hines: Thank you Isabella. And can you just reiterate what organization you're with?

Isabella Chu: I am making this comment as an individual, but in my day job, I manage an Academic Data Core at Stanford Research University.

Greg Richards: Once again, if you would like to submit public comment, please us the Q&A button at the bottom of your screen to submit a text comment or use the raise hand button to indicate that you would like to give a verbal comment If you are on the phone that is star nine.

Rebecca Hines: Okay, I hear silence. Rich and Denise, I think we can move towards wrapping up. And just for the public, if for some reason you have trouble getting through, please do use the email option for sending your public comment, and we will append it to the meeting summary. Thank you.

Closing Remarks and Adjournment

Denise Love: Thank you all the panelists, and thank you the subcommittee, and thank you staff. My head is exploding.

Rich Landen: I think we have some interesting work and some heavy lifting ahead of us, so echoing Denise's appreciation to panelists and staff and subcommittee members. Expect us to call upon you again as we crunch the information and try and translate that into recommendations for the country. So thank you all very much, and much appreciated, and I will pound my virtual gavel.

Rebecca Hines: I just want to extend a huge thank you to Mariette Squires and Lorraine Doo, for the incredible amount of work you both did pulling this together, bringing together these experts and making this happen. And to Greg Richards and Kim Williamson for the Zoom management today from RLA Associates, fabulous work, it's not easy to do these meetings virtually, I know we prefer to do them in person. So just thanks to the support team behind the scenes and our experts behind the scenes. Thank you all. This is definitely a team sport.

Rich Landen: Okay, I think we can call this a wrap. Gavel is banged, thank you all very much.

Denise Love: All the slides are going to be out there on the site, is that right?

Rebecca Hines: They will be. And come back the morning of September 10th and the afternoon of September 9th, we'll be doing some follow-up with the full committee. So stay tuned as we move this forward.

Denise Love: Thank you all.

(Meeting adjourned at 5:22 p.m.)