National Committee on Vital and Health Statistics

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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Catherine Donald	Alabama Department of Public Health	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Tammy Feenstra Banks	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Angela Alton	City of Hope	Member
Melissa M. Goldstein	The George Washington University	Member
Michael Hodgkins	Healthcare Consultant	Member
Richard W. Landen	Individual	Member
Valerie Watzlaf	University of Pittsburgh	Member
Vickie M. Mays	UCLA	Member
R. Lenel James	Blue Cross Blue Shield Association	Member
Steven Wagner	University of Pittsburgh	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Gwen Mustaf	NCHS	Staff
Donna Pickett	NCHS	Staff
Marietta Squire	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Travis Hoppe	NCHS, CDC, HHS	Associate Director for Data Science and Analytics
Greg Singleton	ICIO, IO, HHS	Chief Artificial Intelligence Officer

Gil Alterovitz	National Artificial Intelligence Institute	Chief AI, Officer, Director
April Foreman	Veterans Administration	Deputy Director of Technology & Innovations
Farhan Khan	FDA, HHS	Director of Operations and Delivery
Lakshmi Grama	NCI, NIH, HHS	Assoc. Dir, Dissemination & Digital Communications Officer
Asif Rizwan	NIH, NHLBI, HHS	Program Director
Kathryn Marchesini	ONC, HHS	Chief Privacy Officer

Call to Order/Roll Call

Rebecca Hines: Welcome to Day 2, everybody. It has been a good 24 hours. I hope you all got a decent night's rest. We have a wonderful panel here today. Why don't we start off and take care of roll call? Right now, we have about 30 people from the public online. I am sure as we move forward that will increase. Let me turn it over to our chair to start us off.

Jacki Monson: Good morning, everyone. We will start with roll call and then I will go through the agenda. Good morning. Jacki Monson, Sutter Health, Chair of NCVHS.

Rebecca Hines: I am going to go in the other direction. Val, you are up.

Valerie Watzlaf: Val Watzlaf, University of Pittsburgh, member of the Full Committee, Co-Chair of the PCS Subcommittee and member of the ICD-11 Work Group. I have no conflicts.

Denise Chrysler: Good morning. Denise Chrysler with the Network for Public Health Law. I am a member of the Full Committee, a member of the Privacy, Confidentiality, and Security Committee and I have no conflicts.

Michael Hodgkins: Good morning. Dr. Michael Hodgkins. I am an independent consultant. Member of the Standards Subcommittee. Member of the ICD-11 subcommittee. I have no conflicts.

Vickie Mays: Vickie Mays. Member of the Privacy, Confidentiality, and Security Subcommittee, member of the Executive Subcommittee and member of ICD-11 Workgroup and I have no conflicts and I am at the University of California Los Angeles.

Angela Alton: Good morning. I am Angela Alton from City of Hope. I am a member of the Full Committee and serve on the Privacy, Confidentiality, and Security Subcommittee and have no conflicts.

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

R. Lenel James: My name is Lenel James, Blue Cross Blue Shield Association, member of the Full Committee, member of the Standards Subcommittee, have no conflicts.

Wu Xu: My name is Wu Xu. (inaudible)

Steve Wagner: Good morning. Steve Wagner, member of the Standards Subcommittee.

Rebecca Hines: Remember to speak up. Thanks.

Catherine Donald: Good morning. Cathy Donald. I work for the Alabama Department of Public Health. I am a member of the Full Committee and the Workgroup on ICD-11 and during discussion about reproductive health standards and HIPAA, I will recuse myself.

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

Jamie Ferguson: Good morning. Jamie Ferguson, Kaiser Permanente, member of the Full Committee, Subcommittee on Standards, the PCS Subcommittee, and the co-chair of the Workgroup on ICD-11, and I have no conflicts.

Tammy Banks: Tammy Banks, member of the Full Committee, Executive Committee, co-chair of the Standards Subcommittee and no conflicts.

Rebecca Hines: Thank you. And online, Melissa.

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

Rebecca Hines: Beautiful. We have a quorum. Very good. Let us turn it over to Sharon Arnold.

Sharon Arnold: Sharon Arnold. I am the Executive Staff Director of NCVHS. I am the Associate Deputy Assistant Secretary of ASPE, Science and Data Policy, in the Office of the Assistant Secretary for Planning and Evaluation.

Maya Bernstein: I am Maya Bernstein. I am the senior advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation. I work for Sharon. With respect to the committee, I am her lead staff in the role as Executive Director and lead staff to the Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Lorraine, are you in-house this morning? I think you might be in a meeting. Lorraine Doo is with us online. She will be joining us especially for the AI panel and the Standards Subcommittee conversation after lunch. I would be remiss if I did not acknowledge Marietta Squire, who is the engine underneath the hood of this entire operation and Gwen Mustaf, who is the assistant engine. Just really grateful for everybody making this happen today.

For the members of the public online, we will have a public comment period later today. On the agenda, it is 2 o'clock. There is a slide. We will put up the instructions at that time. Do stay close to proceedings. It might be before or after 2 o'clock so somewhere in that neighborhood but that is a good time to have your audio line open and you could also email us comments at NCVHSmail@CDC.gov. I think we are ready to review the agenda.

Welcome Remarks/Agenda Review

Jacki Monson: Good morning for the third time. Let us go ahead and go through the agenda. First, we are going to have a panel discussion or actually Travis is going to talk about the conversational AI strategy and standards and we are going to have a panel and presentation and discussion and committee discussion. We are going to take a break at 11 o'clock. Then we are going to have an update at 11:15 from HHS Office for Civil Rights. We will take a lunch break and then we will have updates on NCVHS workplan development for Subcommittee on Standards and some committee discussion. At 2 p.m., we will stop for public comment and then we will move on. At 2:10, NCVHS 2023 Report to Congress, a quick update. And then at 2:45, next steps and wrap up. And at 2:55, closing remarks and we will adjourn.

Rebecca Hines: Super. That is our agenda for today. Anything we need to check in on before getting started? Without further ado, I am so delighted. Today, we have Travis Hoppe here who has graciously organized his colleagues for us to provide an update on conversational AI strategy and standards. For those of you on the ICD-11 Workgroup, you probably saw Travis' handiwork, helping us summarize the RFIs, which are posted on the ICD-11 page of the website. He was able to use AI to summarize those results. If you are on the workgroup, you saw that. It is a huge resource for us.

I think we will go ahead and get started. It is a blended format. Some of the panelists are here in the room and some are on Zoom. I see Farhan. Did you want to test your audio, Farhan.

Farhan Khan: Absolutely. Can you guys hear me? Good morning.

Rebecca Hines: Very good. Good morning. And Kathryn, did you want to test your audio?

Kathryn Marchesini: Good morning.

Rebecca Hines: Good morning. Okay. We are all set, Travis. Over to you.

Conversational AI Strategy and Standards

Travis Hoppe: Thank you so much. I am so excited to be here and thanks to Rebecca for inviting me and helping to get all the logistical support for this to happen. Actually, I am excited to listen to you all of you today and bring my colleagues together. We have had so many conversations internally within the Federal Government, HHS about what to do about conversational AI subtext and what it means for us, what it means for ChatGPT, and what it means for medicine, what it means for everything out there. I love that this conversation can now be done in the public a little bit so that we can figure out what we should be doing.

Before I turn it over to all the different panelists for introductions, I want to point out that we are talking about ChatGPT, which is a piece of conversational AI. You may have heard of other things, I think one of the panelists will mention this, that there is generative AI that is out there, which is a broader scope than just a conversational AI.

But there is also this even wider scope of AI that is out there. All of these discussions we are having today and all the slides that we are talking about, they pertain to conversational AI and the standards. That is what we are here for, but they really are a little bit more general, and I think a lot of things we are saying do apply to AI and all of these that we are talking about, it is kind of hard to eliminate what's one piece or the other.

I just want the panelists and I want the committee members to come at this with a very open mind. We are having these discussions, aligns between one type of AI and another (inaudible). But I think there is something very particular about conversational AI and the way it has ignited the public, the way it has ignited the federal workforce, that I think is worth having a panel just on this. We are going to talk about AI generally, but conversationally I needed something unique and new and I am super excited to hear what our panelists have to say and the discussion questions we are going to have.

Let us begin the panel. We are going to have each of the panelists to have three to five minutes to discuss their role within their agency or work that we have done and then we have a bunch of questions.

And then in the middle of our questions, we are going to open it up to the committee members to ask questions of us. If we have more time, I have more questions for everybody else.

I will turn it over to Greg Singleton.

Greg Singleton: Thank you. I am Greg Singleton, Chief Artificial Intelligence Officer here at the Department of Health and Human Services. I want to start off thanking the committee, thanking the committee leadership, thanking the committee members, committee staff for having us in for this important topic. As Travis mentioned, just such an interesting time we are here in AI technology development. A good time to be having this discussion.

I am going to start off this morning and going to talk about why AI matters, the challenges we are looking at, and how we are approaching it as a department. I want to briefly lay out how we are thinking about it and how we are thinking about what we might be doing. And then I will turn it over to my esteemed colleagues to cover a lot of the material in-depth about what we are up to.

Why does AI matter? The most useful description I have heard of artificial intelligence is human insights at machine speed. Beyond all the discussion to algorithms methods - human insights at machine speed. Why does that matter? There are things that machines are good at and there are things that humans are good at. Machines are good at being fast, reliable, repetitive, not getting tired. Humans are good at insights, connecting disparate topics, being free to coming up with new approaches, that sounds kind of cool.

If you think about what is happening in our society over the prior two decades, three decades, we have had cheap communications, cheap data, just vast increase in the volume of data and emails that we are getting into our inboxes. But we have roughly the same workforce than we have had in the 2000s. Certainly at HHS, it is about the same size workforce. We have more volume, more data, more information flowing around. But the same number of people, same amount of attention. Do you do a worse job, slower, or do you find a new way of approaching it. Artificial intelligence is a way of taking some of those mundane tasks or tasks that are not the really creative things, but we still need people to do them. Maybe we can offload some of those onto machines, get through those, allow our people to focus on the really interesting and challenging things. That is kind of where we get a lot of the promise of AI.

What are the challenges we face? Certainly, there is the promise of new drugs, new generative technologies, text. But there is also the risk. There is a risk that if we are being cautious, if we are not careful that we could cause harm, that we could exacerbate equity issues, further enhance disparities in our society. Maybe we should be careful and have some regulation and be mindful of it. There is also a risk that we are too careful, too cautious, and don't move forward and take advantage of these.

I think of it is if we are on a mountain pathway. Up on the hill on top of the mountain, there are those goals we want, new medicines, new precision medicine, new approaches, new insights for our society. But on one side, on the left-hand side is a valley and if we are not careful, we go into that valley and cause harm to people and we have outcomes that we do not like as a society and things that do not reflect our values. Okay.

On the other side is another valley. And that is if we are too careful and too risk averse and we do not allow ourselves to advance and develop these technologies. Mind you, if we do not develop them, there is no saying that our geopolitical adversaries are not going to take advantage of them. We are in a

unique position as a nation where we have a great advantage on (inaudible) at this moment in time. We have the data. We have the algorithms. We have the computing horsepower. We have data centers. It is a significant advantage that we have. There are others that may want to see us pause on that development and do not race to catch up in this environment.

The point being there is a lot of promise. There are risks. But there are opportunities for us to be deliberate and cautious and moving ahead and come to those good outcomes we are looking at for society.

I want to talk about how we, as a department, are approaching AI right now. There are three primary areas we are looking at. We are looking at it internally for our operations so emails, the traffic, the letters, the correspondent, all the things we need to do inside the department to make things work here for society and the citizens.

We are looking at in our mission space so things that are components, our operating divisions, different parts are using to delivery services to (inaudible), programs that are delivering value to the frontline citizen.

And then we are looking at it for the health sector in general. Where are the opportunities in the health space? Where does it make sense to leverage AI? Where are the areas where we need to be cautious? Where are the areas where we need to think of good common-sense rules and guidance for proceeding? We're looking at all of these areas, working on landscape assessments, doing deliberate assessments of what things look like in each of these spaces and then working with all of our colleagues and team members here to come up with deliberate and cautious approaches.

I think all in all what I want to convey to folks is there is a lot of opportunity in AI, something that can deliver great benefits. There are certainly risks to it. There are also risks of not proceeding and we are working to proceed in a deliberate, cautious manner stepwise, taking advantage of those low-risk, high-value opportunities for AI first and learning a little bit as we go along at each step so that we can build to greater and greater capabilities in the AI space inside the government, in the mission set, and for the American people directly.

With that, I will conclude my remarks and turn it over to my esteemed colleagues.

Travis Hoppe: I will start us off with the agency response. I am Travis Hoppe. I am your chair for this panel. Super excited to be here. A tiny bit about me and part of the reason why I am here is I led CDC's Tiger Team where we started this in February and March to really figure out what those ChatGPT conservational AI mean for public health. It was a really preliminary assessment. We had some of these people on the Tiger Team and we came up with some really great recommendations. I am not going to delve into too many of these details. I am going to spend most of my time today talking about some of the work we did at NCHS, which is super exciting. That is the center I belong to at CDC.

I have a lot of experience in AI. We published policy work when we are at NIH that used AI to examine funding rates between African Americans and whites to kind of analyze and this is getting to what Greg said about what can we do at scale. Things we cannot do – you can analyze 200 documents. That is something you can do in a month. You cannot analyze 20 million documents. You need AI to work at scale and we were able to do some of this.

We have published models with NCHS. We have published public models. I want to talk a lot about model cars and the sort of things. Some of the questions on the panel are for this. I published a paper that was related to some of the data sets. We talk about data sets here. That is the rival to ChatGPT. I say this more so like set the stage that there is a lot of work both in federal agencies doing cool stuff and the public for publishing and academia and industry. All of these pillars need to be considered.

I want to talk about some of the cool things about NCHS. I think you guys are familiar with NCHS.

Rebecca Hines: Actually, we have some new members who do not.

Travis Hoppe: Great. We are the National Center for Health Statistics, part of the CDC, but also a statistical agency and we care about statistics. We do population surveys. We collect vital statistics, which I think was a topic yesterday. We do health care surveys, ambulatory surveys, all this cool data that we collect and we need statistics for.

But why do we care about AI? What are some things that we could do with this? We have collected these traditional statistics. But there is so much data that we are not analyzing or statistics for.

Some of the things that we have done since I started. We are coding cause of death with ICD-10 codes. If the cause of death is not very clear, we have built a non-response detector, which is really cool because people but all sorts of stuff in the surveys we ask things on the internet. And detecting that at scale – that is what we publish out there.

We look for opioid misuse and use within EHRs, electronic health records. We have used Whisper, a speech to text model that has taken 20,000 hours of recorded interviews and improved the accuracy of the speech detection by 20-fold, which is really good. This is something I have worked with Maya on. We have talked about private AI, detecting PII within free text. There are so many good reasons for that. That should be kind of obvious. That is kind of why we are doing this. Again, we did this report on conversational AI within CDC.

I am going to use my last couple of minutes to – one, I love this slide here. It is a bunch of things that have been happening within the Federal Government. Just a timeline. You saw that that was an EO that we were responding to. We don't work on this in the Federal Government. But again, I am so happy that this panel is here to provide input and tell you what is going on. This is the landscape picture.

Use the next couple of slides to really talk about ChatGPT and really the speed of research and development. What you are looking at here is a chart on GPT 3.5, which kind of came out in November. And 4.0 came out three or four months later. And it was getting scores on the LSAT is passing - super cool. And then four months later, it was acing the LSAT. That speed of innovation is happening right now so anything we say about ChatGPT is outdated. So we need to be thinking not just about what we need to do but how we need to be approaching AI technologies in the future because they will be here before we make a decision.

Some really quick things to set the stage for specifically ChatGPT. ChatGPT reports also if you ask it to talk about all of the things for this made-up virus in the 60 states of the United States. Cool. Let me tell you something about the 60 states. If you give it false information it is happy to reproduce those.

It can create fake references. If you ask it for references from CDC from the injury center about fentanyl and xylazine, those look like real references. They are not. None of those are real and I can generate a thousand fake references.

It has a limited knowledge window. If it was trained with a specific time, beyond that time, it will make up information just to please you. It is not a human. I should say that. But it is designed to give more information. It knows about fentanyl, but it does not know about xylazine kind of mixed with fentanyl. It is a very CDC kind of thing here. But it will make up information to fill in the gaps here. It is so important that we keep that in there when thinking about policies and standards. Super important.

Systemic societal biases. You have heard about this before. I hope you have. And if you have not, we can talk about this at length. It will reproduce what it sees in society because that is what it is trained off of. Huge amount of data. This is the slide that kind of illustrates the gender difference. If you give it a he or a she, it will change the adjectives it describes people as. These are built into all our language models of which ChatGPT is part of.

This is just a slide. There are so many great uses of AI, so many cool things. This is kind of one story I want to just throw up on the screen here to talk about – this is not even ChatGPT, but it is a conversational AI, which is the panel here. There was a Chatbot that was designed to prevent eating disorders. It really was not vetted well and it gave dieting tips, which is not a good thing to be doing for people who are talking about eating disorders. These sort of things kind of speak to how, yes, you can build the technology but implementing it and integrating it and testing continuously is so important.

I will stop with that. I think that is my last slide and I will turn it over to Gil.

Gil Alterovitz: Thank you very much, Travis. It is great to be here. I am Gil Alterovitz, Chief AI Officer and also Director of the National Artificial Intelligence Institute. I think we may have a couple of slides, which we can go into. VA has the largest innovative health care system in the country. There are medical centers across the United States, and they are also actually in other countries too, in the Philippines and other locations.

Just to really quickly give an overview. We are here to really build that capacity, that AI capacity, to build that AI for veterans and a lot of that involves health applications. But there are also benefits. There is the National Cemetery Institution, and other parts of VA as well that all comprise part of that system.

You might ask why AI at VA. I think we heard some of that a little bit here, which is that there is a lot of knowledge and information that we have that is all set for our mission, which is really to help veterans. We are approaching a million donated genomic samples from veterans. There is the electronic medical record system, which being used across these different medical centers, a billion images generated a year. So there is the potential to use that for the benefit of the veterans.

I do want to say that one of the other things that was mentioned in AI is that if we think about it, really the language of human is storytelling and that is kind of ways is kind of new in a lot of the generative AI and conversational AI. It has the question/answer or dialogue kind of interaction, which we have not had before in a more natural format. Before there were things that may seem to us to look like a conversation, which were really rule based approaches before where they were kind of preprogrammed what the responses would be where there would be limited number of responses. But now, the opportunity of and also risk, is that we can talk to the system. We do not actually know what it would

say given a set input that we give it. It can probabilistically have different answers at different times, change, and without guardrails, there can be risks with that.

One of the things we have been thinking about is how to leverage that. As I mentioned, really this new type of AI is kind of like storytelling. Way back. Those stories may have been told through images in a cave, kind of a type of language and now through words. The AI is now able to develop images that were never seen before. You can go online and see the image of a person that unless you are an expert will look to you just like a real person, a real face, but that person never existed.

It is also possible to create videos and texts. It is hard to tell. In fact, there is this idea of a Turn test where you can tell if someone is a human or not. And just a couple of years ago, it was pretty easy to tell. But about a year and a half ago, it really became much harder to tell if it is a human or a computer that is trading that. Once you have that, you also have additional risks.

What we have been doing at the VA is creating a list of different execution priorities around AI to both build and use our existing AI approaches as well as develop new AI approaches and to really leverage that to build in the AI community.

One of the things that we are really looking at is building it based on a risk profile. There are some very exciting applications of AI, many of the ones that you may hear about on TV and other places and some of which we are already starting to see in some cases whether it be diagnosis and prognosis and things like that. But some of the areas where we are seeing the potential to actually make the biggest difference immediately are things that are kind of less exciting-sounding type of AI that actually make a much bigger difference certainly in the short term, and maybe even in the long term. I will give you a couple of examples of those that we are looking at in our strategy and moving forward. Again, it is very exciting.

We do have one application, for example, where in a colonoscopy, you have an image and using augmented reality it will actually show you an image where it thinks there may be a nodule that you should be looking at and certainly that can help in that application.

Now, look at one of these other ones that I think is going to make a huge difference is faxes. It sounds like faxes are from the ‘80s but they are still here with us as a number of us know and especially in the community care setting, we will see faxes being sent from one location to another. That essentially gets included as an image, not an image that captures all the language but just as pixels.

Using I guess you could say kind of earlier type of AI, although now there is deep learning and other approaches that will make it better. You can do optimal character recognition. You can do natural language processing, those images not only detect, but structured texts, potentially SOAP notes and other structure types of – more structured types of information that are more easily searchable. And that alone even though it sounds quite simple when you do the calculations, it affects so many different providers and actually saves you a lot of time, costs, and provides a lot of value compared to let us say being able to diagnose one disease potentially a little bit better. This affects many diseases.

Another example is a transcription dictation. Listening while the physician is actually talking and actually converting that into text kind of in the background and turning that into a structured note. Again, because it affects such a large group, these are the kinds of things that we are looking for. Things that affect a large group and optimize things a bit but because it is so many people, it is going to make a big difference. Again, not a disease-specific one.

And then the final one I want to go over quickly is policy. There are so many policies, and every place has policies. We have a lot of directives and things like that. Being able to interact either through chat interface and be able to learn about those policies aggregated across many different types of policies. That is another one of these lower risk ones that we have that do not involve interaction directly with a patient, but perhaps with an HR specialist or with a specialist who wants to quickly interact and put together a number of policies and then they can make the judgment of how to use that information. Again, a very general application that can be leveraged.

In our VA strategy, we were happy to be one of the first to come out with a strategy. It is publicly available. Basically, it goes through a number of different areas that I kind of mentioned about how to leverage existing AI, build AI communities, and so forth.

Let me go on to the next slide because I think people can look on that one offline and just say I think this has been really useful for us and other agencies that have looked at us. There have been a lot of different frameworks, executive orders/bills and acts around trustworthy AI and different frameworks to use. Also the VA Office created Data Ethics Framework.

What we did is we built a trustworthy AI framework for our specific agency that puts all those together with aimed at a veteran approach. We took all of these different ones out there plus the Veteran one, as I mentioned, and have looked at it as experts but we also did clustering and actually used AI to inform us about AI in a sense. It kind of matched with what we put together as experts in terms of how to categorize these different concepts and then we are now creating an implementation guidance on how to do that. That is moving through the VA.

We shared that with other agencies. We are also learning from other agencies that have also created a playbook. HHS has a trustworthy AI playbook that we have learning from as well, and other agencies to see what are commonalities, similarities, and differences.

Just to wrap up, there is a lot of potential in this area. I think what is kind of different in this new AI is that you cannot quite predict what its output is and that is speaks in some sense the same language that humans do, which is storytelling, which means that it will be easier for AI to engage people. It will also be easier for AI to potentially mislead people because we are more likely to trust something that comes in terms of our own way of processing information, which is, as I said, storytelling.

I will stop there and pass it back to Travis.

Travis Hoppe: Thank you so much. I want to remind – there are many panelists – let us keep it at three to five have looked at VA. They are doing really cool stuff. VA is on top of it.

I want to go to our next panelist, Dr. April Foreman, the Deputy Director of Technology and Innovations, Veterans Crisis Line and Suicide Prevention at VA.

April Foreman: I want to thank my good colleague, Gil, for doing so much of the lift before I came on. First of all, I have been interested in conversational agents and suicide prevention for some time. In early days, we had implementations like Robot or Coco. In early days, computational linguists talking about the promise of conversational AI to possibly help provide support or provide innovations that would prevent suicide.

I am passionate about the use of elegant and effective designs in service of helping in suicidal pain. For level setting at any given time even though we might lose 50,000 Americans to suicide or so a year, we have about 10 million Americans in suicidal pain and it is reasonable to think about tools that would help us scale because we once did some wonderful calculations and we found that if we were treating people just at high risk for suicide and we were just doing care as we know as it exists that is gold standard care and that has an evidence base, we would have to train and employ at the top of their license about a third of the US workforce in various levels of mental health service provision and we would have to practically conscript everybody with an independent mental health license.

We clearly cannot continue because it is an engineering problem working on preventing suicide with the best interventions of 50 years ago or talk therapy, which is a Victorian era innovation. But at the same time, leading edge innovations like conversational AI are things that are tricky to pull off.

I am excited to be at VA and the reason that there is an innovation's hub at the Veterans Crisis Line or that I get to know Gil and work with many of his people or being in the AI community is because there is a real focus, I think, on working with people like me who are practical experts who understand and deal with real-world use cases and also work very hard to be educated by many of you here who are subject matter experts for very technical disciplines.

Just to wrap up my comments, I find that – the VA, of course, launched a chatbot on our website and they did just such a lovely thing, which is they said we would like to help people in suicidal crisis. We would like to – if you could give us some language samples and if we could just figure out how to get the chatbot to get people to you. And there was what technicians might think of as a good design idea, but people reached out to me and the reason why I am on this panel is one of those persons, Luciana, said I need to find a suicidologist who knows something about this and worked on a practical implementation that was reasonable, helped with accessible, but also was safe, practical, and was a good standard for what we needed to do then.

We need to be working with subject matter expert who are leading edge and have some vision and are comfortable with leading edge implementations and also are good conversants with many of the fine people here. I just want to thank Gil and people like you for letting me be here.

Travis Hoppe: Thank you. Next is Farhan Khan, director of Operations and Delivery at FDA.

Farhan Khan: Thank you so much for this opportunity. My name is Farhan Khan and as Travis said, I work with FDA. My official role within FDA is to manage the data center operations and application development.

But the way I see it my role is to manage data, manage data at scale, make sure the data is secure, make sure that it can be transferred from point A to point B. My job is to basically make data available at the point of need and allow users to use that data to innovate at the speed of science.

Since we are talking about AI and conversational AI, all of it is kind of fueled by the data. And the most important thing is the quality of data. As we used to say, garbage in garbage out. If we give AI bad information, most probably the outcome that we receive is not going to be that good quality information. The quality of data is critically important.

My role within FDA is to contain that data, to store that data, to provide the backbone, which can basically take that data from point A to point B and all of that and then provide that quality data to

machine that are housed within the data center whether it is in the cloud or whether it is on premise or the applications – the 150 applications that we have within our FDA ecosystem to make sure that data is readily available for all disciplines and platforms, including AI. That is my role within FDA.

Travis Hoppe: Thank you very much. We will turn it over to Lakshmi Grama, the associate director of Digital and Dissemination Communications Office at the National Cancer Institute, part of NIH.

Lakshmi Grama: Thank you, Travis. It is a real honor to be part of this panel. As you said, I am the associate director for Dissemination and Digital Communications.

While many of my colleagues at NCI and NIH focus on AI in the context of grantmaking for scientific research projects, I come to conversational AI from the perspective of a health communicator and a former student of linguistics and information science. We live in a very interesting time, as you have all talked about and as is often the case with technology that can dramatically transform our experiences, it is the best of times and the worst of times.

The experience of conversational AI or what passed for conversational AI in pre-ChatGPT era was oftentimes frustrating from the user's perspective. Most of them focused on tasks that organizations wanted to move out of the content center environment or where they thought guided navigation to content on websites might be helpful. Actually, very often they were trying to mitigate the impact of some poor design and information architecture on websites. Many times users left this interaction feeling dissatisfied because their real question was not answered.

One of the chatbot enhancements that we saw was during the pandemic where we saw a significant increase in chatbots to disseminate health information as well as to help assess risk, check symptoms, and to counter misinformation, including those from the WHO and the CDC.

As many of you have said before, most of these were system directed and they used decision tree structure responses and focused on a narrow set of simple tasks with text entry on a screen as a primary mode of interaction.

The inherent risk in these applications was not very high except for the risk of frustrated users who might not find the answer to their real question. Conversational AI, on the other hand, in the world, particularly in the world of generative large language models is way more exciting but also scary at the same time. It is exciting to think that we can get to a real conversational approach both through text and voice, where the true intent of a question someone has can be jointly explored and then answered where we move from rudimentary anthropomorphic qualities to some level of human likeness so conversations feel more natural.

But therein lies a problem too, and many of you have alluded to it. Being human-like yet computer-driven might engender a level of trust among users that might not always be warranted. As government agencies, we want the tools we developed to be based on authoritative information we create or vet based on science rather than on a general body of knowledge scraped from websites.

ChatGPT and large language models have focused on applications where scale is large, the impact of consequence is somewhat low because buyer beware and all of that. But in government, we are looking at solutions in an environment where scale might be smaller and the consequence is high. Our approach definitely has to be more cautious.

At NCI, we are still in the very early stages of looking at use cases where we see potential in conversational AI. One important use case that we have been talking a lot about and trying to work through a pilot project is to help augment the excellent service that our cancer information service provides the American public through phone, email, and live help.

It may not be direct to the consumer. It may not be direct to the citizen. It may be to enhance the quality of response or the speed of response of the contact center operators, the information specialists who are answering these questions.

Other use cases we have been thinking about include helping our content creators. The volume of literature that is coming out that needs to be reviewed in order to really keep our content updated is a big challenge. Augmenting that process, supporting that process for content creators is another area where we think there is a great potential.

And this may not happen in the next few years. I just have this vision someday. But I can see conversational AI powering the entire cancer information seeking experience of the website where all the information is personalized and presented to the user through the lens of their needs explored through an emphatic conversation with them.

I know it is early days but that potential exists and I am excited about that. I look forward to the conversations today. I know that I will learn a lot more from the experts on this panel. Thank you very much, Travis and the team and others who are inviting me.

Travis Hoppe: Thank you, Lakshmi.

Next up Asif Rizwan, Program Director at NHLBI, the National Heart, Lung, and Blood Institute.

Asif Rizwan: Thank you. Thank you for the invitation. I am Asif Rizwan, a program officer and the program director at NHLBI NIH. Lakshmi has covered most of the activities that we are thinking to do at NIH.

I will just add that this generative AI can be used to find patterns, patterns in the research data. Once a scientist or a researcher or a PI can identify the pattern in the data, then they can create the hypothesis. That is a big use of generative AI and generative AI is based on transformer technology so that means it is trained to predict what comes next. We see a lot of opportunity that is generative AI – conversation on AI, can bring to the research community.

I strongly believe we are just at the beginning of what AI – of what generative AI can do. We, at NIH, will continue to develop this tool to support research activities to develop more tools that could help us to identify new and exciting ways to help research. Thank you.

Travis Hoppe: Thank you. And last but not least, Dr. Kathryn Marchesini, the Chief Privacy Officer at the Office of National Coordinator at HHS.

Kathryn Marchesini: Thanks, Travis. Good morning. I think there will be some slides that are pulled up. I am Kathryn Marchesini. I am the chief privacy officer at ONC within the US Department of Health and Human Services.

Basically, before diving in, you will need to know that I will do my best to recite the rules with accuracy. However, the official proposal that I will speak to in the proposed rule are published in the Federal Register. I will not be able to elaborate or clarify the other proposals today beyond what ONC has stated publicly in the proposed rules.

With that out of the way, I know my federal colleagues did an awesome job talking through some of the areas that the Federal Government has been focused on. What you will see here is just a snapshot of some of the AI capabilities in health care and various ways in which there is potential for it to health. I am sure many of you on the committee are fully aware of this activity that is going on, but thought that this is a helpful graphic that GAO put out in 2021 just to level set some of the conversations that I will share in a little bit.

In June of last year, we started to share publicly some of ONC's expiration on the various activities related as well as issues to the use of AI in health care. And over the course of six months, we issued a series of blogs that reflected on some of the emerging AI and ML in health, especially those for applications designed to derive relationships from training or example data. I know much of what we are talking about to today. And then used to produce a predictive output or a predictive algorithm.

We have spoken to a lot of experts, reviewed scholarly and academic literature as well as conferred with numerous of our colleagues here today across HHS, as well as the Federal Government.

You will see here just at a very high level some of the areas that we thought in order to optimize the use of AI, some of the fundamental aspects of the challenges needed to be addressed.

Also, realizing that certified health IT, especially electronic health records, play a prominent role in the growth of predictive algorithms in health care. They serve both as a wellspring to develop predictive models but also as the delivery mechanism for outputs of predictive algorithms.

Moreover, I would say certified health IT serve as a way to deliver algorithmic results or AI results, either as outputs in what are more traditionally maybe known as clinical decision making, but also administrative decision making that would have clinical impact.

The metaphors I know that metaphors we often use health IT as a wellspring as well as a delivery mechanism, it also helps scope the way in which we, at ONC, think and contribute to the broader understanding of how I would say what role that ONC can play and do our part regarding the development, deployment, and advancement of algorithms in health care.

In ONC's authorizing statue, you may or may not be aware that Congress charged ONC with certifying health information technologies that provide appropriate information to help guide medical decisions at the time and place of care. We believe this is an opportunity to leverage our authority, to improve the transparency of predictive algorithms leading toward and improve quality and trustworthiness of them overall.

In April of this year, many of you may be familiar that ONC included proposals related to algorithms, AI, machine learning. Choose your word of preference. In the recent ONC NPRM, you may have heard it referred to as HTI-1. And our 60-day public comment period actually closed last month.

But you will see here on the slide the intent as it relates to the proposals intersected with AI is to foster an information ecosystem in which information is available to the users of the technology.

You will see here promoting the transparency for not only risk management but also the governance on the predictive decision support and also what we refer to as source attributes. I will touch a little bit on that of the technology. But also, making available or promoting consistent and routine electronic access to the technical and performance information of predictive decision support and just at a very high level, really trying to focus on – enable the public to understand how developers in some cases have managed the risk associated with some aspects referred to as fairness, validity, privacy, and security. There will be some information on the next also but also supporting information salient to health equity by design.

Just at a very high level because I know I am short on time, building off of existing requirements as part of ONC's program. We are proposing to rename an existing certification criterion. But what you see here on the slide is a proposed definition that really is trying to get at the scope of technology. I know some of what we are talking about today is included in that definition.

What I did want to point out was the definition as proposed. It turns on derived relationships, a technology that derives relationships from training or example data and then are used to produce an output or outputs related to, but not limited to. It is independent of the purpose of use. It is independent of the risk associated with it as well as who developed it. You will see here included NLP, LLMs, things of that nature.

A very high-level look at what our proposal entails. It really turns on transparency is a prerequisite for trustworthy AI. This is a little bit of the logic. We coordinated very closely with our federal colleagues at FDA, AHRQ, OCR, as well as the VA. But we understand that there are different ways of looking at the problem and some of the solutions. But what you will see here is our proposals really turn on providing transparency around the data to the extent a technology that enables or interfaces with certified health IT. It touches on or uses our relevant data elements. We will see some of that related to health equity.

And also about what we refer to as performance transparency. Many of you may be more familiar with model cards or nutrition labels. This is really getting at the attributes of the technology so what the intended output is, what the intended use is, things of that nature.

And then lastly, the organizational transparency. This really gets at the governance, the behavioral, more of the socio-technical characteristics that the developer has in place that is developing the technology. A lot of this is built on the AI Risk Management Framework for those that are tracking that.

Lastly, just to close out, there is information that is available publicly if you are interested in diving into the rule. It is a not a fact sheet, webinars. Hopefully, we will talk a little bit more about that later today. Thanks.

Travis Hoppe: Thank you, Kathryn. I want the committee to see that we have so many levels of expertise and I guess leadership and people who are – we have an agency official, we have a VA official. We have practitioners of AI and we have policymakers that are all on this panel. We tried to gather a bunch of people, a bunch of different opinions.

Just for the panelists, I will be asking the questions and then turning them off to one of you. And then if you have a comment, if you have a follow up, it is a little hard for us here to see the panelists so I missed you just speak up. But if you would like to chime in, please do. For the committee members, we have a set of questions we are going to go through and again just to remind you, once we get through the questions, we are going to open it up for people's feedback as well.

Let us get started off. We will start off with Farhan. What innovations in conversational AI do you see would be transformative for state, local, or territory governments? How can the federal sector support these partners?

Farhan Khan: That is a great question. But before I answer that question, I would really like to thank everybody, especially Rebecca and her entire team that organized this event and giving us the opportunity to speak at this event.

Let us turn to conversational AI and the role that government can play in implementing conversational AI. But before I even delve into conversational AI discussion and how it can really transform the local and federal government sector, I wanted to take a moment and highlight this remarkable gift that sets us apart as humans and that is the power of language, the ability to engage in intellectual, sometimes not so intellectual, emotional, and actual conversations with one another is kind of remarkable. I do not think any other species can do that. That is something that is amazing that we can do.

Now, let us take a moment to really reflect on how far we have come in this realm of human machine interaction. In the past, like I remember when I was in college, I had to learn C++, java and other languages because that was the only way to communicate with the machines. But now, we have AI. We have conversational AI and all these amazing technologies that make it so much easier for us to really communicate with the machines, using natural language. We are at a point where we can really leverage AI to take us to the next level because communicating these machines is much easier now.

Now, to answer your question, how can we transform, how can we use conversational AI, the first thing that comes to mind is multi-language support. When we look at the US population, the diversification over here, according to some data that I found on the Internet, there are almost between 350 to 430 applications as far as languages is spoken in this country. English is only 72 percent of that. It is going to be like the conversational AI can really help us bridge that gap so people with different backgrounds, different languages can now get help from organizations, from government organizations, agencies and all that. They can interact with them. They can get the help that is needed to basically take it to the next level. That is something that is critically important and that is where it can help.

The other area where it can help is emotion recognition and sentiment analysis. Basically, what that means is that now with the help of AI and with the help of data that we are collecting, we can really understand sentiments of the public. That is another thing that we can do.

The third area that comes to mind is personalization and context retention. There are many use cases but something that April said, in the suicide prevention. That is huge. I was reading an article yesterday where it was stated in very sad statistics that the first three months of 2023, 49 service members died because of suicide and compared to 37 service members a year ago. Even one suicide is too much.

We can use emotional ignition and personalization and content retention to prevent suicides. That is what I feel. Of course, I have already sent an invite to April, and I will send an email because I want to be part of the effort that she is working on. But again, these are the kinds of things that AI can be used – conversational AI can be used to help prevent suicide and so many other things.

I just want to highlight one thing. I do not want to confuse chatbots with conversational AI. Chatbots are great but they have boundaries. They cannot account for human barriers. Yes, if I ask chatbot a question, they have particular boundaries and they can use those boundaries to answer the question.

But if I use variance and I change the rules of the game then yes, chatbot will have problems. But conversational AI is something that can fill that gap. This is slightly different. That is one of the things.

Now, of course, conversational AI can reduce administrative overhead and so many other things that happen within our agencies. Now, what can we do? There is a lot that we can do to basically make sure that it is – this AI implementation, also, conversational AI implementation, is done in a secure manner, in a manner so that everyone can use it. And the first thing is like master government aggregator or we can become that. We can take this data. We can aggregate this data. We can make the data available. We can set the rules of the game. We can basically provide grants to invest into conversational AI and AI as a whole. Research and development. That is another huge thing.

Believe it or not, at this point, China has more patience when it comes to AI and they have at least more papers around AI. There is a little bit of catch up that is needed over there, but we should be spending more time and more energy and more investment dollars and putting it into research and development. At the same time, data sharing is huge. We need to set the rules on how we are able to share this data.

And then one thing that we are also supposed to do, the taxpayers pay us to do that, which is creating new regulations. The regulatory guidance that is I believe to some extent is slightly missing. I think we need to aim to provide an unified or uniform regulatory guidance for everybody. So those are the kind of things that I believe we need to invest in and really to be focused on. Back to you, Travis.

Travis Hoppe: Thank you so much. Turn it over to any of the other panelists about comments on how it's transformative for the state, local, or territorial governments. How the Federal Government can support each other's plans. We have lots of questions. So if you do not feel like jumping in right now, that is fine.

The next question – we will go to you, Gil. What are some of the technologies and methodologies just on conversational AI, that will be influential in your domain? I know you talked about some of them already. But these could include reinforcement learning. They can include traditional machine learning, audio, video, forecasting, even AI with moral domains.

Gil Alterovitz: Thanks, Travis. I think there is quite a bit of intersection with a number of these different technologies. We looked at, for example, at the VA we had an application of deep learning that was developed where essentially acute disease where you have this issue that if you can predict it ahead of time, you can actually prevent it, not prevent it but essentially prevent the clinical symptoms from occurring because you are looking at preclinically and through (inaudible) and other means. This approach led to a paper in Nature where they were predicting in this case, like 48 hours ahead of time. Deep learning is certainly one area.

I think the conversational AI piece is especially helpful as sort of that interface. The interface, as we said before, storytelling interface. But that is sort of one part of the human experience.

I think another one is kind of interacting with the environment. And that is the part that we do not quite have yet with the conversational AI. And that is one reason why it can (inaudible) without kind of getting feedback.

If you have a toddler and you see half of the time they spend kind of experimenting with the world whether it be throwing an object and seeing the law of gravity just kind of at work or whether it be naming a color that they see in their environment and then getting feedback immediately that is correct or not.

Embodied in AI, AI that is within robotics, I feel like that is kind of another area of intersection of conversational AI. We are already starting to see – there is an example of this robot from a particular company where they added in a GPT-like interaction with it. It is a little slow right now because it takes a while to get your response, listen, transmit it and get that information. But in the future, you are able to do competing at the edge, which is I think another area that I think we are going to start that is going to be important for conversational AI. You will have much faster responses. Right now, many times through an API, you have to send that information out, get it analyzed and bring it back. But in the future, some of those models and some that work can be embodied right into your phone, right where you are in that robot and that is going to make for much more natural interactions.

Another piece I wanted to mention is I think we had an NCI speaker earlier, say it may be interesting to have conversational kind of agents and so forth. We actually had an NCI tech sprint a couple of years ago where we actually interacted with HHS and some NCI colleagues to collaborate on a few things around clinical trial matching.

One of the entries was actually around leveraging an early form of conversational AI because this was a couple of years ago for helping to find different resources on cancer.gov and things like that. We are beginning to see some of these intersections between different pieces.

The other thing I want to mention is that we are we are interested in health and bringing these different technologies internationally to the VA and so forth. We are going together with – we are going to have some HHS colleagues there as well. I think Greg Singleton will be there as well. And we are going to have the AI summit September 6 to 8. If people are interested in that, that is going to bring a lot of people together, talking about all these different methods that can be useful for – that combine conversational AI to facilitate AI in the field, in our case for veteran care but (inaudible).

Participant: Is it going to be here?

Gil Alterovitz: I think it is the Hilton Wharf. I can send the notice that's useful. We will be having a number of speakers from agencies, White House, and other places so it should be an exciting time.

Travis Hoppe: Thanks, Gil. Super exciting. There are so many transformative technologies prior to coming to the CDC, I was at the NIH and did my post-doc in protein folding but that is a solved problem now, not fully solved, but solving for the structure of a three-dimensional protein from the sequence, it was transformational. That field has completely changed. All the work that we were doing is kind of done now. I like to think that we helped AI get to the point, but it has been transformative. I am going to open it up to any other panelists that can talk about some of these transformative technologies that are potentially not conversational AI.

Lakshmi Grama: One of the areas that I am really excited about I think in generative AI is how it can help enhance digital experiences for people with disabilities. This has always been a challenge for many of us who are in the public communication end of things and also internally within organizations.

While there has been automated – generating audio description of automated captioning, most people with disabilities will tell you that that is really not giving them the full experience of what they want to see.

I see that with these large language models, it becomes much more effective. Alternative text for images being able to describe in better ways. Making digital experiences more inclusive is an imperative, particularly for us in health communications.

Hoping to see real, practical areas of improvement so that our colleagues and our fellow citizens who have disabilities, are able to participate in the health information, seeking health information interaction journeys so much better.

Greg Singleton: Thinking of things beyond conversational AI or some of the exciting opportunities that we see in the health care space, I want to hone in on – there are two, there are really a tone of them but one of the things that Travis mentioned was to scale the processing digestion of information and knowledge. We've had for a while precision medicine initiatives, which is the idea that you go to your doctor or clinician and they know everything about you. This is your history. This is what happened. This is the blood test you had in 2013 that had this weird protein anomaly. But the reality is we all generate even when relatively healthy, we generate a lot of data. We go to the doctors and the doctor is looking at the past few months, the past year, and they are trying to get through it. The AI technology have to really understand the whole person's entire medical record and look at factors and service them for attention and knowledge generation. It matters to the person, and it also has huge potential in the realm of medical literature. The ability to say, hey, I've got this patient who has this unique thing. Maybe this patient doesn't fit into 82 percent dominant case that is prominent in literature, but it is a three percent side case or 0.3 percent side case.

There is one study out of South Carolina – you might have a look at this one study. That clinician is never going to find that otherwise. I am very excited about that potential.

The other thing is kind of other modalities of data. A lot of our medical data is technical-based texts, chemically based diagnostics, and we do a lot of imaging as well, obviously. But then visually we can get movement or motion data from phones. We can get voice data from recordings. A lot of this stuff we do not leverage in our current clinical care practices. There are opportunities here.

Another really out there, one, is folks working on – you have seen studies where they used dogs that can detect Parkinson's through smell. So people are working on synthetic noses that can smell in the air in a hospital, in someone's home, and understand what are the chemical signals that we all put off through our lungs, through other sensors of our body. Alternative domains we do not harness today. I think there is a lot of potential there and I am very excited.

April Foreman: I would love to follow that and I will be brief. Which is that when it comes to mental health diagnoses, often we know, hopefully the people in this room know, that doing good mental health diagnosis is actually really hard, and it is hard for there to be standards.

And the computational linguistics and clinical psychologies sort of network, which really marries clinical psychologists and computational linguists to get them talking, Dr. Rebecca Resnik, who I believe is President of the Maryland Psychological Association right now, talks about wouldn't it be great for people to be able to leave language samples with their doctors for analysis just like they'd leave a urine sample for example, that we could probably leverage this. And we in fact can, using language samples, do fairly accurate and better than clinician diagnosis mental health disorders today. There's no reason why we can't try some of these things. Of course, it is about implementation.

Travis Hoppe: Any other comments from the panel on this question? In the interest of time for the panelists I'm moving around some of the questions, because at 10:30 I do want to turn it over to the committee for questions, I'm sure you have lots of questions.

But I did prepare a bunch of fun questions to get us started. This one is going to go to you, April. So how can the government protect patients from unfavorable decisions in healthcare or provided services? For example, there are growing concerns around the use of AI generated fee prediction models from insurance companies. They leverage these patient specific AI or ML driven data, you just hinted on this fun thing, collecting data from ML covered data. So I'd love your input on this.

April Foreman: I will try and be concise. I am totally co-opting a classical quote about war. But in innovation, great ideas are simple, and everything simple is incredibly difficult when it comes to implementation. And I think this is a great question that exemplifies that. I have a couple of thoughts about that.

First, I get to talk to wonderful people like you all, and there was a professor at Johns Hopkins in their Computer Science Lab who said we really could use experimental labs where we work these out, just like we work on experimental treatments where people consented and understood things were being developed in safe ways with a lot of attention. I think one of the ways that you could protect people is by asking for real development, the same way we develop drugs and other things, make sure they're safe, but we do have to work with real people to do that.

I think when you're dealing with black box related AI tools, if you have a black box tool that does something, we can't use black box sort of in the wild, we need to white box things before we're using them in healthcare settings, we need to know how the AI is helping or not helping, and what some of the factors are in predictive analytics, or conversational agent, or pick a thing, we need to understand what it is focusing on, especially when it comes to patients, and know that those things are correct things and safer things.

We also have, I was just having a great dinner last night with a couple of experts in AI and suicide in Bethesda, and they will tell you that they would love to see AI that tells on itself, that AI tells you how biased it is, what some of the risks are of using it, what some of the appropriate applications are or not, and that we don't use anything in the wild that can't tell you what the risks and limitations are of using a particular tool and what it's based on.

I also just think that there has got to be a strong role for informed consent. So patients should have informed consent about what data is collected about them, what analyses are run on them, and how those are applied. My doctor can't just do a drive-by blood sample with me, there are a bunch of things I have to consent to before it's done, and those risks are explained to me. And I think when we're talking about doing analysis on individual patients, even if it is something we could do in a very automated way, we need to get consent first.

I think that we've got, the National Health System in England talks a lot about how they budget, that question that you asked was so great. They don't budget like what service can I allow for one person, they think about cost per head for population. They think in this population about how much am I going to spend, and they use great models, and they think about costing and resources in terms of population needs, and then distribute them, and then measure population outcomes to get it right.

When you're using these tools, making sure that they're serving population health, and maybe sometimes not applying some of these tools to individuals might be a wiser application. AI applications should be able to flag instances where there may be an adverse impact. So the application should tell you, hey, I don't think this person needs that opiate, but not prescribing an opiate could have an adverse thing, so this needs a human in the loop review.

And I think that we need to have real outcome improvements that are related to health and quality of life, not, while I appreciate all these wonderful mathematical sort of statements about the reliability of a tool, or how much money we might save, or things like that, the point of all these things is the public good and public health.

And so we should be looking at how it serves the public effectively, ethically, and with good optics, moreso than just is this a great tool that does the tool job really well. And thank you for asking me.

Travis Hoppe: Thank you. Any other comments on this question for the panelists? Moving on to Kathryn, I would like to ask, this is a really long question, and there are a lot of different pieces to it. Take the pieces you want, we talked about some of them already in the introduction. But I'm going to ask all these questions to all the panelist because I would love to get your thoughts on that as well.

So what are some of the ideas around governance, particularly things like model cards. What about the creation of datasets specifically for training AI models? Should the government focus on the creation of datasets specifically for this purpose? What sort of meta data strategies do we have, data integration, data management should be considered for this. So pick any piece you want.

Kathryn Marchesini: I guess to start off, I am fascinated by what April just shared about AI doing some of these things, or telling users about the information of the model itself, which is I think a lot of what the model card and the nutrition label idea speaks to. They should be able to tell you to flag things, or information. So fascinating to see where the future may be.

I guess I will share a little bit about, from ONC's perspective, we understand that there are numerous and parallel efforts that are led by various industry groups. They're developing methods to evaluate what we're referring to as predictive decision support interventions, but for various aspects.

So it could be the fairness, appropriateness, validity, effectiveness, and safety. I didn't touch on this previously, but we've kind of called that phase, and that's what we're referring to as trustworthy. So that is really the pillar of, for us, what we're proposing.

I know you asked about governance (inaudible). There's a lot of ways to evaluate the technology. And so part of what we're trying to do through proposals is there's a lack of consensus, or that has not been widely or consistently implemented to date, the way in which if it's model cards, or how the technology is evaluated.

So we believe that it is premature I would say to propose requirements for specific measures, or I'd say thresholds, when you're looking at what is actually in the model in terms of the ingredients of the model card. We are just really hoping that, I guess you could call it governance, but try and enable consistent and routine access to certain types of information. I mentioned that earlier it's the actual technical and the performance piece.

So everything, I think some of what April spoke to, but the output, the intended use, the input features for the training and test data. Also validity and fairness, how did the developer look at that, as well as how are they updating the schedule, the monitoring of the model as things change.

The other kind of piece is there is the conversation around data. I would just mention that in our proposal we did have a request for comment and request for information asking the public about some of the other topics that we see as a pillar to making headway on some of these challenges. And one of those is technical standards and data management.

So this really gets at the source or the input data, the fundamental kind of data collection or capture, I know April shared some thoughts about informed consent. So I would say from my perspective this is an area that I would say transcends AI, the concerns around should the data even be collected to start with, should it be used, I know NCVHS in the past has put forth recommendations around data stewardship. And so we invite readers to share their opinions, their thoughts about some of the proposals aimed at helping this area, to address the priorities, such as public health as well as health equity and disparities and health outcomes.

So not probably the answer you were looking for, Travis, but we'll share that AI I would say in this area magnifies a lot of the existing challenges related to data itself. And so I think it's a great question to think about from a scalability perspective, at least when it comes to this technology. But I think in the current state we are really just trying to focus on I would say having a baseline set of information just to get some type of visibility into what people are doing as it relates to the development and use of the technology.

Travis Hoppe: Thank you very much. And for those on the committee or in the public who have never heard the phrase model cards, oh my gosh, they are so useful, and I am a huge proponent of them. What they are are essentially like a nutritional facts label. And Kathryn mentioned it's trying to decide what should be on the facts, what we need to include.

But typically, model cards tell you who built the model, which is kind of important, what data it was trained on, how you actually use the model, maybe some programming code, that's all basic stuff, how it was built. But we heard kind of as a community, both the industry, academia, the government, we need more than that, we need things like context for use, where the model is biased, what could go wrong if you use the model in this particular way.

And so the industry is trying to formalize some of these things, and those questions kind of pose should the government have a role in this, should standards or policy apply to this. So the model cards kind of encapsulate a lot of these questions that we have here. I'll turn it over to other other panelists for thoughts.

Gil Alterovitz: A couple things, it was mentioned about the model cards, and thinking about that. Two things we have, one is this IRB model we've been looking at and piloting. And the idea there is not to reinvent the wheel, so have existing IRBs, but to make sure people knew the right question to ask, and then once they have that, that kind of spurs the right conversation.

We actually saw a couple cases where an industry study, a couple other things have been rejected based on that, because they didn't get the transparency or this issue around data harvesting and things like that. And then the other one for operational use we've been holding an AI oversight committee, looking

at leveraging principles of trustworthy AI that are included in executive orders like 13860 about promoting trustworthy AI.

And then the last thing I want to add is around the datasets. There are some datasets that were put out there as part of another executive order, 13859, which was around maintaining AI leadership. And so VA and others have included datasets that may be applicable for AI R&D with a special label.

For VA you can find that at Data.VA.Gov, you can also look at Data.Gov for more general datasets. I just wanted to highlight that. That is kind of a place for potential open datasets that are created by VA or other entities. I know researchers are always looking for datasets, so I wanted to share these open datasets, they've been kind of vetted through these processes.

Greg Singleton: I will come back to what Travis, Kathryn, and April talked about in terms of governance and the oversight. As April said, getting models to tell on themselves, which in a more formal manner I might call auditing models.

What we have here, and what is very interesting is we are looking at these models, looking at where they perform well and looking where they don't perform well. But we're bringing them in in comparison to existing human systems, human methods of making decisions, and we shouldn't fool ourselves and think that the existing human methods are perfect and unbiased and perfectly equitable.

And what we have in this case with artificial intelligence models, if we get the models to tell on themselves, we can now measure the performance on these metrics, and we can design them for improvement. We're not comparing against a perfect human system, we're comparing against the human system that we have. And I'm not expecting the AI systems to be perfect, but there is the opportunity to know where they are not perfect and do better on those measures.

Kathryn Marchesini: I know for us at ONC that is part of what's driving the thought about creating the information ecosystem, and really trying to think about the encouragement of high quality models. And I know that could mean different things to different people. But to your point, ideally if information is provided, therefore you can evaluate. I know there are some guidelines that are currently used, and there are things that are happening, but it is not I would say consistent, and it is not used by everyone. So I think it is a great point to bring it all together.

Travis Hoppe: Additional comments? I think we are going to transition now from the prepared questions to questions from you all here.

Michael Hodgkins: I have a question, if you could clarify hallucination, that has come up in several discussions, I would like to understand what that means.

Travis Hoppe: Good question. I will let the panel go first.

Greg Singleton: At the basic level a lot of these models are based off of predicting the next word in a sentence. So they train it on large bodies of text, and they train it to say what is the most likely word that we're going to have next, keeping in context what we told you to think about, and maybe the article we fed you, and other things.

So it is generally a probabilistic answer that is frequently correct. But it's just based on probability, it isn't always correct. What we call that, when it generates something that probabilistically looks okay, and probably makes sense when you read it, but isn't accurate as fact, we call that a hallucination.

But I want to go back to something Travis said early on, in that we should be mindful where the models we have today and the models we have tomorrow. Everyone is discovering that these models can hallucinate, and poking holes in it and finding issues, that's important, I want to see that happen, because that allows people to learn and do better and say, oh, let's build models that have a hallucination checker. Let's make sure they have the opportunity to evaluate and check their sources.

So right now the team is working on this problem feverishly, and the current generation models will hallucinate, that's why we don't use them right now to treat and diagnose patients, do things like that, we don't rely on them for court submissions as one lawyer learned. But they're learning on improving that performance aspect of it, and so I am quite optimistic that we will be able to address that.

Gil Alterovitz: I think there is this probabilistic nature, you can change variables like temperature and so forth, or for it to explore a different past. I think one of the things that is sort of interrelated in some ways that makes it believable is there has been a lot of improvement in something called alignment, alignment of models. In the past you would get an answer, and it might not seem relevant, or it won't be convincing to you.

But these models are trained to make a convincing answer, whether they're correct or not. So that is part of what the training process is, how to answer a question in a way that whoever was asking that, because in the training they use thousands of human reviews like yes I think this is a better answer than this one.

And so they are more likely to be convinced by an answer that can actually be wrong but is kind of portrayed as correct. And so aligns with making these more story like tellings because they learn how humans interact in a sort of question-and-answer format as well as dialogue format, but it also leads to hallucinations, because essentially it's almost like they want to please the audience. Give me a citation, here's one, it's the closest I could think of, in a sense.

Travis Hoppe: I want to add that in this body we think of things as hallucinations as inherently bad. And for many of the use cases those are bad. Like if I'm looking for a reference for a court case, I want the right answer. There are so many other niches of AI where you want the quote-unquote hallucinations, you want poetry generation, you want it to write a script, or help fill in the gaps, you want creative writing, you want storytelling, that is the intent, the hallucination is the intent.

AI is not, especially ChatGPT, is not inherently aligned to either of those tasks, it is aligned to answer questions, not factually answer these questions. And so there are many use cases where that is the whole purpose of AI. And I think a lot of the work right now, we see the power of this and we're like why is it making these mistakes, because it was never designed to do this, and many companies are working on that specific alignment problem.

Gil Alterovitz: Sometimes you can change a parameter. So you can be like I want to be more creative, I want to be less creative. So depending on your application use case, even today you can fine-tune some of –- that has another meaning, technically, but you can kind of adjust the parameters for your uses.

Travis Hoppe: Any other comments for the panelists? We have it looks like eight questions in the room.

Michael Hodgkins: Thank you. You may or may not be familiar with some of the charges before the advisory board, one of them has to do with standards in healthcare, and one of the issues related to that is the harmonization between (inaudible) and one thing we can say about healthcare is (inaudible) being able to all talk to each other, and harmonization is the goal, but I think difficult to achieve. So I was curious to hear from the panel how you think various forms of AI could be used to advance the cause of harmonization of data standards.

Travis Hoppe: Just to clarify for the panel, are we asking how AI can be used to help harmonization, or how we should harmonize all of the AI standards?

Michael Hodgkins: How AI can be used to help harmonize healthcare standards.

Travis Hoppe: Fantastic. One of the things that is really hard, and so I did this at the NIH before, I did a lot of natural language processing, we analyzed grants, we analyzed publications, we did stuff with the text. Congress would say, how much did you spend on model organisms? I'm like, oh my gosh, what is a model organism? Did you use drosophila, did you use a cell line of drosophila? And you go down this rabbit hole, but you have 20 million publications to analyze. And so you have to use some form of AI to answer that.

The place where it comes in and where harmonization can happen is public comment. So these groups, this group and other groups, anything that is in the federal register, can get two comments, or it can get 20,000 comments, depending on how significant, or how influential, or how many focus groups you want to chime in on. And I don't know if you've ever sat down and tried to analyze these things, it is a lot of work, to pull out the information, to summarize, to kind of get executive pieces to make actionable decisions off of that.

And so one of the places where AI can help these bodies is gathering these inputs from the various stakeholders, in one case public comment, but all of the other groups together, and summarizing them for you. Large language models are actually really good at summarization. It's one of those things where it generally doesn't hallucinate, because you're giving it input and it's being condensed. So you can really use those to pull together and then have the human actually use the system. So that's my perspective.

Michael Hodgkins: That's very helpful, but I was thinking more along the lines of translation, harmonization between language, between standards.

Greg Singleton: I think you are speaking definitely to a point in terms of one of the fundamental issues why we don't have harmonized regulations and standards is a processing cognition, like a bandwidth problem, in terms of these standards are so dense and so long. They're great to read if you want to go to sleep. And so you're trying to go through these things, and you're like well we've got to do another standard over here, but there are three or four other standards, and between them it's 2000 pages of stuff.

And so when he's talking about digestion and kind of summarizing, so the ability to summarize and understand what is this standard over here, what does it mean when you boil it down, what does the standard mean over here when you boil it down, actually helps the cognition and awareness, to the point that as you're developing and working on new stuff you can say that standard is pretty good, let's use that piece over there.

So I actually do think, not that AI can do everything, because it can't do everything, but there is a case for it to be made here in helping with the cognition, the understanding of standards for harmonization.

Steve Wagner: So it sounds like one of the uses of AI in this case then would be to analyze all these different standards and say okay, here are the similarities and here are all the differences, so that you actually have a map of okay, what do we harmonize.

Rebecca Hines: One of the challenges this group is dealing with are sort of traditional standards and emerging new standards, and basically I think Rich you talked about a question we're posing to some of Kathryn's colleagues, is we have these traditional standards, mature I think you called them, and then emerging standards, and we have a mess right now, and it actually resulted in the committee not making a recommendation people would hope it would, because it's hard to have multiple standards operating when you have trillions of healthcare transactions going on, with VA being one of the biggest healthcare providers. So I think that's where we're sort of thinking, in literal standards that move data between all the different boxes on the healthcare transaction chart.

Travis Hoppe: It really does sound like you need a data scientist to embed and do all this work. Because while AI is really useful once you get it in there, you have data from all these different places, and you're pulling them together to actually get this actionable result will take some work.

Gil Alterovitz: I was going to say the problem that we have often found is the granularity sort of problem. So one where it can map, but it's like one of them is sort of a superset or collapsed partly and not fully, and AI is going to find that yes, they are related, or they overlap, it can sometimes be hard, those nuances, having human in the loop can help on this.

So we did this mapping as part of that exercise I mentioned about trustworthy AI to get to those common elements analyzing all the different documents. It definitely picked up more nuances when we gave it all the text as opposed to just like summaries of what the actual principles were. But at the end it was definitely helpful to have the human in the loop and to look at it and to see what nuances it picked up and which ones weren't quite. It's just sometimes hard to make an exact match.

Steve Wagner: Is there an existing national US governing body for AI or is there discussion of establishing one? Most scientific disciplines have --

Greg Singleton: The short answer is no one consolidated AI governing body. There is extensive discussion of how we should approach it as a nation. And when we consider this question, I want to highlight that AI is not one thing, it's a whole bucket of tools that all work and look and feel differently, and have different outcomes. And there are also vast differences in the domains and applications of AI in terms of how we might want to use it.

And our concerns in using AI in criminal justice are very likely going to be very different from some of our concerns in using AI in healthcare, where in one case we may want to blind the AI to certain facets of what it's working on, and in other cases we might actually need that information to understand the person.

I will also say there is a lot of value in a measured, cautious, mindful approach to AI in pursuing those high value, low risk opportunities first, and largely seek to avoid going to those really sensitive, tough, difficult AI cases right away. Or we might not ever go to those, because they're maybe things that that's just not appropriate for AI, and we need to have human in the loop at all times.

But a lot of what we're working on, what we're hopeful is very beneficial, low risk, not chat bots, but the concierge service for someone engaging with their local government, that is like hey, I need to know the local regulations on lot zoning in zone type R9, can you help boil down for me, and go through and help the person out in a very customer service-oriented manner. It's how we're approaching a lot of these things is again, crawl, walk, run, low risk first and then proceed from there.

Travis Hoppe: NIST put out an AI risk management framework. It is dense, and it is amazing. If you want to look, they have done the careful work on how you should consider the AI lifecycle. So, are they a governing body? No. But did they make this risk management framework? Yes. Should we all be using it? Absolutely.

And I would also say you should look to like OSTP they are thinking about the answers to questions like that, things like a national AI strategy, not just within the Federal Government but throughout the rest of the US government, how we should be approaching these things, though we have regulations here but we also have legislation, and we are coming to court rulings too, like can ChatGPT create a patent is something the US PTO is dealing with. So they're like all the different branches of government that are trying to deal with this thing, there is not a single governing body as said.

April Foreman: A couple quick comments. It would be nice to be able to have one governing regulatory body for AI, but we don't have one governing regulatory body for plastic. But a lot of people in their industries, I'm glad I tickled someone, we have a lot of people in the industries who consider parts of how their industry interacts with plastic, and makes regulations and guidelines, lots of different governing bodies. I think there is a role for encouraging people to consider this for their industry and start to think about what that might look like.

A comment, we talked about this exact thing at dinner last night, and a psychologist said it's amazing, sometimes we think that creating governance is very hard until there is a disaster that is expensive and has great human impact.

And so I would love for us to consider, I always want people to be deliberative and to also understand that we have every reason to believe that an event like that might happen, and it would be very hard to predict when and how, but we have every reason to believe that it should. And what would we want to say that we did now, knowing that was coming. Because history will look back on these moments, right?

And when I think about, to hand off to other folks, I really believe that people are very smart when engaged and can start to think proactively and then iterate. And I think one of the challenges with governance, and you are all so much smarter than me, and I'm just a psychologist, but what can we do that is iterative, what can we do that doesn't require final decisions, but that moves us or inches us towards smarter and lets us move more quickly.

And I think there is reason to think about that, and to ask ourselves what is possible besides these deliberative processes and procedures, when innovation couldn't happen quite at this speed, can we change our governance and deliberation processes to keep up. And I'm really grateful for this committee's attention.

Greg Singleton: A really important point on the NIST risk metric framework very briefly is they treat the risk at the mission and the organization level, not at the algorithm level. So they're not necessarily regulating the algorithm, an algorithm shall or shall not, what is the algorithm in the context of your organization or mission, your mandate, and your responsibilities, is very important.

Travis Hoppe: And if you don't want to read an 80-page dense PDF, they have a playbook that is just like here is some high-level stuff. Just google NIST AI RMF and you will be there. A strong recommendation list. I see other questions.

Debra Strickland: AI has fabulous potential definitely, in the governance space, in the VA, in medical and so forth. However, we are riddled by bad actors. I just want to understand, the bad actors aren't going to look at the playbook, they're not going to try to figure out where the guardrails are, they're going to try to find where the guardrails aren't.

And I'm concerned about who is policing, can we police it. AI out of control is not going to be a good thing. AI, to what you have explained, I am not highly educated, however I will be next time. It appears to me that AI can supersede our smartness pretty quickly. And so if you pick an area of focus that could be badly, I guess bad for the population, that would be really bad. And I don't know how we can control that, or if we can. How big is that? Because there are a lot of other rabbit holes.

Travis Hoppe: Before I turn it over to the panel, I want to add on to your question to make it even worse. I think one of the areas where AI can be harmful (inaudible) outside the standards we're talking about getting thoughts on, we talked about scale.

So AI, especially generative AI, which conversational AI is part of, scaling up bad actors, scaling up social media attacks, creating fake profiles is something that used to take a couple minutes to do, to create one profile. But to create hundreds of fake profiles, to flood an RFI with comments that look real.

And I've analyzed RFIs before, and people have form levels, they fill out forms, it's easy to detect and group those all together. But a signal to noise ratio I think is a thing that we don't have good regulation on social media. I agree with you. I'm not exactly sure what the question is but I'm opening up the panel for comments.

Gil Alterovitz: I will address AI in government. The other part is AI outside of government, people spamming and so forth. I may have addressed the other question a little bit earlier. Right now the kind of regime is centered around this executive order on making trustworthy AI, Executive Order 13960, which has these nine principles, and the point each agency can have responsible AI officials. Actually, Greg and I are the ones for our respective agencies here I believe.

But each of the agencies that kind of fall closer in criteria there have one of those, and there is a whole list of procedures to ensure that even at the design stage the different use cases for AI kind of follow those principles. So there are reports that have to go to OMB, Office of Management and Budget, and these inventories, and different processes. That is administered under the Office of Management and Budget.

There are also a couple of acts from Congress that fall under that similar type of structure with OMB and so forth. So at the VA we are working under that structure to ensure and analyze the different use cases as they come up.

What I will tell you though, it's interesting, it's kind of growing exponentially, it's like 10 cases, then it's like 40, hundreds of cases. So we're trying now to develop ways of scaling how do you analyze these different use cases that come up, not only in the central office but all these different medical sectors. That's where oversite committees and these things may be decentralized can feed and analyze and work on these systems.

Greg Singleton: It is certainly a tough challenge that we have before us. I want to assure you that we here, the panelists, across the federal government, across the branch, are looking at these variations very seriously and looking to come up with ways for addressing them. One of the principles in 13859, which is American leadership, is on ensuring we develop AI that looks like our American values, and that we don't leave a gap for where the only ones funding and developing AI are those malicious actors.

So we're working to develop the frameworks, the approaches, as well as the tools for adapting and adjusting to the scenarios that we don't want to see occur. At the end of the day, AI are tools, they're a toolset, and I'm unaware of really any tools that can't be misused. I can misuse hammers and hurt myself and others. That's the question of scale, and how we manage it.

Travis Hoppe: One of the questions that we opened up this panel with was what are some innovations that will be transformative for state, local, and territory governments. We are all speaking as federal employees, we have our sphere of control, we have all these things in place. We're trying to do a good job. But I do think we can extend as a federal government to our partners, to our other stakeholders. Is that all the bad actors? No. But will that help? Absolutely.

Your question is broader than the people here on this panel, and I recognize that. But we can do more than just fix our house, just fix the federal government, there are state governments, and they're looking for help, they don't have the resources necessarily to develop these frameworks or implement those, and this is where we can be useful for our partners.

Rebecca Hines: Can we squeeze in a few more questions in the remaining whatever few minutes we have left.?

Wu, you are next.

Wu Xu: I think your successful use case, like the price line, can be adjusted to the state, we have similar hot lines, but a different culture and the suicide reason is different for different patients. So I see that has potential for a successful use case the state accepts.

Then for another conversation, AI you might unload risk, broader impact, I think from the state eligibility issue for the health and human services, like Medicaid, food stamps, housing. So the connection is not tied there. The state are consolidated from different departments, but with AI help we can help as a service.

April Foreman: Thank you so much for mentioning that there are crisis line and help lines at many different levels, not just national levels. When we ask what can be done, I think that the Federal Government is good at convening national partners.

And there are national contact center bodies, there are things like Contact USA or ICMI, when it comes to crisis lines there is the American Association of Suicidology or things like that that are accrediting bodies, or that create standards, and I think convening some strategic documents that are useful for state and local partners, or regional partners to consider this issue, I think that's a really, convening people to create guiding documents that are industry or use case specific isn't a terrible idea, and thank you for saying that, and you're 100 percent right.

Rebecca Hines: Vickie, you need to get your question in.

Vickie Mays: I want to start by really congratulating the VA in terms of the process (inaudible) the number of lived experiences that people have anticipated to see and it's bidirectional. What you all have done is you do this then our people need to really benefit from it.

I think ONC has been also trying to take into account things like social aspects and behavioral aspects, and I think NIST also is doing a good job. But where I worry is HHS. I think that what we haven't heard is a lot of the discussion about accountability, about Greg in particular, when you said on the one hand we have AI is potentially impacting disparities, and on the other hand we have wanting to move ahead. I don't think those two hands are in comparison to some extent.

For me it really is more caution. I see the excitement here, but I don't hear the caution being discussed. We know that studies are coming out particularly in terms of minority populations that are demonstrating the ways in which AI is a problem in terms of the delivery of either screening or healthcare services. That's the excitement that I would love for HHS to be working on. We know for example if Travis we use your study, it said that at NIH the topics of concerns to address some of the science by black women is the least likely to get funded. So when we use all this science, whose voice isn't there?

So in some of the other groups, particularly when you look at some of the groups like Microsoft, et cetera, they're starting to talk about inclusiveness. And that is if you have a model, it's like if someone from the FDA says, you're going to do a new drug, bring me the data of who participated, and that if everybody that I think is critical to this is not there, I'm going to send you back in the field.

The issue of inclusiveness in terms of the model, the issue of inclusiveness in terms of the voices that you bring for the trustworthiness. I'm on the side of more caution, because we get people who for example now don't want to go in for healthcare in terms of worrying about that it is some AI thing that is going to determine whether they're going to get surgery or not get surgery. Those things aren't being addressed as quickly as the excitement about all the different models. So I'm just going to raise that as a concern and ask the question.

And because the issue came up, I am funded by NIH, I do have a project on AI in suicide and homicide, so I do have some expertise, but I also have to say -- So I would really like to hear where you are on answering your IRBs, answering these studies that are coming out, the priority for that.

Travis Hoppe: I have so much to say. So I represent NCHS, my center, but I can speak a little bit about CDC because we've done some of this. First of all I want to call out the NIST AI framework which we keep bringing up calls out so many things. Who was in the room when you're having these discussions.

And if we don't have inclusiveness in the room, tell people that when your report comes out. When you write a report, who made it up, what's their socioeconomic status, what did they look like, that is so important to understand any of these things that come out. It's written there in that framework.

And the same thing is true for datasets, what is in the dataset and who is missing in the dataset is a key consideration, because that's how these models are trained. I will say when we at CDC are thinking about how to stand up our AI strategy, which is happening right now, we are trying to engage with the other groups that are in here that are not necessarily AI related but are DEIA efforts.

I think bringing those groups together and getting their feedback is so important. And I know it is difficult to bring these groups together because oftentimes the people do not show up at all. So we are

making efforts I think at CDC to try to come at it from this perspective. It is very difficult. But we are doing this but until we publish AI strategy there is not too much more we can say, but internally we are thinking about it.

I know Greg is itching to give the HHS perspective.

Greg Singleton: I really appreciate the question. What you're reflecting is the topic of conversation here, kind of what we chose in terms of generative AI. It may be worth a more thorough discussion on the very important issue of inclusiveness, which I will say broadly on all factors, when we look at health and health disparities and questions of fairness when we look at these technologies.

There are things that we have public right now that are out and available in terms of draft regulations from ONC. Our HHS AI trustworthy playbook that is all about the equity and inclusiveness, fairness, transparency, understanding how these models impact the uses that we're looking at.

The NIST Risk Management Framework again is looking at the impact of these models and measuring and assessing it so we understand how it impacts the people if we go to these cases where we're using it in this realm. Largely today many of these models are not deployed in these manners because we're testing and understanding where they work and succeed, where they can come up to our values, where they fail and then we don't use them.

I think Gil highlighted some cases where they take AI models in front of IRBs and said hey, this isn't ending up with results we want, so we don't think you can go forward. What we can say at this point is that all across the agency we're working on these issues, and issues of equity, fairness, and inclusion are infused throughout all of our efforts, from the executive order at the White House level, 13859 on American leadership that reflects our values, and the 13960, trustworthy AI, make sure the AI reflects our values as a nation.

So I really want to thank you for bringing it up, and I just want to assure you it's something that is all throughout all of our work on these things as we best look to proceed forward. I think the panel discussion reflects the excitement about this new technology. This stuff is very new. I think GPT4 came out in March or February. It takes us time to come up with the models, the frameworks and governance and regulations around it to deal with new developments that are real and only a few months old.

Kathryn Marchesini: I know we're at time. I just want to add to Greg's comments. In our proposed role we made note that we understand that collaboration and use of an interdisciplinary, or some people say a cross-functional approach, when developing the life cycle of these technologies, so integrating patients as well as clinicians, data scientists, programmers, things of that nature, involving interested parties of representative actors from the various groups when they're developing the model, as well as a way that this could help address some of the privacy and equity concerns around data practices.

So we ask for comment, to echo Greg's point, it's on our radar at ONC. Granted, we're from the use of health IT and delivery. So not so much on the I would say research isn't just the specific use case, it can transcend treatment, payment, healthcare operations, research, public health. I just wanted to mention that, if you weren't already aware.

Tammy Banks: I really appreciate the good work that you guys are sharing with us, obviously with the appropriate protections, this is new. And this may be too premature of a question, but I just want to ask a self-serving question here. With the expertise in this room, obviously we are charged, speaking to

Michael and Steven's question, when bringing in and modernizing the data infrastructure using HIPAA standard transactions, and this is a very costly endeavor, to implement new versions of different standards.

Do you see in your opinion, again trying to be visionary here, will this reduce the burden? I mean, I know you can code with conversational AI, you can do a lot of different things. Do you see an easier mapping from endpoints into systems, or do you see a mandated standard being easily generated, this is Pollyanna world, can you make this easier, less expensive, in that we can actually exchange the data we need and meet business use cases quicker and faster?

Greg Singleton: I would just say that the potential and promise for translational interfaces between systems is very significant and could reduce the workload. One of the areas that we are very excited about for AI in healthcare is addressing labor shortages. We're having trouble attracting transcribing, entering data, all those other things that are very critical to help someone get successful treatment at the end of the day.

And using these tools to enable that and empower that, increase the productivity of employees and increase patient health at the same time. I think a similar question on kind of the interfaces and translation, there is definitely potential there. Are there a lot of details, nuances? Yes.

Travis Hoppe: I want to add on to that because I think Greg started with this. One thing that we haven't talked about at all is that a way conversational AI can enlarge language models can do is it has changed the world fundamentally is writing programming code. If you are a programmer, or even if you do stats and you want to learn R and have it translate from one language to another, it is so powerful in this regard.

And so getting to Greg's point about interfaces, the dirty details of actually writing one technical thing into another piece, large language models, you can see all these and can help with labor shortages, can help accelerate changing from one standard to another.

The writing of the standards, and I think we addressed some of the other comments, the crafting of them is still a lot of work, and I think AI has its place in there. But from the data engineers, something has to happen, move legacy system from X to Y, there is so much potential for AI to help with those pieces.

Rebecca Hines: I know we are overtime. Before we close out, I wanted to just put out for you all to have in your mind that this is the HHS Secretary's Advisory Body, and you obviously are really just getting your head around this.

If you are interested, you've got an interested sounding board, if there's a role for this group as an advisory committee with HHS's best interest in mind, the committee is here. So I just want to remind us of that.

We could probably talk for another hour with the questions, and you get a sense of where the members' concerns and interests are. but I think this is probably the beginning of this conversation, just given how new everything is. A promise and a peril.

Jacki Monson: Thank you so much for your time today. We are going to go to a break, and let's do 10 minutes since we're running behind.

Rebecca Hines: Thank you everybody.

(Break)

HHS Office for Civil Rights Update

Melanie Rainer: Thank you for the opportunity to speak. I am Melanie Fontes Rainer. I'm the Director of the Office of Civil Rights. I'm here with Tim Noonan, who is my Deputy Director for Health Information Privacy, Data, and Cybersecurity at the Office of Civil Rights.

We are here today to talk to you about the HIPAA Privacy Rule. So I think all of you know there have been multiple executive orders on this. One of the executive orders actually calls on HHS through the Office for Civil Rights Secretary, convenings around the country to talk with stakeholders about federal compliance, inclusion of patient privacy, and the laws that we regulate at the Office for Civil Rights.

As part of that we have done lots of listening sessions in person, remotely, in Texas, Louisiana, Alabama, Arizona, California, all over the United States to have conversations with providers and advocacy organizations, lawyers representing these organizations and patients, government officials, et cetera, as well as a lot of the national organizations, ACOG, AMA, AHA, Planned Parenthood, AAP, AAFP. There are a lot of interested stakeholders in this space.

I think it's not an understatement to say the Dobbs decision, there have always been restrictive practices when it comes to reproductive healthcare, that's not new, but sort of the removal of the base I think has caused a bit of chaos and frankly confusion in the healthcare space. And in a lot of these conversations we heard a lot of things bearing and the need for more in the patient privacy space.

I heard from folks in California say even here, where the care is legal, we have other states reaching in, trying to go after our doctors who we regulate in our state where the care is legal. Our doctors are scared to travel to certain states, even just on their own personal capacity, that they're going to be arrested once they land in an airport to visit family members.

I've heard Colorado for example with the medical board, they felt like they needed more from the federal government, that even in some of these instances where they have strong state law and the care is legal, when these other entities are reaching in, and they go before their medical board, or these other medical boards, that they don't feel like they have enough from the Federal Government to stand up with some of their providers.

I've talked to pro bono council in a lot of these states who think anything from the Federal Government in this space will be immensely positive because they need support from the Federal Government.

So I think there is a flurry of concerns here. And it's not just in the states that don't have the care anymore, it's in a lot of places where frankly the care is legal and they still have providers in capacity providing that care.

We have started to hear some of these concerns before these executive orders went out in doing these sessions. As soon as Dobbs happened, when that late decision came out, we were starting to get questions about some of these things, which we had initially put out a guidance within days of the Dobbs decision to make clear what HIPAA today means, and we can take a minute to talk about that.

But I think overall this is an area where covered entities, people across the country, government officials, we've gotten a lot of incoming questions, we've gotten a lot of questions and increased ask to do more. Members of Congress, we've gotten multiple letters, I'm sure a lot of you saw the political article yesterday that was sort of all over the place, nobody was happy.

But I think just to put a better point on it, there is a lot of interest in this space, this is something that even in the rulemaking as we noted in the preamble that NCVHS and others predicted and thought that could happen. And so I think an important point to the work that we're doing.

So we put out a proposed modification to the HIPAA Privacy Rule. It was no small feat. We had to sort of work pretty quickly on it. The team had to rejigger some of the work that we had going on. Obviously, we worked really closely with the Department of Justice because of the implications to law enforcement to make sure we were doing what we needed to do to protect the healthcare and to protect the patient privacy, but not in a way that confused or undermined legitimate law enforcement efforts.

The proposal is to regulate and to make sure we're prohibiting use or disclosure of protected health information for criminal, civil, or administrative investigations into proceedings against any person in connection with seeking, obtaining, providing, or facilitating reproductive healthcare. Those things are intentionally broad because of the kinds of examples we were hearing. It's not just the doctor, it's not just the provider.

States like Texas that have these bounty hunter laws where it literally could be somebody getting somebody a list, those types of questions. And so intentionally made it quite broad. Making sure we were prohibiting regulated entities from using or disclosing this information to identify for any purpose.

Again, I think when people think about this they think it's a very discrete question, did somebody have an abortion or not, did somebody go in and get contraceptives or not. And I think if you think of a woman, a pregnant person, person of reproductive bearing age, any point in their reproductive bearing age they could have data that would be relevant to these inquiries.

So, I go in for a kidney stone, I have to have a pregnancy test before I'm treated. That pregnancy test is now part of my medical record that might be used to track me and my healthcare. I go in and have a pelvic exam. And in some of the instances where we talked to providers or pharmacists, pharmacists in particular, law enforcement requests that come into them, they're not narrow.

They're not going in and saying I want to know if Melanie Fontes Rainer had a pelvic exam in the last six months, they are, for the last ten years, anyone of reproductive bearing age who had a pelvic exam, they're fishing expeditions. And so our goal was to try to tighten that up, making sure if in fact the data was being used for Medicaid fraud or even an OCR investigation that it was as particular as possible within the confines of the regulations. Again, what we're seeing, what we're hearing are really just targeting and tracking of people's healthcare I think in a way that HIPAA didn't contemplate or intend. And that's why we're worked on this important rule.

The comment period closed just a couple weeks ago. I think we have had over 25,000 comments, which is a lot for HIPAA, not for any of my other (inaudible) where those are like hundreds of thousands, but 25,000 comments is a lot for a HIPAA rule. And so we're continuing to move forward on that. And then I'm going to turn it over to Tim to give more of the specifics on the proposal.

This is just on the current HIPAA Privacy Rule. So we put out guidance making it very clear that these are permissible disclosures and not required disclosures. Again, we contemplated whether or not to put out guidance on this, because we had previous done it in the gender affirming care space when Texas started utilizing child protective services to go after parents and doctors and kids. And so we had put in examples and put out this guidance alongside some nondiscrimination guidance. It isn't the full thing that is needed.

But we did hear from a lot of providers even putting out this, so that covered entities understand they're not required to disclose this information, they're not required to hand it over, that these are permissible, that HIPAA itself doesn't require it, that would be really helpful and powerful.

And so really we've been trying to educate providers around the country on this space, because remember, and you all know this, HIPAA applies to everybody, and so it doesn't change based off of how big or small you are.

And so making sure that we're doing as much education and outreach as we can when we have these committee conversations and events, make sure folks aren't for the first time thinking of these instances when law enforcement is coming to their lobby. Because as I think a lot of you know, a lot of large hospital systems, they have private law firms, they have a privacy officer, they have an infrastructure in place.

Some of these smaller providers, it is the front desk assistant between whether or not the records are released. And so making sure that people have a plan and they're thinking about these things, understanding the sort of new reality in which healthcare information is being used.

So we talked a bit about the need for rulemaking. I think we can just talk a little bit more about the proposed prohibitions in the actual NPRM we put out.

Tim Noonan: Okay, as Melanie said, we issued guidance last year. As you know guidance doesn't change the law, it just clarifies the law. So we did everything we could with respect to guidance for the existing privacy rule. And then we took efforts to come up with a proposed rule to address the changing of the landscape.

So to address concerns about protected health information being used proposed for a person based on a state restriction of reproductive healthcare the NPRM proposes to established prohibitions against using protected health information for particular purposes.

So as the slide shows, first it would prohibit a regulated entity from using or disclosing protected health information for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive healthcare. We tried to make it broad. We see so many different changes in state law, different proposals, and really trying to capture what is happening in real time.

Second, the proposal will prohibit a regulated entity from using or disclosing protected health information to identify any person for the purpose of investigating a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive healthcare.

These provisions would prohibit for example disclosures, a prosecutor, a subpoena, or a court order to a hospital demanding records of all records who obtained a particular reproductive healthcare procedure or medication.

And that's true whether the prosecutor was seeking records of a specific named individual, or as we say is on a fishing expedition, asking for all records of reproductive healthcare provided, looking for people to prosecute. There are limitations to the scope of this proposed prohibition, and we've created a tool of applicability, which essentially provides that the prohibition applies only to lawful reproductive healthcare.

Specifically, the prohibition applies only if one or more of the following conditions exist. And so where the reproductive healthcare is sought, obtained, provided, or facilitated outside of the state where the investigation or proceeding is authorized and where such care is lawful in the state in which it is provided.

So we're talking about out of state investigations. For example if an individual leaves their home state to travel to another state to receive reproductive healthcare, that is lawful in that state in which the healthcare is provided, the proposal would prohibit any regulated entity that has information about the healthcare that was provided from disclosing that protected health information in response to a law enforcement inquiry, again aimed at imposing liability on the individual healthcare provider or someone who facilitates it.

Melanie Rainer: So like a woman travels to California from like Texas, she sought that care in a place where the care was lawful, and the state reaches in to try to go after the patient or provider.

Maya Bernstein: Tim, can you speak up just a little bit?

Tim Noonan: And so the prohibition would apply to any healthcare provider. In that scenario, where the healthcare was provided, in California, the California healthcare provider would be prohibited from disclosing that information.

If that information got made part of the patient's record, the doctor in Texas would be prohibited. So it would apply to any healthcare provider that had that information. Again, it's lawful. So in this case it's the out of state, the investigation is in one state, the healthcare is provided in another state where it's lawful, all of the healthcare providers connected to that.

The second example is where reproductive healthcare is protected, required, or authorized by federal law, regardless of the state in which such care is provided. The best example is where someone is seeking reproductive healthcare such as miscarriage management, as required (inaudible) healthcare is needed in order to save lives to help where federal law applies, and so that information will be (inaudible) The same thing, that information is shared perhaps with other treatment providers as part of someone's health record, the prohibition would apply to all of the (inaudible).

Melanie Rainer: I should just note in our conversations emergency medical care has come up. We have all read the news stories. I have talked to providers in a number of states with banned healthcare where they have patients who were pregnant and intend to stay pregnant and want to carry to full term, when they get to their last trimester if they are older or they have health risks, they are advising patients to go elsewhere, because if they have complications they don't feel that their patients can get, A, they can't counsel their patient, and B, the patient isn't going to get the kind of care that they may need.

And so that to us, it should be scary to all of us. If you've heard me speak on this matter in the last month, I've spoken a lot on it, it's like putting immense posture on the law and lawyers in a medical room.

And I think we've seen the stories of women having sepsis or not bleeding out enough, and being told I have complaints in my docket right now, women being told to wait in their car until they have more blood to show. This is not made up, it's real. And so I think we were trying to draw these circles, both narrow enough that they will survive legally, but broad enough that we will capture the situations in which we are actually getting a lot of feedback on.

Tim Noonan: The last example is where the reproductive healthcare is provided in the state where the investigations or proceedings is authorized, and it is permitted under the laws of that state. So for example if a resident of a state receives reproductive healthcare such as a pregnancy test for an atopic pregnancy in the state in which they provide, and that reproductive healthcare is lawful in that state, then our prohibition would apply to not disclose that information.

The main key point in addition to the three examples that I want to emphasize is the prohibition applies not just for uses of protected health information against a patient, but any person. That also protects the healthcare provider and any facilitator. Some of the states have laws now about people who assist an individual seeking access to healthcare. And so this prohibition would apply.

In addition to the rule of applicability, we added a rule of construction so that the proposed prohibition does not prevent a regulated entity from using or disclosing protected health information for other permissible purposes under the privacy rule. This is the key language, where the request for protected health information is not made primarily for the purpose of investigating or conducting a legal proceeding against a person in connection with seeking or obtaining reproductive care.

So what does that mean, what am I saying? In other words, it's to permit a covered entity to be able to defend itself in a legal action or other proceeding brought in connection with the provision or facilitation of reproductive healthcare.

And so a healthcare provider could, with the rule of construction, be able to disclose information in response to professional misconduct or negligence claims. They would be able to use or disclose protected health information to defend a person against a lawsuit for providing lawful reproductive care. And the health oversight (inaudible) disclosure for the purpose of investigating where reproductive healthcare was provided in connection with a claim for services.

So for example investigating allegations of violations of federal nondiscrimination laws that are connected to reproductive healthcare, a regulated entity will be able to provide that information without violating the prohibition. So the rule of construction is to limit it to the examples that I gave but not become so broad that it is interfering with the usual disclosures of health information that are necessary for our health care sector.

The last main topic I want to highlight is how we're going to implement this prohibition through a proposed attestation. So in order to be able to apply with this new purpose-based prohibition, a regulated entity will need to know the purpose for a request for PHI. And we're mindful of how to do this without placing too big a burden on a regulated entity.

And so what we proposed is for certain types of disclosures, which I'll discuss in a second, an attestation that affirms the attested use for disclosure is not for a prohibited purpose will be necessary before that disclosure will be permissible. So think of some of the existing HIPAA permission that adds a condition of an attestation for certain categories. These are requests that come for health oversight, judicial and administrative proceedings, law enforcement purposes, and to coroners or medical examiners.

And we talked in the rule about perhaps creating a model attestation to make it easier. One of the things, the attestation needs to be a separate document so that it doesn't get buried in a bunch of paperwork, it's its own standalone document. And the attestation will require certain information that should give the regulated entity surety that they're able to make this disclosure without knowing (inaudible).

So some of the information that we included in the attestation would be the name of the individual for whom PHI is sought if it's practicable. If it's not practicable, then a description of the class of individuals whose PHI is sought, name or class or persons who are requested to make the disclosure, the name or class of persons the regulations used to make the requested disclosure. A statement that the use of disclosure is not for a prohibited purpose through the proposed rule. And a signature of the person requesting.

This last slide is just some resources the department has for view or download, a fact sheet that explains some of what we've discussed today, and there's a link to our webpage, to subscribe to our listserv where we do put out regular information and announcements about rulemaking, (inaudible) And then lastly is a link to the department's reproductive healthcare website which provides all the department's published material. With that, we'll open it for questions perhaps.

Valerie Watzlaf: I just want to thank you first, commend you for all of the great work that you have done, all the research that you have done, as well as work on the NPRM in this area. Thank you so much for that.

My question is around, and we had a lot of discussion here in our committee, I also want to thank you for citing our past work. We have had a lot of discussion around why there was a distinction between the lawful care versus unlawful care, when it's so difficult to make that distinction in a moment, and states are changing all the time in relation to that. I don't know if you could talk a little more about maybe how you came to that decision, or anything you could add to it.

Melanie Rainer: We are in rulemaking, so we can't say much. I think to say everything we do right now is closely watched. And I think we were trying to write something that we thought would survive. And so it's not perfect, it never is. And these are complicated issues at a time when the laws are, as you are noting, changing pretty rapidly, and so I think our goal was have this be as legally sustainable as possible while also minimally burdened on the covered entities.

Tim Noonan: We had requested a rather vigorous comment solicitation. In the preamble we did speak about, for lawful healthcare, (inaudible) interest if any for seeking that type of information, whether it's for reproductive healthcare, or someone has an earache, the state's interest in that protected health information for law enforcement (inaudible).

Valerie Watzlaf: We heard yesterday, we had a panel on just the fear physicians have in documenting if they are in a state where it is considered legal, and I don't know if you've heard these issues too,

because this will affect even further treatment and so forth, when the documentation is not accurate. So I don't know what you've found in relation to that.

Melanie Rainer: I have heard extreme in some states, I won't say where, like physician organizations are considering going to paper records, because it's not a secret if you're in a MyChart or an electronic health record and you go and seek care in California, it's lawful, you went to get the care, and then you go back to a place where it's not lawful, I have heard of those providers then in the banned state saying oh, I see you went and had an abortion in California.

I don't think it's limited to reproductive healthcare, unfortunately. I think we're seeing that in the gender affirming care space right now, especially as we talk about trans kids and their providers. So I think it's something that we hope the rule is a starting point on, as the Office of National Coordinator often emulates our privacy posture and position in the regulations, and then they're able to take (inaudible) we're also in pretty close collaboration with them on if there are more immediate things for us to do in the interim, because it is something that frankly comes up quite a bit.

Michael Hodgkins: A comment and a question. Although the number of physicians practicing in small practices is diminishing, the notion, they're already heavily burdened, the notion of them having to manage attestations when inquiries come to them, I think just adds to burden.

I don't know what you can do about that. You mentioned the front desk is sort of the manager of information access. These are not necessarily skilled individuals at small practices, there's a range of requirements imposed on them and this is just another requirement. It's going to be difficult to address.

Melanie Rainer: I don't disagree with anything you just said. I think we are trying to strike a balance where I'm sure you can appreciate putting out a rule like this takes a lot of careful coordination and choreography across the various federal agencies that have equities.

And so I think we'll try to do so in a way that is still permitted statutory law enforcement functions, even though those might be pretextual, the attestation gives the covered entity the opportunity to say no if the attestation comes in and they think it was pretextual, which we thought was important.

And also we think it is important to have that documentation, because again what we are hearing is even if they do have a schema sometimes what we've been told in pharmacies is folks walk in in uniform and just demand records. And so we were trying to be as particular as possible, understanding we want it to be as easy as possible, understanding that's an impossible line to draw.

Michael Hodgkins: I understand. I guess a concern I have apart from that is now there are a lot of entities that are not covered entities. And I'm thinking the patient's right of access is guaranteed under HIPAA, but then patients provide their information to an app or other solution that isn't regulated. There's real opportunity for leakage there. Is there anything that the Federal Government can do in that regard?

Melanie Rainer: Yes. I am going to ask Tim to pop in, but you are absolutely right. If you look back to the Dobbs decision, we actually also put out a guidance with respect to applications, tablets. Because I think at the time the Dobbs decision came out there were a lot of articles about period trackers.

And I think now a lot of those applications and providers that have those applications have made appropriate changes. But everything on your phone, whether you download it or not, may have

implications for your information. We regulate maybe a very small percentage of that. So we have tried to be vigilant in putting out information to the public, we're working very closely with the FTC in this space, we don't have jurisdiction over some things where they have jurisdiction.

And I think the best practice there is if a covered entity is releasing information to an application that they have a business associate (inaudible) agreement in place, which is something every time I talk, I know Tim talks, we have guidance on our website, those are some of the things.

But yes, there is just going to continue to be a gap regulatorily because we don't regulate all the things on an application, FTC gets some of them. So then that gets to a question of how they're being used.

And I think we're seeing, and I'm hearing, I met with Apple a couple weeks ago, and I said I know not all the applications that go through the App Store are yours, but you can use some front-end tools to help regulate. Because we see a lot of products that say I'm HIPAA certified. Well neither us or anyone who works for us certified them, so I don't know who certified them. And that's giving people false hope or false security that that information is going to be protected or regulated, and it's not.

And I think we are thinking of other ways to work with, whether it's AMA, AHA, some of the reproductive healthcare groups or privacy groups to try to educate folks, because I think it's an opportunity right now, it's an opportunity and a curse where we need to educate people about privacy right now, understanding that we're sort of in a new reality for how health information is being used, and the best, most diligent person for this is the individual thinking in the first instance so I put this on my phone, do I download this in the first instance, do I store PHI on my phone.

Melissa Goldstein: Tim and Melanie, thanks so much for coming today, we really appreciate it. Tim, it is nice to see you again. Melanie, it is nice to meet you in this environment, we appreciate it. I very much appreciate the balance that OCR is trying to strike here, and it is very important to me that regulations survive, and that you have to balance all of those equities.

What I wanted to ask you was, we tossed around the idea of what happens in these other disclosures that are allowed without the attestation that Tim just mentioned, and the possible quote-unquote leakage of information that comes out from those other disclosures, and the idea of a part two with the prohibition on redisclosure and whether that might work here, and is there any way for us to get at that type of redisclosure that then can be used by law enforcement, such as law enforcement, I read in the press today, there's talk about trying to prohibit law enforcement from buying data when they can't get to it without a warrant.

So if law enforcement can get to the data by getting the data that is otherwise leaked out, that's what I'm thinking about. The two of you, I know that is not included in this rule, but ideas that are percolating out there would be helpful to us.

Tim Noonan: You raised an excellent concern, the limits of our jurisdictional authority. You are quite correct, if health information flows to an entity that isn't regulated by HIPAA there are no redisclosure prohibitions that we are able to effectively implement, it would require new statutory authorities extending our jurisdiction.

I think, as Melanie had expressed earlier, in the absence of statutory jurisdiction for now, the best thing we can do is educate individuals about the choices they make with respect to their health information, about where it's stored, who their record might be transmitted to, disclosing into.

But yes, if reproductive health information is given by a patient to an app that's not regulated by HIPAA, there is potential there for law enforcement to be able to access that information, and our proposed rule isn't able to address that because it's beyond the scope of our authority.

Melanie Rainer: There has been a number, this is all public, it's in the news, not in the reproductive health space, but you are seeing instances in some of these states where gender affirming care is being banned where somebody that works in a facility is taking it upon themselves to disclose information, whether it's to a state attorney general or a news publication using this so-called whistleblower hat under state law.

It's a new area, not new area in the use and disclosure, that's their bread and butter, but I think this wearing of this hat, I think that's a trend we're seeing, there are a number of instances where people have gone and posted a bunch of patient files, kids visits to news sites or disclosed them.

And so that's another area I think that bleeds into this, where it is really important on the front end to have all the security and privacy controls, who has access to the data, why do they have access to the data in the first instance, that's what we can regulate. But I think re-educating providers is really important right now, because I think these are things that people did not anticipate having to talk about with staff or trying to face, and I think we're seeing it more and more. I honestly believe it's only a matter of time before we start to see it in the abortion space.

Jacki Monson: I have an ask and a question. The first is we were lucky enough to have Rachel Seeger for a long time who was part of your Office, was actual staff to our Subcommittee on Privacy, Security, and Confidentiality, and we miss her in that role. And I don't know if there's a possibility to get an additional staff to help us, but we would love to have more connectivity with you all, to make sure that we are really helping in any way that we can with the agenda that you are pushing.

Melanie Rainer: Yes, Rachel Seeger has taken a new position at AHRQ, and she has got a promotion, so we are happy for her. I think folks know our resource situation is dire. It has been that way for over two decades. Our settlement dollars are dwindling and will run out by the end of 2024.

And so that's something we've been working separately with Deputy Secretary and others to make sure that there is a plan in place. But I am happy to directly engage with you, I'm sure Tim is happy to directly engage with you to assign someone in the front off that is the point, but we are happy to as you all see fit. Understanding that sometimes we might not respond right away, it's not because we're being snotty, it's just that we're understaffed pretty severely.

Jacki Monson: I work in healthcare too, so thank you for that. The second question I have is changing subjects a little bit. In my day job I am a Chief Privacy and Information Security Officer for a large organization, and the bulk of my time and my team's time is now spent on cybersecurity, cyber attacks of third parties.

And I know it has been a while since the security rule has been updated. It is one of our biggest challenges to even getting notification timely, and two, the impact of these cyberattacks, the most recent one being that you've been flooded with hundreds of letters from our business associates and third parties at those business associates who have been impacted by that file sharing issue. Is there any plan to update the HIPAA security rule or otherwise provide guidance in this area?

Melanie Rainer: It is an area that obviously I think the healthcare industry is on the front end of cybersecurity threats, ransomware. In our own data alone we have seen a nearly 300 percent increase in ransomware hacking cases. We've seen 100 percent increase in large breach reports. If you go from January 1 to this point in time this year, it's double the number of large breaches filed this year.

These are just some data points from our own website that you all could come up with. It's something that continues to come up, it's a priority at the department level. We work very closely with the Deputy Secretary, ASPR, ONC, FDA, others on this. We have not formally committed to anything yet, but I think there is a growing fire and need.

And not that we don't share those things, it's just we have limitations on how much, and how much we can move fast. So I think there is interest in this space. I think we are trying to think through how to execute on something like that, understanding not an insignificant thing.

R. Lenel James: Yesterday, we had ACOG visited, and one of the surprises to me at least was the amount of pharmacists who are blocking. Are you guys familiar with anything related to pharmacists, because they seem to be they're concerned about giving medications that don't require certain -

Melanie Rainer: Two things. So one, in the days of the Dobbs decision the Office for Civil Rights put out a guidance. I like to remind folks, just because you live in a banned abortion state doesn't mean that you don't have civil rights anymore, or you don't have protected rights under HIPAA or other federal laws.

And so our guidance focused on Section 1557 of the Affordable Care Act, which is nondiscrimination in health programs and activities, and section 504, which is disability-based discrimination, because at the time we were seeing a lot of instances in these banned states where women would go in, and they have rheumatoid arthritis, they've had it forever, they're being denied their methotrexate, which is a medication used to manage that condition.

Women were going in having already experienced a miscarriage, the best practice in miscarriage management is to take misoprostol so that you don't develop an infection, they're being denied that misoprostol. So we put out guidance examples, we're being sued on it right now in Texas, surprise. So that is what it is.

But we actually did an investigation of a bunch of national pharmacies, and we didn't find a finding of violation, but what we were able to do is with both CDS and Wal Greens, which are two of the biggest national chain pharmacies, come up with additional things that they are doing.

They have, these are new things that we got them to do, a hotline for these kinds of matters, because they don't have those kinds of things. You get denied, typically you'll call your insurance company or the provider, but now there's a hotline to help triage that both at CVS and Walgreens. Bringing forward on their webpages some of the information about appeals, again understanding that they do this in the opioid space, it's really the only other place that they've done that, but trying to be very clear about the appeals process.

Making sure that they have training with respect to civil rights and privacy, because a lot of the complaints we got were delays, never a denial but delays of the scrips, which is not uncommon unfortunately for other medications, it's just in this instance you have these big pharmacies, at a regional level, it just really depends on the day of the week, the pharmacy you're at, the person at the

front of the line, and like other healthcare industry people they are under capacity because of other issues.

And so training for them, understanding that we've had complaints of people being stigmatized because of the kinds of medication they were seeking, or they just left the pharmacy, went somewhere else, to another part of Walgreens or somewhere else and got that medication.

So I'm happy to share the press release, you can all see it, but we did announce that a couple weeks ago, and so there are a number of steps, and we continue to monitor additional pharmacies around the country. The complaints that we had received, we got like 20 or 25 complaints.

Valerie Watzlaf: I have a timeline question. I know you received 25,000 comments on the NPRM, so I think we probably know how you're going to go through all of these, we heard a wonderful panel on AI, so I don't know if you want to consider using that. Can you give us a timeline maybe of when you think we might hear, this will be final.

Participant: They did actually suggest it was a good use of AI, is to summarize comments, because you're using the true information of your comments.

Melanie Rainer: It is obviously a priority for us. Tim's team is small, and we're also the same team that's working on part two, so we're doing our best, but it's a priority to do it in the next year, understanding it's not a hypothetical rulemaking, it's a rulemaking that's actually solving a problem, so we understand the urgency.

Valerie Watzlaf: I didn't know if you could say anything more about the part two, harmonization role and the timing there as well.

Melanie Rainer: It is a significant priority for the office to get that done, given the law was passed in 2021, it was a bipartisan proposal that helps with behavioral healthcare coordination.

Valerie Watzlaf: So that's urgent too, that rule.

Melanie Rainer: That rule we didn't get many comments on. It's a priority for us to complete it.

Maya Bernstein: I have a quick question, I don't know if you could answer. If I remember correctly, we're really only allowed to amend the rule once a year. Are you at liberty to say, does that suggest that you might, as you've done in some past rulemakings, combine a couple of the high priority ones so that we can get that kind of thing done? It's complicated to do that, but is it possible?

Melanie Rainer: Anything is possible. We are aware of that provision. My team is very smart and very dedicated. I should note, Tim's team is 17 people. If you talk to CMS or other large agencies, that is like a drop in the bucket in terms of the number of people who do regs. They do significant policy legal work in a space that is constantly changing critical stuff like people's health care (inaudible) national security and so we're very privileged that they have such a great team.

Literally one of the employees that worked on the HIPAA privacy rule was in the ER during it because she had a medical condition, and she was texting us. (Inaudible) some of the red lines. A person came out of retirement to work on this rule because she was so mad about Dobbs and thought this was the opportunity to help people.

Jacki Monson: Thank you so much for your time. Let's break for lunch.

(Lunch Break)

Updates/NCVHS Workplan Development

Jacki Monson: So, the first agenda item is the updates to the work plan development. So I'm going to kick it to Standards first, and then we'll go to PCS. I don't know do you have anything from ICD-11?

Jamie Ferguson: I think we covered that yesterday. I think the only thing is in terms of the work plan we want to write a report based on whatever the analysis and findings are from the August 3rd Roundtable. And that's likely to take us into the next fiscal years, which would take a reauthorization.

Tammy Banks: Before I start, I want to thank Rich Landen and Denise Love, she's not here, for being cochairs. I'm going to be going through some historical overview, and there are a lot of predecessors that have invested their time and efforts. And also you guys all know the current subcommittee chair, committee members Jamie, Deb, our new one, Steven, Michael, Lynel, and Margaret is not able to join us today, but has been a participant in all our activities that we're doing.

I really hesitate to give out this Standards Subcommittee report, because we are supposed to be sort of advanced and our partner Subcommittee, Privacy and Security had to come up with QR codes. Well, I learned how to do QR codes, but I did take the time to implement them in our – But I will remedy that. You will not be ahead of us next time. Anyway, it is wonderful to be here in person, and I appreciate this time.

I am basically going to give a report out on the activity of our Standards Review, and then I really would love your active participation as we talk about the evolving Convergence 2.0 Project. I did a little history lesson in regards to how we got to where we are, based on resolutions and recommendations, not a big overview of the whole project. So I just want to bring you up to speed on where we're coming from and why we're where we're at in regards to the Subcommittee on Standards, as well as again commend all the historical work that has driven where we are today.

The CAQH/CORE letter with the recommendations that were approved at our June 14th meeting was sent to the Secretary on June 30th. Again, instead of a QR code I did the beautiful URL underneath the explanation of that letter. If you go to the next one, the same thing, the URL will get you to the X12 recommendations that were approved at the June 14 meeting and sent to the Secretary on June 14th.

We received another request from X12, we're affectionately calling it X12 Request Two, and that was received on April 11 of 2023. We really didn't have a chance to review that two fully until after last meeting. That request asked NCVHS to recommend to the Secretary to adopt version 8030 for the claim status, which is 276/277 for the techies in the room, which basically is an inquiry from a provider to a health plan to determine the status of a healthcare claim or a response from the health plan.

According to the 2022 CAQH Core Index, the adoption rate for the electronic claims status for medical is 72 percent and 25 percent for dental. So you can see there is more room for improvement than we saw previously with the claims.

In addition, they're looking at the benefit, enrollment, and maintenance transaction, the 834. This transaction set is used by employers, government agencies, enrolling members, insurance agencies, union agencies, and others, as well as their business associates, in a healthcare benefits plan.

HIPAA requires that specific administrative processes must use standardized electronic transactions for these functions. This transaction may be used to record changes in the member's enrollment, reinstating a member's benefits, enrollment and/or disenrollment of any member, termination of a plan membership.

And then the third transaction is the payment remittance advice, or the 820. That transaction is used for the following business usage: transmit payroll deducted premiums for a wide variety of insurance products, to include life, health, property, and casually and disability. The guide was also designed for healthcare premium payments between federal and state governments, government agencies, and private industries. And similar to the last request, these transactions, if moved forward and the Secretary decides to put into rulemaking would go to 8030 version, the rest would remain at 5010.

And as discussed before, but always good to refresh, the NCVHS role related to the HIPAA standards review is we receive requests for new or updated standards and/or new and updating operating rules from operating rule authoring entities.

When we receive them we receive input from the standard developing organizations, as well as the industry and public input to ingest that information and determine whether the request meets the requirements of the HIPAA administrative simplification as amended for efficiency, effectiveness, cost value, et cetera. And then we would make a recommendation to the Secretary who then has a choice either to accept or reject.

So our review steps for this proposal, we were fortunate to have Kathy visit us and give us an overview presentation of these transactions earlier this month. In addition as our traditional process will be collaborating with WEDI who is a named advisor to the HHS in the HIPAA statute. They have been very helpful in the past in collecting additional member feedback that we may not have access to.

Then we will develop and publish a request for comment. At this point we're expecting that to occur in early September. We're going to be extending the comment period because we also want to add some additional scoping document questions depending on how our work plan falls after this meeting.

We also always engage in consultative conversations with CMS, OBRHI, the NSG, as well as ONC, as we review these types of standard reviews. And also as I said before obtain the input from the DSMOs, draft the recommendations, and then these recommendations always come to the executive subcommittee, and then we bring to the full committee who makes a vote on whether these recommendations go forward or not.

We went through with more detail, again just for the new members, to understand what is the process, why do we do things. I know this is repetitive, but it's important to bring everybody together on the same page.

And when we review these standards and operating rules, we always do it with the same set of questions, which you'll understand more how these questions were drafted based on the history of our committee.

Number one, is there industry consensus around the need for the proposed change and updates? That's why we have the RFC and we have the listening sessions and the hearings.

Was there sufficient cost and value data, and applicable use cases, along with identification of the burden, opportunity and efficiency for the proposed standards upgrades to assess impact for implementation? That information all goes into the deliberation on the value of moving to a new standard or operating rule.

Was there availability of information to confirm the backwards compatibility, as we're looking at subsets of a suite, or we're looking at independent transactions, how does it impact the environment in which it needs to operate?

How does the proposal address industry concerns? We're going to talk about some of those with the Predictability Roadmap and the Convergence 2.0 projects, which you'll see listed.

And does the proposal further the objectives of HIPAA, ACA, and other applicable laws? Which is really the paramount of the deliberation.

Before I go on to the Evolving the Convergence 2.0 Project, does anybody have any questions, or Rich, would you like to expand on any of the updates?

Richard Landen: (Inaudible)

Tammy Banks: That is one of the reasons we are looking at a request for comment versus setting a hearing right away, because we're hopeful that that feedback will inform our next steps. Thanks, Rich. Any questions?

What I would like to go through, and I'm going to want your active participation at the end here. As a subcommittee we did have a lot of time, we are extremely in draft format, but I'm just pulling some of this stuff that we've compiled in order to have a discussion. And one thing on our subcommittee calls, just to add clarity on the process of the full committee, in that while we're a subcommittee, we're focused on standards, it's the full committee that all the work product comes through.

And so even though we're delivering, and sometimes we have a privacy and security concept or idea, we always work closely and share that with the privacy and security. We are blessed to have Jamie serve back and forth to keep us aligned, because anything that's developed in the Standards Subcommittee, and this is just for my group, and I know it's the same for you, gets brought to the full committee, so we want to make sure that it's understandable and it's something that can be voted on based on the NCVH full committee overall, which I think is an important concept that we hold out in our deliberations.

When we're looking at our work plan, it was really important for us to clarify the different roles the Standards Subcommittee has under the charge. The one that we've been operating most frequently in the past eight months is the review of standards under our HIPAA Administrative Simplification Requirements.

But in addition to that we're also responsible to: Identify issues and opportunities in health data standards, provide outreach, liaison, and consultation with, and serve as a public forum on health information technology standards for the health care industry and federal, state, and local governments.

Make recommendations, which is what we have been doing, not just for standards and operating rules, but also for health terminologies and vocabularies.

Make recommendations on strategies to promote a continuing process of developing, coordinating, adopting, implementing and maintaining standards. As well as the report to Congress, which I know we'll get to. And also collaborate with other federal advisory committees as these different issues arise to make sure that we all are in lockstep and barrel and being the most effective advisory body we can to the other federal advisory committees.

So we're working on reviewing Convergence 2.0 in order to better understand where best to put our resources and our time to be most effective in the current environment. And so we took a step back to the Predictability Roadmap that was created by our predecessors, who did an amazing job, and I would love to name names, but there are so many and I don't want to miss anybody.

So all of you who have worked on it, and I know Rich you are in the room, so I'll say Rich, and Deb, and many others, really took a look at how do we streamline the submission, the review, the adoption, or the recommendations, the adopting and the development of the proposed rule and to the final rule and the implementation process, that whole process.

So they were looking at how do we get the industry driven standards development and adoption more simplified, more concise, and more easily implemented. So that's where the regular updates, the movement to more frequent but smaller, more digestible updates that we saw was the subset versus the entire suite of X12.

This is where the enhanced pre-adoption testing was raised, where it becomes more important when you're looking at those smaller, more digestible updates, and also the need to build in that value assessment, because the environment has changed from 4010, and we really need to understand when it makes sense based on the competing priorities as well as the different proposed rules and final rules in the pipeline or the roadmap so to speak.

And then Convergence 1.0 and 2.0, and ICAD, were really focused on the harmonization and integration of the standards. So it was the second piece of the bigger picture that we were trying to take a bite out of, or the pie we were taking a bite out of may make more sense.

And the convergence of administrative and clinical data to meet business needs, which was all the work around prior authorization, and how there is no administrative and clinical data now, it all converges to meet the various use cases. And as I mentioned before, this is all in collaboration with the Privacy & Security Subcommittee.

I'm trying to take a snapshot and not go into this too deep. So what I'm only going to be focusing on again is the recommendations we made to the Secretary. So there was a lot of work that was done to get to those recommendations, because this is where we convene the forums, we do the focus groups, we do the listening sessions, we do the RFCs in order to really get the pulse of the industry before these recommendations are created. And so I am going to lay the recommendations out, and then hopefully that will help inform where we have our discussion.

So I think I already mentioned where the Predictability Roadmap was going from a high level, so if you want to go to the next slide. So the recommendations that came out of the Predictability Roadmap,

which is 2017 through 2019, was to remove the regulatory mandate for modifications to adopt standards and move towards industry driven updates.

There was a lot of conversation, and I think the conversation is still being had in regards to the relevance of HIPAA in this current environment. What makes sense, what doesn't make sense, innovation is strongly hindered in HIPAA, and that recommendation one clearly represents the same conversation we're still having today.

The second recommendation that went to the secretary is to promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules, which falls in the same bailiwick.

Recommendation three, improve the visibility and impact of the administrative simplification enforcement program. This recommendation comes up in every testimony we have, and remains relevant today.

Recommendation four, provide policy related guidance from HHS regarding administrative standards adoption and enforcement, which is an ongoing process that's occurring.

Recommendation five, reevaluate the function and purpose of the Designated Standards Maintenance Organizations.

Now, these five recommendations were built off eleven original recommendations that really fell into seven calls to action, and then there were three measurement recommendations. And so anybody who is very interested in the history of this roadmap, and I know all our committee members have this information, it's found on the NCVHS website under work products. It is again still very relevant today.

So, Convergence 1.0 and 2.0 resulted in two sets of recommendations. The first one is published in the CMS Interoperability and Prior Authorization proposed rule, which we're very pleased to see that the NPRM was published. Adopt a standard or standards for electronic attachments, and we're very pleased that the NPRM was published as well.

And HIPAA transaction rules notwithstanding, evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as the FHIR standards and implementation guides. So you kind of see a theme here.

And recommendation four, streamline the process for adopting HIPAA transaction standards so that it is reliable, efficient, and timely. And the underpinning of that recommendation you can define in a predictability roadmap which clearly outlined where the needs were and where opportunities existed.

I believe it was in June there were four more recommendations. The first one and the second one are ones I think that there is still a little bit of confusion on what the intent of those recommendations are, so I'm going to elaborate on those a little bit more after this slide.

Recommendation three was to expand the authority of ONC regarding social determinants of health. And then the recommendation four was one that we referenced in the recent X12 letter, HHS should develop and publish a guidance framework for SDOs and other industry stakeholders that outlines how to develop and report quantitative estimates for new and revised standard readiness, cost, and overall adoption, value to support HIPAA standards development, testing, evaluation, and adoption.

So again, just to understand why actions and why the discussion occurs the way it is, you can see that progression of thought in regard to where do we go from where we are standing today.

So recommendation one, update relevant HIPAA policies to allow the adoption and use of more than one standard per business function. Right now, today, only one HIPAA standard is mandated for a business case. One example is the X12 278 for prior authorization, because that is an easy one to explain. So a potential future use case, and I want to be clear this is just visioning, these are examples, no-one brought anything for us to review, this is to help add clarity to what that recommendation could possibly do if it's acted upon.

A prior auth is triggered in different locations. It can either be triggered in your patient scheduling, your patient management system, your electronic medical record, and there are other places where prior auths could be triggered in a revenue cycle management system, it all depends on your vendor and whom you choose to work with for your business associate. So each of these platforms are built on different standards.

So the X12 278 may be the prior auth transaction choice for a practice management system, while an HL7 FHIR API could be used when triggered in the EMR which is built on the Hl7 standards. Or if a provider would choose to have an enhancement with their electronic medical record that uses a Smart on FHIR application, they may choose to use the Hl7 FHIR API.

What this recommendation is intended to do is give providers and their business associates a choice, so that they can choose through their vendor which standard would bring the highest business value to them, is it through the practice management system, is it through their EMR, the payer would have to support both of these transactions, but the provider or the person who is sending the information would have the choice based on their revenue cycle workflow, which underline transaction, if again those two standards would be the ones that would be chosen to be mandated for a business use.

Just again to give you an example, a provider who chooses to use their practice management system to send a prior auth that uses an X12 278 transaction with the workflow. While another provider is going to choose to use that Smart on FHIR app with their EMR that uses an HL7 FHIR API within the workflow. With this change that type of decisions by the provider and their vendors could be made. Any questions on that, in regard to recommendation one, and Rich, please, any clarity.

Participant: Is it difficult for the payer to support this? Because they have to be able to handle either one.

R. Lenel James: The answer is yes, very expensive. However, payers, thousands of them, not all payers are fully engaged on FHIR and the next API, because if they don't do Medicare/Medicaid government business they didn't have to do it at all.

So it's unclear how many small payers (inaudible) and the burden may be for payers that aren't pacing with the latest API change because they're not covered by CMS, then we might have a situation where a provider says oh, I'm a large health system, I'm sophisticated, I want to do FHIR, and they have a payer that is like I'm not doing FHIR, there's no federal regulation to do FHIR.

So it's both expensive, and there may be some smaller sized payers that aren't (inaudible) the advanced technologies for which there will be a problem for the industry on doing this. Don't know for sure, most of us are active (inaudible) HL7 but there are a whole bunch of payers that don't follow the standards,

they just do what the industry is doing. So I get concerned that there may be a pocket of both payers and providers that can't handle both, and (inaudible) somebody will be left out on both ends.

Tammy Banks: You're asking the right question. And the reason for this recommendation is to allow that question to be asked. Because this is a hypothetical example. Right now under HIPAA, we can't have that conversation, because there is only one standard per business transaction. So just remember this is not up for debate, this is not something, we're not saying the industry is ready, this is an example of trying to make HIPAA more flexible to meet future business needs potentially.

Richard Landen: Any change to the standard is the result of a request for new business functionality brought by either a member of the standards organization or by any of the stakeholders, whether it's through the DSMO process or not. So every change made has a value to someone. So your question about the costing, yes, as Lenel said, there's nothing at this scale that doesn't cost some people an awful lot of money.

But the counterbalance to that is there is needed functionalities, because healthcare is so diverse, those needed functionalities may not be universal, maybe if you're a dentist or a very small practice or a surgeon but not an ophthalmologist, so the benefit is not evenly distributed.

It's part of our job to take all that into consideration and say on a national basis at scale is the net benefit there to impose this option cost on the entire industry, because we can't just single out those who would directly benefit from any one given change in the standard.

Rebecca Hines: And I know we don't have a member who is with Cigna but Cigna actually wrote into the chat, since we have a parallel universe going on here on Zoom, and he says that Cigna has already discussed the likelihood that we would need to support both of these options and are prepared to do that, we think it's a good way to go to help reduce burden to providers.

Debra Strickland: To that point, this could be crafted in such as way as to either/or. So those who want to stay with the current standard and don't want to advance to FHIR should stay right where they are, because do no harm, let the system work the way that it needs to. But the problem is the regulation is restrictive and doesn't allow that. So if we were to open up or make changes such as letting a standard such as FHIR have its day in the sun, maybe we will find partners that are willing to do that and will find the financial benefit from it.

And, just so people understand, no-one just goes into this with their eyes closed. Everyone has trading partner agreements and business associates' agreements, and lots of things happen before connectivity is done. So it's not like they're going to whip out FHIR things and they're not going to be prepared.

Jamie Ferguson: I just want to also point out with this particular example of using prior authorization, the HIPAA prior authorization transaction is only used something like 12 or 13 percent of the time. The vast majority, over 85 percent of prior authorizations do not use the HIPAA standard. So people use phone and fax and it's a very high burden. One of the reasons for allowing the use of the more modern technology that is easier for most to use is to increase that compliance level above the 12 or 13 percent level nationwide.

Tammy Banks: So again, it is trying to look ahead to provide the flexibilities based on innovation that is coming on.

Tammy Banks: Ok, any other questions? I think it's just a really important distinction, and there was confusion, and this is very important as we are evolving, and we've got to be able to evolve, and that's why the recommendation from the committee.

So, recommendation two, enable HIPAA covered entities to support one or more versions of adopted standards for business functions. This is a little bit easier to explain. Because the current use right now is if we would move to an updated standard, payers would support the existing standard and the updated standard. So that's at least two. And I'm going to stay with two as the max. That's a whole other conversation.

So this occurs today, and then when there's a deadline of when everybody needs to move to the higher version, then in theory everybody moves to the upper version, but it doesn't happen. What happens is the payers try and move as many as they can, as quick as they can, and sometimes they keep those two versions for the laggers, to make sure that they keep the information coming.

So it happens today, it's probably still in effect today. I know we've talked to payers that are keeping more than one version active, because again they want to get that information electronically, which totally makes sense. So again, it is occurring today.

But let's think about this from a visionary perspective. What is the potential future use case? Again, this is a hypothetical, just came up with it to help understand why we think it's important.

If the past review of the 8020 claim, the professional, the dental, and institutional standard, the implementation guide, if that would have gone to the Secretary and it would be mandated, payers would be supporting version 5010 and 8020 claim standards for professional, dental, and institution, both he lower version and the upper version.

Each provider and their business associates could then decide if there's a business value to move to the updated version. So when an additional updated version is mandated, then providers and their business associated would have to move to either 8020 or the new version.

Let me make it a little more clear. We're saying if the 8020 claim would move forward, not everyone has to move to 8020. It would be a choice between the provider and their vendor. The payer is going to support both. Again, hypothetical. If there is value there, they would move, if they're an innovative partner and they want to move forward they would, the other ones would stay on the original standard and not incur that implementation cost. However, if another upgrade came, then they would have to move up, right? If we kept two as the allowable versions that are out there. Again, hypothetical, I'm using two, this is Tammy, this is something that would have to be talked about.

Let me give you an example. When we were talking with the 8020, the dentist, we're showing that they have a lot of fields in there that are more specific, and they can report more clearly what procedures were performed in that 8020 version. We have to look at nationwide implementation, and we have to look at the cost value. We've already went through what questions we need to go through to really be clear on how to provide the recommendation that best meets the nationwide implementation and the industry feedback that we receive.

So, in that case, if 8020 would move forward, the dental community could choose through their vendors to move to 8020, yet the providers and the hospitals could have stayed at 5020. So there's room for innovation across our national implementation if there's more than one version that can be enacted.

And remember, those versions are still being enacted anyway, but now we allow, let's say a specialty, there's some major innovation, and they have these fields that are needed, I'm making this up, but just for an example, then you could do an upgrade, but not everyone would have to move if there is no value.

Within the proof of value to the overall community, the nationwide implementation is lower, there has to be enough value for enough of a subset to go to the next version. So now you represent even the smaller pieces of the national implementation versus it has to show value across the majority.

So I'm thinking that is where the value was in this recommendation, again a vision to try and open up HIPAA for future innovation and help us move a little quicker within the framework that we are. Rich, do you want to add any clarity?

R. Lenel James: For recommendations one and two, just an open question for clarification. These standards have content requirements. So what happens if the new standard has different or additional required data content? Basically the vocabulary that we use, when I go from FHIR to X12, sometimes FHIR (inaudible) let's say require code set that it isn't available. When X12 was built, it is available right now, so it's in the new standard. Has any thought been given to that challenge?

Tammy Banks: No, but wouldn't that be enough value to move to the next version? So you would move to the next version, correct? So if you're saying ICD11 would be in the next version, people would have to move to the next version, because you have to have the ability to code it, if it was a mandated code set. Am I hearing it? That's the question?

R. Lenel James: (Inaudible) when someone comes in I guess I am nervous about the clarity of whether I or the large payer system can maintain two sets of, because we're assuming it's just additional, not changed, because if it's changed –

Tammy Banks: That would be included in the - No, it does now, it happens now.

Richard Landen: Let me say something on Lenel's question. There are a couple types of datasets in the X12 standard world. One is external code sets. External code sets can change at times unrelated to the version of X12 that's adopted. So that addresses some of your concern with some of the code sets. The code sets that only change with the version are the code sets internal to X12. And in that case those who don't go to the new version are locked into the older code set.

That's the way it works now. It's not something that in my head doesn't demand a solution, because the workaround is that's another piece of information, the health plan needs the provider, and there are ways outside the standard transaction to request and receive that information in the X12 world. So it's a workaround, it's not as efficient as incorporating it into the standard, but a solution might exist.

Tammy Banks: And then you've got the testing, possibly more frequent updates. Anyway, concepts, things to think about to loosen up our rigid requirement.

Vickie Mays: What is the incentive for people to do this? We talked about there's this first one, and now there's this second one, you're costing people money, what is the benefit? And if it is that important, is there not an incentive to get them to do it?

And then my second question is, at kind of a bigger level, why should people do this in terms of if it's like a solo practitioner. Where I get pushback is when I see these people who have these small practices and what have you, and they just complain about how the changes all cost them money. And then they've got more work to do with the health plan people. And the health plan people are talking to them about the changes. So I'm just trying to understand.

Debra Strickland: So, the answer to the why, would be, as Tammy said, there's something advantageous in that transaction, either the provider has to send something, or the payer has to receive something that would change the processing significantly. So there is some significant advantage to going up to the next version of the standard.

Vickie Mays: But what is it?

Debra Strickland: It could be anything. It could be new networking fields. It could be new numeration for procedures or something like that. It could be anything they put in the guide. It could be any of thousands of things.

Tammy Banks: They have the numbers so they can actually report more clearly the services they're providing.

Debra Strickland: So the question is, in normal HIPAA if the transaction is a named standard, of which we have named standards for each transaction, if a provider wants to do it then the payer has to do it. So that's clean. In this particular case, who would be the decision maker? So if the payer did have a capability to do it, the provider maybe could do it. So who is going to be the one that says we're going to do it? Neither one could force the other to do it, but they could jointly partner and do it.

So this would be similar to something like a pilot, like a payer would have to advance – When a payer rolls up to a new version of the standard, it is a big deal. It is a lot of money. It's not just even supplementing and putting a couple fields in the process. It is from soup to nuts, top to bottom, and this is where Jamie and I come in with the regression testing and that conversation. You're touching everything along the way.

So you almost have to make a silo that is that transaction, and all those transactions are going to come out of that silo. If you stay on the lower version, then it's going to come out of the lower version silo. And all the code is kind of different, because you're filling the transaction differently at the end of the day, or bringing it in differently.

So as far as what is going to make people do it, they would have to be motivated to do it. We don't in the industry today have a whole lot of people raising their hand to say yes let me just jump on this new version. They mostly will not because of the expense until it is named version, or because HIPAA says we have a NPRM and a mandate that you must do it. They usually come kicking and screaming, and even as we heard from Cathy, they even have a hard time keeping people in pilots and stuff.

So it is a hard sell, and your providers would come later I think. I mean, your providers don't have as much incentive to make changes because they're smaller, unless they're a big entity. They wouldn't have to do it either, because again, if there were options it would be willing trading partners.

Vickie Mays: But is it important enough for there to be a recommendation that you want them to do it?

Tammy Banks: There would have to be, before a recommendation would go to put a new one, all that discussion would occur, there would be value. The question is who is the value to. If the value isn't across the country, and it's a subset value, it's 50 percent of the specialties but not the primary care, I'm making this up, then the specialists, again there is a lot more, could move forward, the small providers could stay on their systems for one more time but they're going to have to move at some point when another recommendation comes in. Because we are hopeful that again we will have more frequent updates that would be smaller. That's kind of the goal, where we're trying to go to.

Rebecca Hines: Can I just read, to Vickie's point, Laura Caldwell has added that please remember that supporting two standards are not only for large and small payers but also state Medicaids and tribal health agencies who are struggling with their budgets as it is.

Tammy Banks: So they would not have to move, but there could be value. Again, trying to preserve the small.

Jamie Ferguson: I want to respond Vickie to your question with just a little bit of color commentary. There is not a single answer to where does the benefit lie, and why would trading partners go through these upgrades. It depend on the nature of the changes between the different versions.

So in some cases it might be adding the ability to have codes, such as whether it's tooth numbers or SDOH codes or other things that you want to add, things that might enable disease management programs on the one hand, or things that might reduce system operating costs and maintenance costs on the other hand. So changing from a sort of a monolithic system to an API-based system could reduce your IT labor cost by perhaps 80 percent. So there are different motivations for different changes. So each case has to be looked at.

Richard Landen: A couple of examples, Jamie you already mentioned when it came time to add in the SDOH data that didn't exist before, that's a change and a positive value for some people. Looking back further in history, the old hospital claim forms that were on paper, the early versions that were electronic carried a limited number of diagnosis codes.

When we went to the DRG system we needed more codes. So the standard had to be changed, both paper and electronic, to support enough ICD codes (inaudible) their software to calculate the DRG. Now, that's great for the payer who is paying on DRGs rather than itemized charges. But as you point out, yes, that is a burden on the providers. So it is all sorts of these balancing acts, nothing is ever clean. The values, as I mentioned earlier, are not evenly distributed.

Vickie Mays: This was very helpful, because I've heard about CNC codes, I've been struggling with getting different groups kicking and screaming about SDOH (Inaudible).

Tammy Banks: Again, it is trying to create more flexibility within a rigid framework. And again, it still has to be proven in order to move. But it's less, you can impact more people without impacting the small, mid-sized, it could be tested. Now, I know I am running out of time, so I did active engagement, we're not going to get through our scoping document and all that other good stuff. So if you don't mind just going to slide 26.

So we have the background and kind of where our scope statement is. But if you go to the vision, I pull this piece out. This is one piece of our vision, which I think it really captures where the subcommittee in our initial conversations are planning to go.

And our focus is to get to the place where there is standardized data captured, improved availability of data across the healthcare data ecosystem that supports individual healthcare and wellness, health equity, social determinants of health, public health, health policy, price transparency, coordination of care, improved patient outcomes, burden reduction, privacy and security, and the usability of personal health information.

And that this standardization allows for the betterment of the administrative and clinical information exchange, and ultimately the delivery of the healthcare. This benefits patients, providers, payers, and the system at whole. And so that is the vision that we are trying to enable.

And if you go to the next slide, I know we're not going to be able to have the discussion that I hoped for. I pulled four of the activities or projects that we had talked about in the past. We're going to continue to debate if these are the priority projects or not. And I know we won't have time to discuss them but would love your input if something comes to your mind.

Review relevance of HIPAA in the current healthcare ecosystem, which is what those two recommendations along with a couple of the other ones really were trying to get at. How do we make it work so that we can get more timely updates with all the advanced technology that is occurring. There is no reason under ACA we wanted the standard versions at least every two years. We've got to get there. It's just moving too fast for us. Examine mature and emerging standards and how they can coexist.

And of course this is in collaboration with a lot of other different partners. Evaluate how different industries, countries, SDOs and other assess standard readiness for national implementation, from both a business and a technical use implementation perspective. And then of course Jamie's work which I don't really need to expand on, but the importance of the ICD-11 activity that you have going on.

So I know my time is up. If anybody has any specific projects you think are important based on the history that we had talked about, please share them with Rich and I or any of the committee members, because your feedback and your questions, especially yours, Vickie, are very important. Thank you for your time.

Jacki Monson: We will make sure we allocate more time at the next meeting.

Rebecca Hines: I know we had lots of discussion on the Executive Subcommittee, oh, an hour is plenty, but we could have gone a lot longer. Thank you, Tammy for all of that work.

Public Comment

Rebecca Hines: So, it is time to move to public comment. And I just want to note we have on Zoom with us Heather McComas and Donna Campbell. Let me know if you would like an open line Heather or Donna, or I can read your comment into the record. The instructions are now up on the screen to request an open audio line please raise your hand.

So Heather McComas has asked me to read hers into the record. And Heather is with the AMA. And Heather wrote during the standards subcommittee discussion we just wrapped up, what if a health plan requires use of one of the standards or versions via contract, providers, especially small ones don't have the negotiating power to overcome this challenge. Providers would therefore also have to support multiple standards or versions.

Tammy Banks: That would be an advisory opinion. However, under HIPAA, the provider would have the choice, that could not be put in contract.

Rebecca Hines: Donna, if you want to raise your hand we can give you an open line so you can provide your comment to the committee. So, Donna, your line is now open. Can you remind us your title and what organization you're with?

Donna Campbell: My name is Donna Campbell, I'm with Blue Cross Blue Shield of Illinois, and I am a Senior Product Manager for the 270, 276, and 275 transactions within my organization. My comment is about the conversation Tammy was having, and the ideas with the recommendations how to move forward in the newer versions without negatively impacting those who want to stay on the current version. I like the idea of giving people an option where the option can exist.

But what I'm afraid of us doing is essentially doing the one size fits all as I put in the Q&A. I know that there was some conversation at the last NCVHS hearing that said it just didn't seem like there was enough big bang for the buck to move the 837s forward. I personally think the 837s, what has been offered in the newer versions is good to many of the organizations that have high volume 837 claim traffic, because we need some of those opportunities that are built into 8030.

And then just like the 8020 837s, there are other transactions that are yet to come to NCVHS for recommendation that I know offer a ton of value add through new technology, new capabilities that they're offering in the transactions that are much needed today when it comes to say the 270-271 and in some cases even as simple as the 275, a small change in these transactions can have a large value add, positive impact.

And I wouldn't want us to be afraid of the dual version support, when as Tammy pointed out and others have pointed out there might be a very strong need for that new data or new element or that new capability in those different transactions, that if we don't support them today we're paying for it via phone calls, or having to do the technology and the capability support another way outside of the HIPAA transaction, which then takes you away from this concept of simplification and making it easier and budget friendly for the providers and the payers.

Rebecca Hines: Thank you. We will also save your comment in the chat for the meeting summary. Anyone else have a comment? I think the public comment period is wrapped up. Jacki, do you want to move on?

Wrap Up and Adjourn

Jacki Monson: Two things that I want to get to before we end, we're kind of in the home stretch, everyone. The first is I want a debrief on that OCR dialogue because there was some dialogue that happened that I'd like to talk about, and I would like to allow Melissa and Val and others to chime in on any of the debriefs from the OCR. So let's use the next six minutes to debrief, and then we'll move into the report to Congress, if that's okay with everyone. So Val and Melissa first, if you have any initial comments.

Melissa Goldstein: Val, go ahead and then I'll chime in if you want.

Valerie Watzlaf: Well, I just thought them coming here and being so open and up front about some of our questions too, I think was really great. I think we should continue to meet with them as much as we

can within our subcommittee, because I think they were very open to making many of the changes that we were suggesting, and I think we do need to really look at the (inaudible) and privacy issues again being what we heard from our panel yesterday as well as some of their comments and make specific recommendations there. And then I know you have had conversation about cybersecurity that you brought up, and I think that is another really good area. I mean you had an excellent letter on cybersecurity.

But when I think you said about how old really the security world is, how that really needs to be updated, I think we could look at that again and make those specific recommendations. I think we should do that. I think they will take that into consideration and maybe make some changes or updates at least.

Jacki Monson: If you share it with Sharon and I it would be extremely helpful for us to give them some recommendations specific to the security rules for potentially updates, they're busy the rest of this year, but if we could do that next year that would be extremely helpful and area that they plan to focus on.

Obviously we did that, it has almost been two years now, I can't even believe it, there is probably an opportunity, we have learned a lot, (?)4:01:15 has changed a little bit, and we have AI now, so there are a lot of other things to I think consider to potentially look at.

Melissa Goldstein: I want to say that I really appreciate both of them coming. I found it very informative and refreshing. And I also think that it was very good for us and for the public to hear really their impressions of the different legal authorities that the administration has from a regulatory perspective versus legislative authority, and what they will be able to do at least in their interpretations as an agency versus what would take legislative authority, and where we might think about aiming our particular recommendations.

And I think this also might be relevant for when we talk about the report to Congress, which of course is a report to Congress, versus where we've settled on some of the things in our comments to the NPRM. As we move forward in the fall and beyond with our additional, if we choose to go there, comments on reproductive health issues.

I also found it really comforting and refreshing to hear the recognition of the panoply of issues that we discussed in our own deliberations including transgender, different gender affirming surgeries, health information exchange, all of it, and the protection of health information no matter where it is, within covered entities, outside, I thought it was a great presentation, and I really appreciate it. Thanks very much for getting them, including them. A special thanks to Maya for working on that angle, and I really appreciate it.

Jacki Monson: I do think the door is wide open, at least from my perspective, to us having regular engagement with them. That's at least where they left it here and so I think that's something else for PCS to contemplate as to what is the cadence and the frequency of that dialogue, so that even though we don't have connectivity directly with Rachel Seeger, we have connectivity to drive some of our conversation about what the game plan is and what the focus is and how we can help them.

Valerie Watzlaf: We also want any member of the committee. I don't think I said that but you're always welcome to our meetings as well, those are open to any institute.

Jacki Monson: Any other comments for the committee?

Vickie Mays: I was struck by not only their welcomeness, but I think we have been a little too unmoved. We were talking about for example some issues, we were being a little reluctant to do them. But I did not get that sense from them, when we were talking about for example the gender affirming care and things like that, that's been really big on their agenda, and I think we stepped back more than we need to.

So I would say that as we do whatever the next iteration of work is, to be aligned with the ways in which they have to solve problems would be great for us, because I think we really wanted to take those things on.

Maya Bernstein: I had a quick conversation with Tim outside during the break, and he reminded me that when Melanie tells us there are 17 people, there are 17 in his whole staff, in their headquarters, and then there are six doing regulation. So I think you get an idea of just how few people there are, when she talks about how many there are at CMS there are a lot more than that, and they are doing an amazing amount of work with just those experts.

I did also on the way to lunch, bump into Council, there's a lot of people in the building today, which is nice, because OCR is having a regional meeting, many of their regional people happen to be in from out of town today, and she introduced me to the Head of Security, whose name I will forget at the moment, I apologize since I'm on the record, but I think they are very open, and I think he would be very open to talking to you when we get to that topic, and Tim also said let us know how we can help, if I can come talk to you again, that sort of thing. So that was great.

NCVHS 2023 Report to Congress

Jacki Monson: Okay, go to the next slide please. We put a few reminders in here of what the Report to Congress statute says, really for our new members. We're responsible for advising the Secretary and Congress on the status of part C of the Social Security Act.

We also assist and advise the Secretary in complying with the requirements imposed under Part C. And then study the issues related to the adoption of uniform data standards for patient medical record information and the electronic interchange of such information, and report to the Secretary recommendations and exchanges.

And will address the following subjects, to the extent that the Committee determinates appropriate: The extent to which persons required to comply with part C of the Act are cooperating in implementing the standards adopted. The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities. Any problems that exist with respect to the implementation of it. And the extent to which timetables under such part are being met.

So that's really the scope. And I think in prior years we have ended up with pretty huge reports to Congress that go well beyond that scope. And what I would really like to do and what we have been trying to do with this report is actually make sure that we're reminded and based on what are we actually required to do and what do we want to focus on based on that, and not have it be a dissertation or a thesis, have it really be narrowly focused and have a very robust executive summary that we hope people will read if they don't read anything else.

So a little bit of history on prior reports. So the last report we completed was the 14th report in 2021. The reporting date was January 1, 2019 to December 31, 2020. And I'll show you the major themes or I guess major trends that we focused on.

So this is just a deeper dive into the five major areas that we focused on. New technologies, platforms, and models for health information. The patients' roles in accessing and using health data. The COVID pandemic had exposed some weaknesses in public health information infrastructure.

And the convergence of clinical and administrative data standards is gaining recognition and crossing the boundaries of traditional data and program silos. The pandemic exposed critical weaknesses again, it repeats. And health information privacy and security challenges have proliferated.

So those were the focus of the previous reports. So what are we tackling today? The reporting period for this report to Congress is January 1st 2021 to December 31 2022. So for our new members you will be voting on this at our next meeting, but some of the work obviously was done before your time. So when Rebecca and others are encouraging you to read past work it will be relevant to our conversations and what we're highlighting specific to the report to Congress.

So, what are we doing in the report? The shifts and changes over the last two years, to provide context. Significant notable policy changes impacting the health data ecosystem. Information and details to address the required reporting. And key takeaway messages.

So here is the report outline, as of today, and I believe our report writer Kate is with us, if you want to say hi, for those who haven't met you.

Kate Ricker: Hi, everyone, nice listening.

Jacki Monson: So she is the writer behind the operations. So the report outline today is an executive summary, introduction and report overview. The evolving context for health information policy. The progress and status of HIPAA implementation, so both the transaction and medical code set standards as well as privacy, security, and breach notifications. Looking ahead. And then obviously the appendices. And the appendix is probably going to be bigger than normal as we try to narrow the scope of this.

Rebecca Hines: Can I say, for the new members, that the longer standing members came up with this outline, and it has lots of detail that was given to Kate. So just for context, any comments midstream, some thought has gone into starting at the December Full Committee meeting. So just so you know how we arrived at this point, you sort of walked in after the movie already started.

Jacki Monson: But we are still drafting, so lots of opportunity. Let's go to the next slide. So the activity today, we've identified a writer, Kate, who is on with us. We have drafted an outline. We are refining the outline, or we've refined it. And then the initial draft of the first sections has been prepared. So I've done a review over the last couple of days, I think we have a lot of work to do on refining it and categorizing it, so I am going to take the lead on doing that, and then I will be sharing it with all of you to get your feedback to see what I missed.

So going to the next slide, this is kind of the summer and fall timeline around it. So today we're talking about it a bit. We would like to get to a point in the August-September timeframe of having a really good solid draft that we can get good feedback from all of you on, and get to a point in the November timeframe, early November depending on what time we end up with a committee meeting, I think we're

looking right now at targeting November 29 and 30, but not to have it be as rushed as we did with the last two letters that went in, at least NPRM anyway, because I would like some sleep. But get to a point where we have good draft of a response and can finish the debate and get the approval at the November 29 and 30 meeting.

So that's kind of the timeline and plan. So I think for my review of it, I don't know if any of you, and I would love to hear your feedback on what you've reviewed so far, to me it still feels like a drafty outline of it, and this isn't on Kate, this is the fact that I think we had other priorities, we had two letters out of standards, we had one out of the privacy, security and confidentiality that was very time sensitive. So now I think we have a little bit of time, we do have ICD-11 stuff coming up, but we have time I hope, and you all can make time in your subcommittee meeting discussions to help me continue to get this across the finish line.

But I personally think the next step on this from my review of it is that we can do some work on categorization, prioritization, we did a little bit of that, but we can do more to really refine it and get to focused categories like we had in the past report to Congress, and then give it back to you all to discuss in a subcommittee meeting to get your feedback to it, and we will be able to continue to refine it over the next couple of months.

But any of you that have had the opportunity to review it, I would love to hear your thoughts around this. If we can move to the next slide, which I think is just discussion.

Tammy Banks: I was just going to agree with you, I think that is where we are at. And again, it was just competing priorities. It wasn't lack of wanting to add additional meet.

Debra Strickland: So Jacki, is it your thought, I know you said maybe a more robust executive summary and less meat in there, a larger appendix in case they're interested. Are you trying to make the report a little smaller so it's a little more palatable? I agree.

Jacki Monson: Yes, I think we do. Good, bad, or otherwise, hindsight is always 2020. I think it is a little long. I don't hear people in the public saying they're excited about reading a report to Congress, we haven't heard that from Congress.

So I would like to make it really meaningful. I think it's hard to write the executive summary as Kate would say without having the rest of it, the meat, to figure out what you're going to put in the top. So that will probably be the last part that is drafted. But I think if we can make that really meaty, a page or less, people are going to read that. And then if they want to dig into further details they can.

But I also think staying at a higher level, a 1000-foot view instead of a 500-foot view would be beneficial to us. I just don't want this to be a dissertation, because it is a lot for us to take on with the work that we already have. Again, I don't think there is value add in that to the degree we were hoping would get out of that review report. So that's my perspective.

Debra Strickland: It's kind of one of those things where having too many options is like having none. So maybe if we get two or maybe three topics it will catch someone's attention.

Rebecca Hines: That is one of the challenges, the first outline had 11 topics in the context setting section. And we did ask, we sent a poll around to the longstanding members, and I don't think there was total consensus, but we sort of knocked it down to three or four. But it's still a lot of context-setting. I

think, to your point, what are the two or three max things that need to be set. They really won't pay attention to pages and pages and pages of context.

Tammy Banks: I did want to echo that Kate did a wonderful job with what we gave her. This conversation is definitely not about Kate's work, so I appreciate Kate.

Jacki Monson: I hope she knows that because we have had that conversation. We like her and she does a good job writing. Any other comments or thoughts on this? I think before we send another draft out and include the new members, I would like to take a shot at categorization, giving it back to Kate.

Once I've done that and really refining it and giving you a really solid draft, before we send it out to everybody, and then once we sent it out I just want you to dedicate some time in your subcommittees, and time outside of subcommittees to look at it, review it, and raise your concerns so that we can start working on what the draft looks like and the end product.

Tammy Banks: Let's focus on three and then come back up to your stuff if we can.

Maya Bernstein: I would say you gave Kate a tall order asking her to be both robust and one page.

Jacki Monson: Any other?

Vickie Mays: There was a question that I had that I think I raised, but I'm not sure if I know the answer. Aren't we also required to do something about the ACA?

Rebecca Hines: I don't think it is specific to the report to congress.

Vickie Mays: And then the question I have is the difference between talking about health policy and health data. I think we spend a fair amount of time talking about health data as well as health policy. So I'd just say as you do your drafting to infuse that in there, because I think we spent time on it.

Rebecca Hines: So I don't know that we have the final answer on whether November 29-30 wins the day for people's availability. I know two thirds of you sent your availability. Just because everyone, or 90 percent of us here are, is anyone not available on November 29-30 for a virtual committee meeting? It's a full week after Thanksgiving, and it would be virtual.

We're just trying to figure out if that works, we're not going to make a decision today, but assuming, or under the premise that that did work, that would be our target date for having a final report to vote on and get off the plate. Just to give you a sense of that timeline. We'll try to get that firmed up next week.

Closing Remarks & Adjourn

Jacki Monson: Alright, if there are no other comments, any other items for discussion? Then I just want to thank our staff, both our support, all over the back as well as Maya and Rebeccah, I know that it takes an army of people to put this together, so I deeply appreciate, especially now that we're in person for the first time, it is probably even more work.

So thank you very much for all of your work on this. And thanks everybody for your participation over the last couple of days, I think it has been great, we have had lots of thought-provoking conversations,

so I look forward to hearing more as you reflect on your airplane rides home. And just thank you for your time, and I look forward to the next meeting.

(Whereupon the meeting was adjourned at 2:30 p.m.)