



HIT Policy Committee

Final Transcript

March 10, 2015

Presentation

Operator

All lines bridged with the public.

Michelle Consolazio, MPA – Federal Advisory Committee Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is a public meeting and there will be time for public comment before lunch and at the end of the meeting. As a reminder for those leaving a public comment it is limited to three minutes. Also, as a reminder if you could please state your name before speaking as this meeting is being transcribed and recorded. If we could just go around the room to take roll and we'll start with Chesley.

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

Good morning, Chesley Richards, CDC.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Troy Seagondollar.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Chris Lehmann, Vanderbilt.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

David Bates, Brigham & Women's.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Paul Tang, Palo Alto Medical Foundation.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Karen DeSalvo, ONC.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

David Lansky, PBGH.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Deven McGraw, Manatt, Phelps & Phillips.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Anjum Khurshid, Louisiana Public Health Institute.

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

Devin Mann, Boston University.

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

David Kotz, Dartmouth College.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Jodi Daniel, ONC.

Gretchen Wyatt, MA – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Gretchen Wyatt, ONC.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And on the phone I see Gayle Harrell?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Gayle. Marc Probst?

Marc Probst – Vice President & Chief Information Officer – Intermountain Healthcare

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Marc. Terry Cullen?

Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration

Yes, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Terry. Is there anyone else on the phone?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Michelle, this is Lucia.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Lucia. Okay with that I'll turn it over to you Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thanks, Michelle and good morning everybody I'll be brief we have a lot of fun things to talk about today. I just, for context, wanted to remind everybody that we're still in our comment period for the interoperability standards advisory and for the interoperability roadmap. We've been getting some really great feedback and are starting now some very discreet meetings with groups of federal folks, community organizations and standards world organizations that are governing in the interoperability space to drill down more on specifics as we go forward and we'll have some additional information rolling out that we can't yet talk too much about because everybody knows that we're still in rulemaking.

On the other hand I really appreciate the work that the Workgroups have been doing to give us some more guidance and feedback on the ideas that we have thrown out and I'm looking forward to having some conversations on that today.

As a broader view, just this opportunity for the federal Health IT strategic plan to get some feedback and I've had some chance to preview the information that they're sharing today and we look forward to having a chance for not only today's dialogue but to think through with our federal partners the comments and feedback we've gotten from this FACA and from the public at large and have the chance to make, where appropriate, revisions in that space.

So, we've been busy at ONC, we continue to be. There be more coming out in the next few months but we really, as always, appreciate the guidance and input from the FACA.

I just want at one internal piece of business that I want to do which is a staff introduction. At that FACA last time I had introduced Dr. Mike McCoy who is the Chief Health Information Officer who is here with us today and I don't believe that Dr. Tom Mason was with us last time he's joined us officially as the Chief Medical Officer, so Tom if you could just stand so people can know your face and there will be plenty of opportunity for folks meet Dr. Mason.

He comes to us from Chicago he's a General Internist with experience particularly in the safety net in Chicago as a leader there, Medical Director and most recently the Chief Medical Information Officer at Cook County Ambulatory System and has just been doing Meaningful Use Stage 2 on the outside and so we're really looking forward to his talent and expertise as he comes and joins this team and helps us think through the application of technology in the real world and how our policies and procedures actually impact the average clinician out on the front lines and health systems on the front lines. So welcome to Tom. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you Karen, let me go over the agenda we have for today's meeting and then we will approve the minutes. We're going to start with the data updates from Beth Myers and Dawn Heisey-Grove from ONC and then go into the big data hearing from the Privacy and Security Workgroup they've been very busy looking at a lot of the issues related to that and she's going to report on that.

The Federal IT strategic plan both the Strategy and Innovation Workgroup and Consumer Workgroups we heard from last time and they're going to give us their final recommendations, their feedback to ONC so we'll need approval for those recommendations.

After lunch we're going to get updates from the various Workgroups that are providing feedback to the interoperability roadmap that includes the Advanced Health Models, the Consumer Workgroup, the Interoperability Workgroup and the Privacy and Security Workgroup.

And then we're going to conclude with Karen updating us on the delivery system reform project within HHS and you remember that the Secretary announced some milestones for the system reform at the end of January and so Karen is going to brief us more on that program or that...

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Effort.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Initiative, effort. All right, so we had minutes distributed to you from both the February meeting and the joint meeting we had with the Standards Committee and I wonder if I could entertain a motion to approve those?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

So moved.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. And second?

M

Second.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks, any further discussions, additions, edits? All right, all in favor?

Multiple

Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you and any opposed or abstained? Thank you. So, why don't we invite Beth and Dawn to the table to update us on the data from CMS and ONC, please?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Beth is on the phone.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

Yes, hello.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Beth, do you want to go ahead and go first?

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

Okay, so I have just a very brief update today. As you all know we have extended the deadline for attestations for 2014 and that will be closing on March 20th now so that means that my updates that we had discussed doing today about performance for EPs to match the one that we did on eligible hospitals previously will be moved back by one month. So we'll be discussing that next month.

So for this month, next slide please, I'm just going to do a quick update on the registration numbers and payment data and then review the attestations through the end of February. Next slide, please.

So very quickly, just noting there at the bottom, we have about 520,000 providers who have, in Medicare and Medicaid and eligible hospitals total, who have registered for the program. Again, registration does not necessarily mean the participation in a given year it is our indicator of providers who intend to participate in the program. Next slide, please.

Medicare incentive payments, we are just under 20 billion for Medicare alone for incentive payments through January of 2015. Next slide, please.

And I want to point out on the Medicaid program the total program to date is up to 217,000 providers who have been paid in incentive payments through the Medicaid program through January. Next slide, please.

Unique providers paid, we are over 430,000 unique providers paid throughout all programs as of January 2015. Next slide, please.

And our total payments we are hovering just under 30 billion dollars in incentive payments made for providers who have made an investment either to adopt, implement or upgrade to certified EHR technology or to demonstrate Meaningful Use of certified EHR technology through January of 2015. Next slide, please.

So very quickly we will go through the EP update, obviously the eligible hospitals have been closed so there are not changes to those numbers. If we can go to the next slide?

I also have a slide, we'll get to the second one there in a second, we had a few questions last time on trying to understand these numbers a little better because these aren't out of the total these are out of those who attested. So, when we go through each bullet I'll explain that briefly.

So, far we've had just under 210,000 eligible professionals who have successfully attested for 2014 performance so far. Again, this is through March 1st so there are an additional 20 days for providers to attest. When we previously extended the eligible hospital deadline we did also see an uptake over the course of December when we extended that deadline by a month so we anticipate that we'll see an uptake as well in eligible professional participation through the end of March.

New participants, we have about 36,000 who have attested so far. We have 150,000 providers who have attested to Stage 1 and we have 56,000 providers who have attested to Stage 2 so that last bullet, let's go to the next slide, please, this is the explanation of the last bullet that you see on the previous slide.

So of the 210,000 total eligible professionals who have attested for 2014 so far and, again, remember so far means by March 1st, out of that total who have attested there were 125,000 who were scheduled to attest to Stage 2, so that means providers who are in their third program year or beyond, anyone in their first or second program year would be attesting to Stage 1 and would already be previously scheduled to do so.

So, out of those providers 56,000 have successfully attested to Stage 2 and again a reminder here, the providers who were scheduled to attest to Stage 2, who attested for Stage 1, that's not necessarily an indicator of any particular Stage 2 measure performance it's an indicator of their ability to have successfully implemented the 2014 edition software in time because that is the reason that providers may have needed to re-demonstrate in Stage 1 rather than moving onto Stage 2. And that's all I have today so I will pass it up to Dawn.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Okay so today I'm going to be diving in a little bit more into the eligible hospital performance on Meaningful Use measures. We're going to be looking at the characteristics associated with performance to show that there are very little disparities in terms of progress to specific Stage 2 measures that I'm going to be demonstrating today or displaying today.

First, again just a brief reminder, as Beth has just mentioned, the hospitals that are doing Stage 2 are those that started in 2011 and 2012, so first attested to Meaningful Use in those two years, those are the groups that were scheduled to attest to Stage 2 in 2014.

The other two, when I'm presenting on the Stage 2 data, are not...the other two cohorts 2013 and 2014 would not be included in that group. So that 2011 and 2012 represents a little bit more than half of the eligible hospitals that have attested so far.

So, this first data slide shows you the hospitals that attested that were scheduled to attest to Stage 2 in 2014. The top bar are those that actually attested to Stage 2 and the bottom bar are those that took the flex rule to attest to Stage 1.

And what you see here is that the distribution, the different colors represent different types of hospitals, blue is critical access, red is small rural those that have fewer than 100 beds and goes it on from there, but the distribution is pretty much the same across those two groups which tells us that there wasn't any one type of hospital that opted to do the flex rule over the Stage 2 rule or the Stage 2 attestation.

So, there is one new Stage 2 rule or Stage 2 measure for care transitions, the data is presented here. What you see here are the critical access, the different types of hospitals by the categories that we've mentioned before as well as the attestation cohorts. So, the hospitals are actually represented in both of those sets of bars there. The overall mean for this particular measure, which is hospitals have submitted an electronic summary of care to at least 10% of their transitions, is represented in these data.

So, our average is 36 for all hospitals for critical access hospitals they have the highest performance on this particular measure 44% of their transitions are receiving an electronic summary of care. The lowest performers in this particular group are large hospitals and those are hospitals that have more than 400 or 400 more beds.

So, just to restate this on average, Stage 2 hospitals are sending electronic summaries of care for about 36% of transitions. Critical access hospitals are performing the highest and large hospitals have some of the lower average rates of submitting electronic summaries of care.

Next is the Stage 2 patient engagement measure, so this is patients...Stage 2 hospital patients who have actually viewed, downloaded or transmitted their electronic health information at least once during the reporting period for the hospital. And here you see again critical access hospitals, as well as small urban hospitals have some of the higher reporting rates, but again with this slide and with the other performance slides that we're talking about, the data are pretty much clustered in that most of the hospitals are doing fairly be similarly.

Hospitals that have been meaningfully using their electronic health records the longest are performing...are doing better at getting their patients to view, download or transmit their electronic health record data.

So, this is another way of looking at those data, the horizontal axis that you see here is the actual month that the hospital submitted their attestation. So what this shows us is that in April and May the hospitals that attested in April and May had much lower rates of patients viewing, downloading or transmitting their electronic health records compared to the month that had the most attestations which was November. And so in November the hospitals were on average reporting 17% of their patients were actually viewing, downloading or transmitting their electronic health record information.

So this again just summarizes on average we see that 15% of Stage 2 hospital patients are viewing, downloading or transmitting their electronic health record information for the reporting period in 2014 and those that have been meaningfully using longest are the ones that have the highest rates for that VDT measure.

So, there are two patient safety measures that were new for Stage 2 that I'm going to just touch on briefly. The first one is the average...this is a core measure that was new for Stage 2 and it talks about the hospital's ability to track all doses of medication orders through an electronic medication administration record, which is an eMAR, and you can see that the threshold here is the bottom number on the y-axis is 10% and the hospitals are basically doing much, much, much higher than that, the overall mean is 70%.

Again the values are clustered pretty much around the mean so they're all doing fairly similarly but again hospitals who have been meaningfully using longest are doing better as well as medium-sized hospitals and those are hospitals that have between 100 and 399 beds.

This measure is ePrescribing for discharge medications and this is actually a menu measure that was new for Stage 2. So hospitals did not have to do this, these are among hospitals that have opted to select this menu measure, this optional measure, so that why the "n" is on the bottom and the x-axis are different then the "n" you saw previously, but what can see here is, again the threshold was 10% and the mean is 56%, so that means 56% of the Stage 2 hospitals that chose to report on this measure were ePrescribing, they were ePrescribing 56% of their discharge medications which is fairly good. Critical access hospitals and smaller urban hospitals have the highest rates of performance and again 2011 Meaningful Users are also performing better.

So on average 70% of medications administered in Stage 2 hospitals had all doses track through an eMAR and the ePrescribing measure, which is again optional, but on average the hospitals had selected this measure use ePrescribing for 56% of all permissible discharge medications.

The last performance that I'm going to be talking about is public health reporting and there's a lot more information on this particular set of measures in a data brief that is now posted on the dashboard, the healthit.gov dashboard, but what we've got here is for Stage 2 the public health reporting measures, that is immunization registry reporting, syndromic surveillance reporting and electronic laboratory results reporting were all switched from menu to required measures and so the hospitals in Stage 2 had to report on all three of those measures unless the public health agency...unless they could take a valid exclusion.

For Stage 1 those three were all menu measures, although the hospitals had to report on at least one of them, but they could, optionally, pick all three for their measure set. What you see here, the graph shows you or the maps show you the proportion of hospitals within each attestation grouping that are reporting on all three of those public health measures.

So Stage 1 were it's not required that they report on all three the percentage is fairly low but in Stage 2 what this map shows us is that most of the public health agencies, as well as most of the hospitals, have the capability to actually exchange this information electronically for all three of the measures.

So, again, the three public health measures that are required for reporting for Stage 2, we've got 72% national average of hospitals reporting on all three of those measures, 5% for Stage 1 hospitals and there's a lot more information again on the data brief that is posted on healthit.gov. And that is it. I'm happy to take questions.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you very much Dawn. Questions or comments? David?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Good catch. Dawn I think this is really interesting data thanks for doing it. It raised two questions for me, one is not maybe the first one is a comment.

From the very beginning of this committee we talked about how to tell our story and it seems like the data you just presented tells a very positive story that is not getting a lot of visibility around the quality benefits of successful implementation of the EHR incentive program.

So I just want to highlight for our awareness that we need to find ways to say this probably in a less wonky way that this program as a whole is having material benefits to people's well-being and the efficiency and operation of the health system.

The second thing, is really a question we had early debates about what thresholds to set for each of the new indicators so 5%, 10% and I know Paul particularly argued that when people across a tipping point they'll be doing many of these functions for virtually all their patients so that a low threshold would be adequate to trip people into adopting the new modes of care and that seems to be confirmed by a lot of the data you just showed up to a point.

And so my question is when we see performance at 36% or 56%, which patients are getting that kind of service and are they appropriate patients is it an artifact of institutional characteristics or is it diagnoses, or DRGs, or some populations that are very appropriate for that service?

So, for example the electronic summary of care document and VDT as two examples, do you have any data that would characterize which patients are the ones for whom those functions are being executed and which patients may be aren't and is it okay or are we missing some targets?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

It's an excellent question and the Meaningful Use data does not have those, that level of information. So, it's something we need to explore on how to get this data and figure that out but it's a very valid question.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

Yeah, this is Beth; we don't collect patient level data through Meaningful Use. So, we wouldn't have a way of identifying that through the attestation system, but I know that there are different Workgroups who actually talk with providers and sort of explore how they're implementing different things and I think we're going to learn a lot from those.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And if I could interject and second David's kudos in terms of the overall program not only are most people from the past presentations fulfilling Meaningful Use criteria but it's across the board as you continue to show.

I have one little question about the critical access hospital versus the large it's a little bit counterintuitive but maybe that's the number of interfaces or how are you interpreting that?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

I think it's an interesting question that we need to dive into a little bit more. My guess and this is purely a guess is that they are...because they're smaller facilities they may be more likely to have to transfer and so maybe they've already set up at infrastructure to do so, purely a guess at this point.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Whatever the reason it's good work. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Thank you and I also want to thank you for a great presentation as Paul and David have said it is presenting the data in a very positive light which I also appreciate.

I had a question similar to David's about some of these numbers where I think it was on the transitions of care where you show some median around 50%, the threshold is like 10%, and I was curious did the data show that maybe there's a lot of people who are doing like 10% and a lot of people doing like 90% and that's how you got a median sort of in the middle or does the data show that there is some group that just do the minimum but there are other people who have really adopted it and that's why you ended up at about half?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

It's a great question and when we look at the distribution by deciles and where the hospitals are falling within that we do have some hospitals that are way up at the top scoring 100% it's not a huge proportion, most of the hospitals are within, if I'm remembering the data, they're within, you know, the majority are in the 20 to I think 60% range. So they're pretty tightly clustered with some outliers on both ends.

Paul Egerman – Businessman/Software Entrepreneur

And that's helpful. I also have a question about the VDT functionality, when we had a meeting, at least a year ago, some people were commenting that, you know, the "T" which stands for transmit, they said basically nobody was using it, and so I'm curious do you have data, you know, there are three different components in VDT, view, download, transmit, do you have any data about to what extent each of those three are being used?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Not through the Meaningful Use data no and I don't know if that's something we have access to through other sources but I think it's something worth exploring.

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks. Chris?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you, Paul. My question is about the public health measures and they're especially important to the group that I represent, vulnerable populations, and I noticed there on your map there were some states that were blank and I was wondering if you could comment on the barriers and anticipated future trends?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

So it's a great question and the data brief does provide some explanations on some of the states that have those lower rates. I think that most states are moving towards...the best way to explain it I think is that there's a lot of public health exchange between hospitals and public health agencies that is not part of the Meaningful Use program, so some of the states are working towards getting those criteria or the certification set up so that the hospitals can meet the Meaningful Use criteria.

But some of the states even though they're blank that just means that the activity isn't there for Meaningful Use but it's probably happening elsewhere, it's just not being captured through these data.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

So, going back to I think the initial comment about the story we can tell with the data, are we capturing any information on the flipside of these numbers so the 72% hospitals that are sending, you know, Stage 2 sending public health data or the VDTs with patients what is the impact on patients or public health entities that are receiving that data in a sense that can we demonstrate or measure how it changes their functions because eventually that's the goal?

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

So...

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

This is Beth...

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Go ahead, Beth.

Elisabeth Myers, MBA – Office of E-Health Standards and Services – Centers for Medicare & Medicaid Services

If I can...yeah, I'm going to sort of address this one and the previous comment about the appropriateness of care that is being used for individual patients and then I'll pass it to Dawn to potentially touch on the public health side of it.

We weren't in partnership with the quality measurement program. So it sounds like there might be an appropriate venue here to invite some of those quality measurement programs to talk about the types of things that they measure.

Meaningful Use attestation measures the sort of broad functional categories of did you electronically send and was this order entered in this particular way, but we have a lot more depth and granularity on both the patient level and we can stratify by demographic data within a quality measure, and the quality measures deal with very specific items like a certain process for example, is this item occurring with specific patients that such an item should be occurring with, so the appropriateness of the care and the appropriateness of the action, and there are also outcomes-based measures, so in other words, how many times did this action result in an improved diagnosis or an improved indicator of blood pressure for example over time for someone with heart disease. It sounds like that's some of the data that you might be interested in hearing about. So, I will talk with the quality measurement team and see if they want to come in.

We do require quality measurement as part of Meaningful Use but that is really handled through the quality program so that patient level data and the appropriateness of care and the outcome data is really something that they're working with and analyzing and then we're sort of working in partnership with them for Meaningful Use to progress it. And with that I'll sort pass it to Dawn if she wants to comment on if we have any reflections on the public health side of it.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

So, yeah, and Beth's point is a very good one and the quality measure data I think has some real value to it in addition to groups like PQRS where the quality measures are coming in, those are only on Medicare data.

The benefit of some of the Meaningful Use quality measures is that it deals with all of the patients that the provider is seeing through their electronic health records, it's still aggregated data but it looks at all the patients rather than just the Medicare population so it has some unique values to it to kind of get at some of those questions.

In terms of the public health side, in terms of impact on patients and things like that we haven't began because it's aggregate data we haven't been able to do that and one of the things you could do is link performance on or just participation in some of these public health reporting measures to some of those clinical quality measures to see if there's an association and that's something that we are starting to work on as well.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Chesley?

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

So, this data on the public health measures is really helpful and it's terrific progress. I think when I'm looking at this map and I was looking at the supplemental forms to see if it's elucidated more, but on this map you're really talking about a capability that exists. So the progress here has been that providers now have the ability to send to public health departments at a much greater percentage than existed before.

Do you have any data on the actual data that's coming to the public health providers and if you don't, I mean I think that's something we have in public health, so for example, we know that for electronic lab reporting 70% of all lab reports going to a public health department are electronic lab reports which has been an enormous achievement over the last few years. We have data in public health around the syndromic surveillance and the volume of data and how that's being used and the same thing for immunization registries.

So I would propose that we might work together and that would give a little bit more full picture of not only the data you have but the impact, get at the impact question of what the impact has been on public health and how we do our reporting.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

I think that would be a fantastic partnership. I think it would be really interesting to dive into that some more. The maps however don't just address capability for Stage 1. The measures capabilities for Stage 2 the measure is actually ongoing transmission. So the measures even though they're the same basic concept...

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

Right.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

They're slightly different.

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

But the ongoing transmission you don't have a volume number...

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

No, no.

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

For any messages and that's the piece that I think that we have...

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

And I think that would be really...

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

To complete the picture, yeah.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Really good.

Chesley Richards, MD, MPH, FACP - Director, Office of Public Health Scientific Services - Centers for Disease Control and Prevention

And I just want to say, because we don't say much about it in here, this work on public health is transformative. I mean, it is rapidly changing our whole perspective of what can be done in public health with the data from EHRs so this is terrific, thank you.

Dawn Heisey-Grove, MPH – Office of Planning, Evaluation & Analysis – Office of the National Coordinator for Health Information Technology

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Any other comments or questions? All right, good, thank you Dawn, thank you Beth.

I want to pick up on what Chesley just ended with which is having this data is very transformative to frontline care and to public and population health. So we could not have done what we're trying to do now without really the push of HITECH and Meaningful Use where we've gone from 0 to 60 basically in provider setting and over 90% in hospitals and across the board as Dawn just showed.

So our next talk is going to be from the Privacy and Security Workgroup and they're talking about the output from their big data hearings which they've had a couple and just to remind us again there wouldn't be any big data attention if there weren't any data to be big about.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Exactly.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So it's really important and significant how much this program, the law motivated just 30 billion dollars is a drop in the bucket to the 3 trillion dollars that are spent every year and yet there is a lot of accomplishments that have happened just in a few short years really.

So, with the capture of big data though there are issues that we have to deal with and the Privacy and Security Workgroup is trying to both illuminate those as well as give us some recommendations on how to deal with those. Thanks.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Great, I want to allow my Co-Chair to introduce himself because I think he's new to those of you around the table. He became the Co-Chair of this working group over the summer but this is actually the first time we've had a presentation where he's been here in person. So, who are you?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Thanks a lot Deven I appreciate it. I'm Stan Crosley and I work with the Indiana University Center on health data strategy as well as with the Law Firm Drinker Biddle & Reath here in DC.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Great, thanks. So, I'm going to start us off and then Stan will pick up the discussion about midway through and then I'll take us home and we hope to leave plenty of time for questions.

So, first I want to start by giving a little context. I mean big data is a term that gets used a lot today and particularly in healthcare it is a really big topic with a lot of tentacles to it. So, frankly why would anyone want to take this on?

And so there have been more than a few developments that are relevant to why we're taking this up and one of them is a report that came out of the White House in May of 2014 on seizing the opportunities represented by big data and it wasn't just...it was a report that wasn't just limited to health but there was a lot of language in there about health and, you know, it started with sort of what defines big data and that there is a distinction in the mind of many people between what's really big data and what's small data in the analytic space.

You know there's some coalescing around a definition for big data and I'm not sure it's quite universal yet but certainly what's put out in this report is that big data is really characterized by three V's which is volume with a lot of it, variety, it's of lots of different types and velocity, the speed with which you can analyze it, it's gotten much greater largely due to computing power.

Some other key observations that were in this report, de-identification is insufficient to protect privacy in big data analytics. The privacy issues do not get raised just by data but also by metadata, which is data about data, and we should not necessarily treat metadata as necessarily less risky from a privacy context than the content of the data itself.

And potentially we may need to focus more on assuring responsible uses of health big data versus trying to control how it's collected since it's become ubiquitous or is already there depending on who you talk to.

And the role of notice and consent in a big data environment really needs to be re-examined because volume and opportunities to get consent from people meaningfully and so it sort the challenges traditional ways that we've thought of about protecting privacy.

So already using sort of the gauntlet being thrown down on two of the tools that we rely on a lot in the privacy space to protect people, one is de-identification and the other one is consent.

A couple of other quotes that are worth noting from this report, the government should lead a consultative process, we are a consultative group, to assess how HIPAA, the Health Insurance Portability and Accountability Act, and other relevant federal laws and regulations can best accommodate the advances in medical science and cost reduction in healthcare delivery that are enabled by big data.

The complexity of complying with numerous laws when data is combined from various sources raises the potential need, potential need to carve out special data use authorities for the healthcare industry if it is to realize the potential health gains and cost reductions that could come from big data analytics.

So partly what our task is...well, what does that mean, what do we have in terms of current law and does that allow us to maximize the opportunities from health big data while also providing some protection?

So a few other notes to sort of callout as an introductory matter, certainly big data analytics is challenging for our policy frameworks in the healthcare space as we move from fee-for-service payment to quality outcomes the need for data is very clear, the need for more data that help providers and others to appropriately managed care, to help patients achieve value from the healthcare system for their healthcare dollar, for their wellness needs, building a learning healthcare system, user generated data and here we're really talking about at the patient level, can be both indicative for medical care but also indicative around lifestyle risks, population health analysis and research is of keen interest in big data, but how do we maximize that with our current policy framework, predictive medicine is another area that is gaining ground that is very much data dependent.

There's a myriad of federal, state and organizational rules in this space, as we'll talk about in just a second, that do make things a bit complicated. This is also raised in the interoperability roadmap and health data really is not just data that looks like health data on its face.

Many times data that doesn't look like health data at all are used for health purposes and to make decisions that have ramifications for people's health. One example that came up during our hearings is predictive scores about people who take...whether people are going to take their medications or not and the algorithms that predict these scores are not based on health data at all they're based on basic demographic data like income level, education level, age, race and gender. And yet they're incredibly predictive of health and it's not health data at all, not need traditional way that we've defined it.

So was at me for policy frameworks around health big data where we tend to focus the privacy rules around what looks like health data and not...or who is an actor in the healthcare system versus thinking of this more broadly.

There are a few other developments and I'm going to tick through this slide much faster, in addition to the White House report there was a PCAST Report that came out around the same time that had some very similar conclusions in it and that dealt more on the sort of technical aspects of big data. The White House announced an open government partnership to look at federal data repositories and how they could be leveraged more to take advantage of health data opportunities.

There is the 21st Century Cures Initiative that's being considered in congress, there's President Obama's recent, fairly recently, announced Precision Medicine Initiative, there's not a day that goes by that we don't hear of another development in the private sector around data whether it's analytics or mobile health or sometimes often innovations in the privacy space and then of course in terms of breaches, the most recent one that has covered the newspapers lately is the one from Anthem which is the largest data breach reported to date. So, it's just a sort of picture of, you know, the ying and the yang of the issue, right, it's lots of opportunity and yet lots of concerns being raised.

In terms of what is the legal framework that we deal with it's absolutely a patchwork even at the federal level, you know, we have the HIPAA privacy and security rules that cover, as you'll see at the bottom of the slide, most of the sort of traditional generators and collectors of health care data in the clinical setting and in the payment setting, and those entities are covered by HIPAA and the contractors that work with them are covered as business associates, but in the data environment that we're in today that leaves a lot of entities that are collecting health or data being used for health-related purposes that are not going to be covered by HIPAA at all.

To some extent they're covered by the Federal Trade Commission's jurisdiction under the FTC Act Section 5 where the commission has the ability to crack down on unfair and deceptive trade practices which largely is about whether companies are being fair in the marketplace with how they deal with consumers and whether the promises that they're making to consumer such as in privacy notices are being upheld.

The Common Rule which governs federally supported human subjects research also applies to research when data are being used and the data are identifiable to the researcher.

We've talked previously about the Part 2 rules which covered federally supported substance abuse treatment programs in the data that they generate.

HITECH had breach notification provisions some of which have been incorporated into HIPAA but there are also provisions for personal health records and Apps that are related to personal health record that the FTC oversees.

And then you've got federal education rules that apply to student health centers and other places where healthcare data are collected within the educational system that's a completely separate federal set of rules that are different from HIPAA.

And there probably are some federal protections frankly that we haven't even listed up here that are relevant to other sectors, the financial sector for example is covered by Gramm-Leach-Bliley for personal data that they collect which may in certain circumstances either have implications for health or be in some circumstances health data.

Then of course there are the states. So, you know, the interoperability report is very much focused on some of these dynamics including the differences in state law.

We've talked a bit about the limited applicability of HIPAA but at the same time it is really a pretty dominant player from a policy stand-point in some of these traditional sources of healthcare data, you know, healthcare data that looks like healthcare data on its face that are collected, again in the clinical and administrative context.

So we really sort of covered where HIPAA applies and where doesn't apply and what we...the challenge I think for us as a Policy Committee, and then of course for our Workgroup, in dealing with this is what are we going to try to say about this enormous space that's out there in health big data.

How much do we say about HIPAA? We have a legal regime there but there might be some things that we would recommend to tweak it. What are we going to say about the external space that's not covered by HIPAA at all?

HHS has limited authorities to reach this space but do we use our bully pulpit to try to say something about the need to have policy frameworks that extend beyond what have been our, sort of, traditional recommendation space.

So we've been sort of at this since late October and we started, as we customarily do, with really gnarly issues like this one, with public hearings. And we have sort of set aside the work that we've been doing on this issue so that we can turn to the interoperability roadmap but we hope to get right back to it and we're actually really glad to have the opportunity to give you some initial feedback on what we've been doing on this issue so we can get feedback from you because we really would like to try to have some recommendations to the committee by June and the earlier feedback we get from you the more likely we'll be able to give you back something that is potentially doable.

Here are some of the folks that we heard from in the hearings that we held back in December, the only...we had tee'd up Linda Avey on the second day and she was unable to join us. We may be able to circle back to her but for the most part we were able to hear from all of these folks even right before the holidays which was terrific.

Big topic we've tried at the outset to limit our scope to what's consistent with our charge as a Privacy and Security Workgroup. We only want to consider privacy and security issues, what are some of the concerns and how would we address them and to what extent are some of the ways that we try to address privacy creating some potential barriers to progress and innovation with potentially very little bang for the buck in terms of privacy protections.

But we are also taking up the issue of harmful uses which is related to privacy but isn't always just a privacy issue but it comes up frequently when people talk about privacy issues you know what are people going to do with my data and what are they going to do with it in a way that could harm me and what is a harm. What does that...discrimination and employment discrimination, and insurance discrimination in other aspects of life and how do you address that, it's a really a hard issue.

Out of scope the quality of the data in big data that's for somebody else to resolve. Data that has resonance with the data standards issue, that's not been our traditional purview. We have to sort of try to keep...it comes up in conversations and we have to keep saying that, you know, someone else is going to need to resolve those.

Another issue that came up in our hearings is the non-representativeness of some of the data that are used to do data analytics that there are populations that are highly represented in certain streams of data and populations that are not represented very well at all and this happens a lot when you think of the commercial data space where, you know, people without the sort of tools and sort of customary trail in commerce are not going to be represented in that data and yet that data is being used to make decisions about people.

We're not going to take on at all how do we make that data more representative because that's not really a privacy and security issue, but it does have a relationship to the harms issue and so to the extent that the non-representativeness of data has an impact on discrimination or the potential for harms then we'll try to take that on.

So here are the topics that we are trying to address. Concerns about the tools that are commonly used to protect privacy both in the HIPAA space as well as outside of the HIPAA space, de-identification when do you ask for patient consent or authorization versus when do you rely on sort of norms of use that should be reasonably expected given the circumstances, data security, transparency, how much do people really fully understand about what happens to data that are collected about them and how much can we improve on that as sort of a tool of both protecting people's privacy and giving people greater awareness of what is going on out there with their data, collection use and purpose limitations, these are all sort of elements of fair information practices and many of our recommendations out of this committee have relied on these fair information practice principles but how well do they apply in this big data environment and how well do current policies instantiate them and are there improvements that could be made there.

We have A, B and C bolded because we've already begun to talk about those in the Workgroup and Stan in his presentation is going to cover the first two and I'm going to cover the third. We have not done a lot yet on topics of transparency or collection use, or purpose limitations.

We haven't done a lot yet on the issue of harms how do you prevent them, limit them or provide opportunities for redress when they occur and then there is this sort of overarching legal landscape question that was tee'd up by what I presented at the beginning, that I think most of your well aware of, which is that we have uneven coverage of the health big data landscape but we also have lots of coverage and overlapping coverage in some circumstances and so is there something that we can say from a recommendation stand-point that would be relevant to this sort of overarching legal landscape, and with that I'm going to turn the clicker over to Stan to talk about where we have been able to do some deeper dives into a couple of these topics.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Thank you, Deven. Well, Deven used the well legally defined term gnarly and I can think of no better term to describe de-identification and the way we've taken this on as a Workgroup. We had a lot of public testimony about this and had some good conversations and we've tried to distill some of the conversations in these slides as concerns followed by possible solutions that we've only now just kind of highlighted and will be diving into in the coming weeks and months.

So to begin with on the de-identification concerns, you know, it was clear, I guess evident in the conversations we had that de-identification plays a critical role in not only research and other uses but also in the protection of privacy but is not a panacea, I mean, it doesn't fully protect nor does it fully enable innovative uses and so it's not the silver bullet.

Re-identification risk is a persistent concern. The safe harbor methods under HIPAA when you look at the two different criteria statistical de-identification or the safe harbor where you strip out all the enumerated identifiers is inadequate to provide perfect privacy protection.

I mean, there is a re-identification risk there is no question it's been proven time and again by external parties re-identifying datasets that have been, you know, de-identified using the safe harbor method. Combining data sets, you know, one of the ways where there is an adequacy. De-identified datasets combined with a mosaic effect can in fact end up having a re-identification aspect to them.

Even where data is de-identified, sensitive information or attributes of a group can be revealed and actions can be taken with respect to that group even if individual actors aren't identifiable within that group.

So, you know, that a certain population is over the age of 65 and certain attributes are given to that age group and so certain policies are passed with respect to that subset that affect all individuals within that subgroup which could be harmful as a collective. So, there are even with de-identified data sensitive information or attributes can be revealed in this way.

And then overly restrictive de-identification may be unsustainable and stifle innovation. So the idea that, you know, this is a slippery slope. How much do you actually have to de-identify before you hit perfect de-identification. Is that attainable and if it is, is the result going to actually stifle innovation, I mean, you get to the point where the data is unusable and, you know, quotes have proliferated for some time now that data is either usable or de-identified, right, and so that concept certainly was brought up again from some of our researchers and their testimonies.

The HIPAA expert determination methods or the second of the two, concerns about this really center around the concept of transparency and is there a enough scrutiny or objectiveness in the process, right, there is no real standard that is created that you can point to, there is no certification criteria for these experts. And so less about the idea or the concept of an expert determination as it is the practical consequence of the de-identification and is it a reliable means, is it objective enough and should there be standards?

No explicit prohibitions on re-identification was a concern that we heard. It seems like a simple idea. Certainly, within the limited dataset and the data use agreements there is a representation that's required that they want attempt to re-identify the data, but in the law itself and in the statute and regulations there is no explicit prohibition on re-identification.

A lack of transparency again back to the way that the de-identified data once it's received by the recipient how it's further disclosed or the uses that are made, in essence once de-identified it steps outside of the rule and then can be used without legal or regulatory constraint.

Shifting now to possible solutions, certainly we talked a lot about the context and whether or not a re-identification risk reduction should be taken in one context versus another. If a dataset is an entire public use dataset that may have a different type of re-identification risk than if it's within a fully contained data enclave.

Consistent de-identification standards were suggested for personal data not just within the context of HIPAA, not just within the context of research but across personal data, could we hit a standard that says this is an appropriate way that data could be de-identified.

And then incentivize the use of de-identified data. Certainly there are many uses where de-identified data is sufficient and meets the purpose for which it could be processed and those uses should be incentivized recognizing that there may be others that would be required but to incentivize as much as possible.

Back again to the concept of a best standard or best practice that could be utilized for expert statisticians when they're doing their de-identification criteria and you'll see a number of these bullets that are very similar certification, accreditation things that could enable a more widely accepted process that if we went through the exact same process you would expect to have the same type of rigor in the de-identification output.

Along the...continuing on the possible solutions of de-identification legislation to prohibit or establish penalties for re-identification, the concern was there isn't a penalty solution, you know, perhaps we could establish this with appropriate public policy exceptions where re-identification is necessary or required, regulation to require a reassessment of re-identification risk by the...from the statistical assessment or from safe harbor when data sets are recombined, so de-identified datasets combined don't we have a different analysis on whether there's a risk or not.

And then a regulation to impose security requirements to protect de-identified data and this is somewhat controversial even in the Workgroup as we discussed it and with the public testimony we received that the benefit now of de-identifying data is that you no longer have the concerns with a regulatory overlay or a bureaucracy and so the use of that information should be uninhibited.

Obviously, the flipside of that is if there is a re-identification risk that occurs and harm could occur with that re-identification then somehow we need to try and understand where security should be used. So identifying potentially those areas where a security would be able to mitigate some of the higher risk that existed with de-identified data. And then along with that, you know, potentially, you know, inviting OCR to reevaluate the very safe harbor itself.

So, this is the flipside of this concept of, you know, de-identification needs to have more rigor is the idea that in some circumstances it may be possible to actually reduce the requirements for de-identification. So, where the recipients are in a controlled environment, a data enclave where they commit to security requirements where there's an internal use only that it's not going to leave a controlled enclave or security environment, or perhaps the data use agreements where like with the limited datasets there is a permitted use and then a prohibiting of re-identification that concept rolling more broadly.

A patient controlled research initiative where the patient is indicating that they want their data disclosed and they want it used in a certain fashion that this would potentially create a lower risk for re-identification or harm as perceived by the patients themselves.

And then where research was approved by an IRB or a privacy board within, again within those uses there is a construct in the Common Rule where the IRB takes into consideration risk that might apply to data reuse or re-identification, in such circumstances, you know, would we say you don't need to remove all of the safe harbor elements or the statistical analysis could be a lighter standard. So that was our de-identification distillation.

We then moved into consent and as Deven indicated, you know, this is one of the other two pillars that we discussed as saying, you know, is this really a viable standard, is this meeting the requirements of advancing innovation and learning, are there limitations that we've encountered now with consent and we'll probably talk a little bit more about FIPs, Deven certainly mentioned then, you know, the fair information practices.

And one of the interesting things about the FIPs is that its automatically assumed the consent is a primary pillar and really its involvement of the data subject that is one of the pillars of FIPs and within that concept it says that where practical or where appropriate consent should be engaged in and so it's that full understanding of a FIPs environment where looking at both the HIPAA framework, within the HIPAA framework, how consent is utilized and then outside how it's utilized and the concerns with each and then the possible solutions.

So as we look at the...as the working group looked at research and HIPAA in the Common Rule and there's been a lot of discussion obviously and a lot of commentary around the harmonization of the Common Rule with the HIPAA Privacy Rule especially as it comes to research and the Workgroup talked about, well is there a low risk research that we could utilize, you know, in those kind of low risk areas, you know, would consent be required, a HIPAA consent, HIPAA authorization or could we talk about just transparency of use partnered with the appropriate use definition so use bounding the way that the data is disclosed and utilized versus the consent as the central doctrine.

Outside of the HIPAA framework we had a tremendous amount of conversation, as Deven indicated, you know, the scalability of consent in a 3V world of volume, variety and...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP
Velocity.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Velocity that's what I was...I always want to say veracity but that would be a fourth V and beyond the scope of what we're discussing. But certainly within the 3Vs, you know, the idea that the collection can be limited is I think fairly broadly accepted that this is going to be a very difficult challenge within the big data world.

Data collection is nearly ubiquitous, you know, everything from connecting cars to Fitbits, to smart shirts, to insulin pumps and so applying consent to a world where you can't peg all the collection that's occurring is a very difficult task and so is it really scalable?

Outside of HIPAA, you know, consent of course is not strictly required. The FTC and the corollary, you know, state laws around deception and unfair trade practices certainly have a lot to say here. You know deception of course requires some type of a positive statement in order to be enforceable.

And unfairness has this nasty thing of showing harm, which has been extremely difficult in this privacy world. And so, you know, neither one of these traditional pillars necessarily establishes how we are going to be able to control or regulate data generated in a big data world.

Health-related data is constantly expanding as Deven indicated, you know, the types of information that can be collected to infer health status or health condition is growing faster than actually the collection of health data itself by leaps and bounds and it's been documented again and again, you know, most notoriously probably with the Target case and the pregnancy predictor score where they used unrelated health data, data unrelated to health, a category of 25 some different indicators that infer a health condition. And so it was with that kind of environment that we're looking at these health-related data, how can consent, you know, appropriate apply in that world.

On the other hand it's very hard to list expected uses. So, if consent isn't, you know, the issue then the other aspect of how do you list appropriate uses, expected uses of non-HIPAA data could we consider a list of factors to determine, you know, what the reasonable expected uses are. Could we identify factors that should not be considered, you know, these health data elements should never be considered.

Concerns go on, the overarching concerns as we talked about the HIPAA environment and the non-HIPAA environment now the concerns for both...the all in or all out, kind of the binary concept of consent either you consent to everything or you consent to nothing and how that is really a limited choice certainly in our HIPAA world but even more so in the non-HIPAA environment of saying if you, you know, download this App you agree to every use that's listed and if you don't then you can't have the App.

The granularity and scalability of consent is I think one of the more key areas we are going to be exploring going forward. The granular choice is clearly limited by policy environment and by technological capabilities. If we enable individual control can it include, you know, broad sharing with that individual control, you know, the types of metadata necessary to do this at scale.

Persistent consents, we talked about this quite a bit and this is a concept that flows not just across...from one entity to the other, you know, your consent was good, I'm not sure it quite meets our standards, but also across environments from a HIPAA world to a non-HIPAA world and back because that's where the data is flowing as we get into patients that are more conscious about self-treatment and self-diagnosis the data is moving from the medical records to the non-HIPAA PHR world and back into the HIPAA world with added data potentially from sensors or devices, or pumps and so how can we have a consistent consent when there are different legal standard that we're meeting every time and different expectations of the individuals controlling the data at that moment.

And then there's of course the overreliance on consent and this is the hidden ethical issue in there, you know, most attorneys who, you know, have actually spent some time on the topic realize that they can draft a consent that is incredibly broad and that since most people don't read the notices that there consenting to that the ability to have a very broad consent for the use of data is not only likely, but happens every day.

And so, you know, the ethical construct is saying the patient bears the burden for how their data must be used is one that when you look at this not only in the HIPAA context where that is challenging enough but when you blow that out to a broad non-HIPAA and big data world and to suggest that the individual is going to control how all the uses of their data and what they believe is acceptable and not acceptable balancing the risks and benefits themselves it really gets overwhelming for the individual. And so there is this aspect of we have to figure out a way with consent to try and relieve some of this burden.

Possible solutions and again, solutions offered to you in the context of things that we have highlighted that we anticipate exploring in more depth, certainly, the proposed rulemaking and how for research and consent and refining that to say that, you know, FIPs should be followed, you know, not necessarily, you know, consent in every circumstance but where appropriate, where practical and then of course the rest of the FIPs which are a critically important piece of this.

An IRB consent waiver for low risk research, so not just have the, you know, highlight more the IRB's ability to determine that, you know, this research has low risk privacy impact and therefore should provide a waiver more readily.

A transparency and appropriate use, you know, if we are transparent, if the use is that which is expected and it is clearly within the kind of the easy to understand uses then consent wouldn't have to be utilized.

Within the non-HIPAA environment, you know, we're back into this broader concept of appropriate or expected use of a consumer and the consumer generated data, context is incredibly important here in order to determine expected use.

The middle ground we think is certainly more difficult. You've got a set of uses and a set of, you know, data collection concepts that you say this is clearly inappropriate, clearly outside the bounds of what would be expected, and then you have some that are fairly straightforward and easy that I don't think anybody would argue that this is what the data was intended to be used for, you know, when it was collected in that context. And the middle ground is a tougher part, you know, which of these other uses, you know, would be appropriate or not and what's the governance framework around those?

Clearly, you know, some of the factors that would be considered, you know, privacy risks, the identify ability of the data, you know, is it a commercial use, is there a profit involved, you know, which goes to underlying motive potentially, you know, and discuss outside initial collection, the collection outside of the initial environment or disclosure I'm sorry so the idea that it was collected in your...your Fitbit data was collected, you know, right off of your Fitbit and onto your smart phone but it's going to be disclosed to third-party data entities for use in other context.

And then conditional consents where, you know, you assume these things are happening and these uses are happening but we are going to condition, you know, the rest of what could be done based on whether you really want to have this done with your data or not. So the idea that if we have an appropriate use category that is set up any additional consent would now, you know, merit greater attention and therefore more conditionality and then we could educate consumers potentially about those uses. And that is back to Deven.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, thanks, Stan. So the last topic where we got some additional testimony on during one of our meetings but that we really have not had a chance to discuss in much depth is the issue of security. We had testimony from the three people who are identified on the slides it was terrific and informative. Here are some of the key themes that emerged from that testimony. There is a transcript for any of you who want to read it in more depth. There was this much richer content than we could capture on the slide.

But, you know, there's really a need to maintain a really kind of holistic and flexible approach to security that's dynamic, that's in depth and in layers in order to address what the risks are but regulatory compliance is highly impacted by organizational resources, so certainly adoption of the latest technological solutions and the highest level of security possible those solutions are out there but sometimes they're quite expensive.

And for many of the actors in this space, particularly in the traditional healthcare space where there are resource constraints, it's hard to ask them to reach this level. So, how do you develop sort of a security framework where you have sort of disparate resources even though the level of sensitivity of the data may in fact be the same.

There are many, many, many threats out there that are both external as well as internal and we heard testimony that the greatest impact may be from focusing internally at least initially now this was all before the Anthem data breach which was an external threat, but nevertheless, you know, if you sort of look at the scope of cyber risks that are out there oftentimes it's the internal issues and getting those nailed down the sort of training and deployment of security and dealing with the human factors associated with maintaining a secure enterprise can be quite impactful and is an area where we're still falling down.

And embracing common security frameworks, I mean, in addition to HIPAA for the entities, for whom it applies, you know, there are sort of best practice security frameworks that are out there and HITRUST was one that was mentioned. So, we have not really had a chance to discuss this topic in as much detail but we wanted to at least put out for you some of what we heard during our hearings.

We have a lot of work to do. I'm trying to think if we...I mean, we've tried to narrow the scope of what we're trying to take on here and already with that narrowed scope we have a lot on the plate. It would be great to get some feedback from you as a committee not just on the substance of what we've presented but what you think would be most impactful in terms of recommendations from our group on this topic.

Where would you all like to see us head, I'd almost personally and this is not...we haven't had Workgroup discussions of this, but I'd almost rather come up with 5 to 8 great impactful recommendations than 25 little ones, but we're heading toward 25 little ones right now because there are so many topics and I just would love to get some feedback from you all on what you think would be ones where we think we could get consensus and where we think it would be more impactful in this space. So that's it for us our presentation. So, we'd love to get some questions and feedback.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It sounds like someone has a line they need to mute.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Please.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Well, thank you Deven and Stan this is truly eye-opening. It's not only gnarly but unfortunately it's extremely important and so I think we need to get some kind of like you say, a handful of recommendations that are really impactful.

Listening to you it feels like this is becoming nearly impossible to protect data in the context of the mosaic effect essentially. The White House Report was saying de-identification is basically insufficient when we're dealing with big data analytics that's been said before but not by everyone and this is a good way of stating it.

And the other point you mentioned was consent which we sort of discarded a long time ago as just being ineffective. So if we can't protect it and we can't really give informed consent and it doesn't have the boundaries that you need anyway, I'm intrigued by your mention of harms and maybe that's an area to go towards if we can't protect it were it sits and we can't fully inform people on what's going to happen, what their expectation should be, maybe we focus instead on trying to prevent harms.

So the tough thing about that is discrimination can happen...it's really discrimination is the harm I think that would impact individuals, discrimination and stigma. So discrimination can also occur without re-identification that was one of the things we were trying to track down, oh, well let's prevent them from re-identifying but you can discriminate without identifying a soul as long as you have the characteristics of a group.

So in a sense I think today's discrimination happens by groups of people like an individual. So patients like me essentially. And so the question is...and then actually the ante has been raised a little bit because as we go from pay for volume to pay for value that's another code word for you want to maximize your score or your performance and just as Deven led off non-health data like SES can be used to predict health behavior which can contribute to the performance of either an individual, a patient or the provider so the stakes get pretty high.

So, I wonder if there's a way that you were asking, is there a way to focus our efforts instead of having 25 different commentaries on the different weak points, is on how to...does it require a law to prohibit discrimination against groups that can be determined outside of the traditional discrimination variables because big data...what it's done is it's gone way beyond the traditional discrimination variables and said so many data can be combined to isolate a group.

Now in the big picture, if they isolate a small group then it's pretty...it may be recognizable. But if they take a bigger group then actually there's a bigger harm because so many people who really aren't in that category but got lumped to try to hide the discrimination parameters.

So there's lots of harm, in other words I guess I'm focusing on the harms. It seems hard to chase the prevention side or as Stan mentioned the collection side, maybe our attention should be focused on preventing the harm side because there's so much data out there that everybody can analyze it and create groups that can be discriminated against and the challenge now is to try to prevent that part. I don't know what you think about that or whether you discussed that approach.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well, so we have harms listed...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

And it's definitely, you know, it came up a lot during the testimony, you know, in the discussions that we've had with ONC staff, there's a desire to have some consensus around some recommendations in that regard. The hard part is figuring out what those recommendations would be.

This would definitely be one of those bully pulpit kinds of recommendations because it's not clear to me unless someone has a brilliant idea around the table that HHS has the tools to fix this, right, there are antidiscrimination laws that exist out there to protect sort of pockets of actors for pockets of behavior but, you know, not...we don't have a sort of ubiquitous environment for data redlining...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

That's what it is.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Which is a term that's been used in some of our conversations. Now one of the more promising avenues is, you know, the Fair Credit Reporting Act provides a certain degree of transparency around decisions that get made about people mostly in different financial context, right, it has limited applicability on his face, but some of the principles that are embedded within it may be worth thinking about in terms of how do you scale those two environments where data are used to make decisions about people but there's very little transparency at either an individual or a population level about how those decisions get made and can you give people the right to understand that a little bit more and both from a transparency stand-point but also to correct data in circumstances where the data that are being used to make those decisions are not accurate and whether that's a population right or an individual right, I think those are two things that have been thrown out but inadequately discussed to date.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, that's an interesting concept just the transparency on, the justification for why you were declined...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

In your case credit in this case insurance or signing up for a provider, etcetera. I'll just go around, Chris, please?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you. So, first of all thank you very much for a thought-provoking and stimulating report. I wanted to respond to you Paul, discrimination of groups exist already. We have actuary tables that are used to figure out whether you either get life insurance so this is not something that is far away from business practices.

I want to start off with a story about the Lieutenant Governor in Massachusetts who got into a car accident and he claimed that there were icy conditions and that it was the reason for his accident and when they downloaded the data from the black box it became very apparent not only was he going 100 miles an hour but he also was asleep and the point here is that we already have devices in our everyday life that can have very important impact on what's going to happen to us in the legal system, in the health system, etcetera.

So, big data is already being collected by cars, planes, tablets and I wanted to cite you Deven, you said what are people doing with my data and there is this underlying assumption that this data is yours...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

While the reality is it ain't.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

The reality is it's owned by car companies, it's owned by Facebook, by Twitter, it's owned by companies who have quantified self-devices and what I was missing in your presentation was some thought around data ownership whether there is a need to change the law of data ownership of these kind of devices that are gathered by individuals and so I think that's something that I would at least like to hear your opinion on because I think that would be one of the things to circumnavigate all these difficult issues that you listed. Do we have to get consent, what kind of consent, how broad a consent because if the data ownership would be transferred, a lot of these issues would already be resolved right there.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I'm only laughing because we were just having this very conversation about 15 minutes before this meeting started.

You know ownership is a hard construct to put around data because it's rarely...the law rarely takes the step of saying "x" owns the data, right, and it's one of those places where if you have it, it is presumed to be yours on some level and then you may have some legal obligation to protect it, you may have some legal obligation to share it, your possession of it either implies certain rights or there...without a prohibition if you got it you're going to use it for a certain purpose, right?

And a lot of...I was recently somewhere were somebody raised the issue of give the individuals ownership of their data and my use of use of the term was a bit of rhetorical license because data about you feels like something you should have some control or ownership over but I think you're right the reality is that that's not the case.

I'm not sure that a full on transfer of ownership exclusive to the individual while it seems very empowering is going to work or going to fly because there are also business records of companies, you know, a medical record is a business record of a hospital even though HIPAA requires them to share it with patients.

A record of data collected by a car is possessed by the entity that collected it, the device that was put in the car whether it's the manufacturer or the device manufacturer or whatever to say that this is going to exclusively belong to the individual is one avenue.

But another avenue is to say, you know, the person who the data is about has either equal rights or a set of positive rights with respect to that data something that we do in HIPAA although maybe we could do a little better in that regard that there is not sort of exclusive ownership of the data but that the individuals have greater rights to it than they do today.

So I'm throwing that back out you it's not...I don't know...we might be able to get consensus in this group that individuals should own their data I'm just not sure how far that recommendation would go given all of the other sort of constraints out there and the potential downsides. Stan it itching here let me go to him.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

No, I was going to say, if I could just add to that. I think that where the data ownership issues comes in probably most acutely is the very example that you gave it's not within the HIPAA construct or the medical record construct necessarily it's the big data world that exists outside because there isn't this legal overlay for consent being required.

So ownership would be a way to force consent to have to occur. You're still kind of back in, is consent going to work and, you know, if it's your data and you're driving and Ford or GM is asking repeatedly over your speaker system, you know, do we have your permission, you know, whether or not it's your data or not eventually you're going to get pretty annoyed with that consent process I think.

So, it does, I think, force the question of shouldn't consent be required. I don't think it necessarily answers the question of, you know, is consent really the method we're going to have to utilize but certainly it's something for us to think continue to think about.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great. Thank you very much Stan and Deven this was a great presentation on a fascinating subject. Actually...and I have a couple of comments and a question as I pick up on Christoph's example, I mean, I thought it was great what you said about de-identification and Christoph's example of the Lieutenant Governor of Massachusetts getting into a car accident that was well publicized and his injuries were well publicized and it occurs to me that it would be not possible to adequately de-identify his data because if his data was in any kind of a dataset even if the demographics were gone you know the person's date-of-birth, you know the date the injury occurred, you know the specific injuries he was treated for and you even know the location where he was treated, the hospital, you'd be able to re-identify that person and once you re-identified him, you know, Paul Tang talks about harms and being discrimination, once you re-identify that person you could use the data for political purposes. You could say, you know, here's the drug this person was taking at the time or perhaps it had nothing to do with the accident but you could look at their medication profile and you could look at other things.

So, just an observation that this de-identification process is, in my opinion, totally impossible to de-identify all data and for any prominent individual, a politician, a sports figure where these things are typically reported, you know, information on injuries are reported and, you know, you know other things like their date-of-birth and height and weight they need to be excluded from these databases otherwise something very bad is going to happen routinely to these people, people using the databases to get information to get an edge in gambling for example on sports.

The question also that I have as we talked...I liked Deven your presentation about harms and saying that we may need to think about harms and my question for you...one question I have for you is, this is all being looked at from the stand-point of harms to the patient aren't there potential harms to a physician, are there reasons why a physician may not want to be included in a database. And I could give you some examples if you need them, but I'm not sure that you do, but it seems to me that might be an important direction to go in.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well that, you know, the committee...so typically the laws don't, you know, protect the individual who is the...but HIPAA doesn't provide protections for sort of confidentiality of the medical provider just by way of example.

The focus of privacy law tends to be more on what's perceived to be the data subject although I think your point is well taken that any particular finding that is going to both have information about what the provider...what kind of care the provider provided and if the provider's named in it than that would be indicative of them as well as the patient. Is that what you're talking about?

Paul Egerman – Businessman/Software Entrepreneur

Well, no, what I mean is there are some situations where physicians prescribing birth control medications...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right, right.

Paul Egerman – Businessman/Software Entrepreneur

But they live in an area where there is, I don't know, a religious belief against that. The physician might fear being ostracized if that information was found out.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Paul Egerman – Businessman/Software Entrepreneur

And so that could be an example or there are some diseases that the public has a sense of almost like panic about them sometimes, you know, like AIDS or Ebola and just the fact that a physician treated some patient with some disease in her office might harm that physician if that knowledge comes out because other people might not just go to their office anymore or somehow afraid that this office is somehow tainted or damaged because a patient with that disease was once there.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, those are good points. Thank you. I will take those. I would like to make sure that we take that under consideration in the harms discussion. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks, Paul. David Lansky?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Thanks, Deven and Stan, I have two questions that are both to your wrap up Deven of what level of granularity should be working on and I want to...on the high end of macro view some of the themes you've raised in the context of big data have also surfaced in other context for other Workgroups.

So the Strategy Workgroup had several recommendations as we looked at the strategic plan which all are affected by HIPAA and the Common Rule and other privacy regulations and the new data environment that you've talked a lot about not only about big data but pluralistic data sources and mobile and everything.

So, I'm wondering whether you all had a conversation about whether this Policy Committee should take a broader look at these issues and really go up a level and who in the country is willing to take on the large issue of whether HIPAA itself is ill suited to the emerging environment and needs to be rethought in some fundamental ways and I don't know if we are not able or willing to take on that conversation what other vehicles there might be for that.

But I hear from many contacts and many subcommittees a concern, as you said several times, it's a highly fragmented regulatory environment that is not very well equipped to dealing with the changing information environment.

So, did you all talk about whether rather than drilling down into 25 specific recommendations we should be looking up at more of a macro view with a regulatory environment, that's one question.

And then the second question is to your test of whether we should do five mid-sized or 25 small items, my vote is we are better off at a level at the five and you all hopefully could identify a small number of high leverage interventions that deal with some of the topics just discussed here rather than getting...I know from the previous work we've all done in these areas one can go endlessly deep into specific complex problems and I think we here would be better served at a more few high leverage items.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

That's very helpful actually, in fact I just got an idea for something, so.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Okay, good.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you for the presentation. I think it's a very interesting topic because when we have implemented, you know, health information exchanges and other clinical data research networks under PCORI these topics have always been, you know, at the top of the list.

So, one comment that I have is just generally when we talk of consent in the policy framework, and we are talking of patient consent, somehow traditionally it has been seen as way of involving patients which consent...the way that we have implemented it not necessarily true.

So, do we differentiate between the use of the term consent and patient control in terms of does new technology then allow us to provide better control because the consenting seems to be much more of a paper/pencil, you know, type of area where you have a record of somebody having signed something versus today when electronics records, you know, allow us to at least also make sure that patients are engaged to a level where they are consenting in a more informed base of every time their data is used. So, that question in terms of using the terminology which maybe, you know, changing with technology.

The other thing is in terms of this discussion of, you know, where to prioritize because some of these issues are more philosophical conceptual issues in terms of who has ownership, who has control or who should have control to what extent understanding that re-identification is always a risk, so, we would never be able to rule it out completely, it seems like when we have thought of, you know, aggregating large amounts of patient data de-identification almost seems like bypassing patient involvement and consent.

In some ways, if we as providers or as people who are analyzing data it seems easier for us to find solutions for de-identification than to find solutions for patient engagement, increased patient engagement. It also seems more costly to some extent.

So, if policy was to be used as a signal to the market in terms of solutions that are more innovative, you know, entrepreneurial than should we be then thinking of what is the end goal and if the end goal is to increase patient engagement in terms of healthcare understanding that, you know, patients would not be just engaged in health but they would be engaged in all other ways where, you know, how they buy their cars or how they use Internet or other things then should we be...by focusing on patient control or patient consent as a policy lever do we then send more accurate signals to the market in terms of what solutions to be coming up because when we decided to talk about de-identification more you saw in the last 10 years more analytic software companies coming up with de-identification solutions than with granular consent solutions. So, from that perspective should that be another angle that should be considered in what eventual recommendations will come out of this committee?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Devin?

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

Thanks, Deven. I really always learn a lot by your presentations and then I try to apply them to sort of my daily experience and one of the use cases that came to mind that I just kind of wanted to see how it fits in what you've talked about and kind of where you think we would go.

I think Stan mentioned Fitbit and it just reminds me of a lot of those integration issues that we're doing both on my research inside but also in the clinical operations, and it's a case and example where there is a set of data that I...depending on who I'm talking to is treated very differently so that when that data, and I talk to the companies that kind of generate that data they have a set rules, I can have the exact same conversation with folks in our legal departments and IT departments in our hospitals and it's treated very carefully as health data.

And so I'm just wondering is there some guidance you're going to give about standardizing or creating some consistency with the exact same data being treated by two very different sets of rules.

It reminds me a lot of a debate we have going on in our academic medical centers about the difference between quality and research, innovation and research. Honestly, the rules seem to change all the time and it's sort of depending on who you're talking to the level of scrutiny and kind of efforts you'll go to protect or not protect this data.

And I just really would love some signal and, you know, I like the phrase kind of if the policy is signaling to the market where we're going with this where is that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

No that's...all of these are incredibly helpful to...it's giving me great ideas about how we can structure conversation with the Workgroup subsequently to try to drive towards the, you know, some big thematic recommendations that we can deliver to you all that would be much more impactful than 25 little ones. So, it's a really good point.

I've been on the phone with reporters before and tried to explain to them, well, you know, the data...it started in the Fitbit and it wasn't covered by HIPAA and then it came into the doctor's office and then it was covered by HIPAA, and then it went right back out to the patient and it wasn't covered by HIPAA, and then it came back in and then it went out to the public health, and then it might have been and, I mean, it's just...

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

It's really...

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

And even, I mean, just to build on that a little bit, even medical devices themselves that are patient worn, so an insulin pump, you know, there are arguments whether that's covered data, you know, certainly if it goes back to the provider then it is, if it goes directly to the manufacturer it likely isn't and if the manufacturer is a BA of the doctor than it has a whole different...you know it's the exact same data to your point.

And so I think it does kind of come to the thing we have been wrestling with is, you know, some of this is use, right, there is...the collection is occurring, you know, no matter what environment you're in, you know, the uses for some reason are different, right, and so, you know, shouldn't there be a body of uses that we agree is acceptable in that context and so I think that's where we come close to talking about what you're thinking about as far as consistency, but it certainly is a good framework for us to consider and continue to consider.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks. David Kotz?

David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College

Yeah, first of all as a member of the Privacy and Security Workgroup thank you for this really impressive summary of a gnarly problem as you said. It remains gnarly and I'm looking forward to helping think this through a little bit more.

I have a couple of comments I guess, one is related to the non-health data, data not traditionally thought of as health data that's increasingly being leveraged for health related purposes and hoping that we can find a way to leverage the fair information practices better so that people, consumers, everyday folks are at least aware of what data is being collected, who is possessing that data of how it's being shared and have access to it.

The car example is a good one, I'll bet most people can't get the data from their cars if they asked for it and as I understand it most medical device manufacturers won't share the data with the person in whom that device has been implanted which boggles my mind. And so, you know, it seems to me that at a minimum we want to strive for more transparency.

Whether I own the data or not at least I know the data about me exists who has it and what it's going to be used for. And then we can be thinking about do I consent to that collection and what granularity and do I consent to further sharing and so forth.

The other thing I would...I'm hopeful for is maybe some regulations or policy around the handling of this data. So, you mentioned this possibility for secure enclaves and policies or agreements around limits to re-identification in the uses of data whether it be traditional health data or non-traditional health data, because I'm all for using the data for all of these great purposes. I want to make sure that we can enable that to happen. And in some cases that's perfectly feasible as long as the holder of the data maybe who is assembling many data sources handles it carefully so that it's used appropriately within the scope of their own work and it doesn't leak accidentally to others.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

I think those are fantastic points, David, thank you and just to build a little bit on your concept of, you know, a device manufacturer, you know, doesn't share information back with the patients. We actually had a project of this at Indiana University where we've worked with a pump manufacturer and the steps necessary to actually share the information back, I'm sorry not an insulin pump an implantable cardio defibrillator, and to share the information back with the patient and the steps are somewhat daunting in that the data generated by the device has very little meaning to the average patient. So, it's that cycle but I think it is the goal and if that's the goal at the end patient engagement and patient involvement sharing the information back that's collected about them I think is one of the key issues that we've talked about access and meaningful access and use. I think those are going to be kind of key issues as we go forward.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Jodi?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Thank you for the presentation. This is great and I always enjoy presentations from this Workgroup and I can't help but comment given my background on this topic.

There are a couple of things I just wanted to suggest, one you're asking about the level of recommendations and there seems to be a lot of consensus around kind of bringing it up a level.

I just would like to highlight that if there is some low hanging fruit and specific things that could be done in the short-term to address some key problems or help advance the discussion it would be good to have those as well. So, I agree with not getting too far into the trees but if there are a couple of, you know, really big trees that might impact the forest canopy that we should hear about this as well.

The other question I have and this might just be more fodder for your conversation in the future is I'm wondering, you know, all of the comments you had about challenges with consent and scaling it and challenges with de-identification I'm just wondering if there have been any conversations in the Workgroup about sort of shifting rather than focusing on harm and consent to thinking more about trust and a different framework that might overlay some of this like, you know, where you are thinking more about the fiduciary duty or something that builds trust as opposed to avoids harm, because harm sometimes is very difficult to show or prove and there is resistance to the availability of data just because the issues of trust even if there is an actual harm, anyway, just wondering whether the conversations have included other constructs and thoughts about how to enable the sharing of information in sort of this new environment that may either build on top of or supplement existing protections.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So, we've talked about it a bit, I mean, probably not in a sort of holistic way but the threads of it come up in terms of we had some great testimony from Denise Anthony who, from Dartmouth, one of David's colleagues, who came to us to talk about security but actually shared a lot of sort of survey data that she had collected about sort of what types...what are trusted environments for people in terms of information sharing and what are they worried about.

You know people tend to trust the immediate institution or organization that they're dealing with and that's why they buy a product for example or they trust their doctor with respect to their data. But they are less trustworthy when it goes outside that environment. So, does that argue for, you know, that's the place where there is a need for greater transparency and maybe in some circumstances a requirement to obtain affirmative consent or authorization when the data is going outside of an environment that is the trusted environment?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So, threads of it sort of pop up in different settings as opposed to, you know, one sort of piece of how do you build trust necessarily, but I think it's a really good point because ultimately that's ideally what you want to achieve, right...

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Right.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Is that people have a comfort level and the data are being shared in the way that they trust, but transparency is also a part of that, right, if you don't know who has it and what's happening to it's hard to sort of even figure out who you could trust because you may not even know that this entity has data about you.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, it seems like there might be will different layers...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Of environments and different...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

You know schemes for those different layers depending on the level of trust either needed or that an individual might have with respect to the use of their data. Anyway it was just a thought...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, no, great.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Not a particular recommendation.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Great input, thank you.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good, thank you, very much. I also enjoy always hearing the Workgroup report outs because they're such tough issues and you've done some very thoughtful thinking about that. So, I heard consensus around the table about focusing on the bigger issues, the five, some of...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

But maybe some low hanging fruit or trees.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yeah and low hanging trees and some of the concepts that came up is just the harms...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

The transparency which is one way of mitigating...at least informing about that, potentially looking at HIPAA and the differentiating concepts is, is it really about the data, Fitbit is an example, is it about the purpose, is it about the trust or is it about the person's expectations or their surprise of something being done with it?

So, those are all concepts that you've mentioned and some of the discussion has focused on, but, so there may be a different unifying way of coming back with your handful of big recommendations. But thank you so much for all the work.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, next before lunch is, the final recommendations or feedback really from the Strategy and Innovation Workgroup and Consumer Workgroup regarding the federal health IT strategic plan.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

I like that. Thank you, Paul, good morning everyone. This is David Lansky we are here together as Jen Covich, myself and Christine Bechtel to report on the request you all made of us to bring together the recommendations from the Strategy and Innovation Workgroup and Consumer Workgroup with our responses to the draft federal strategic plan.

So, to do that I think we've tried to consolidate things but also keep some of the more detailed recommendations from each Workgroup separate so that the Policy Committee can consider those as well as the blend that we've tried to put together today. So, Jen are you going to take the first part of this?

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Sure, I'll take the first part. And I do want to thank David for all of his leadership and he's been great throughout this process so thanks, David.

All right, so we did meet last week, the Workgroup met and Christine joined us for that and the purpose of that meeting was to try to combine the recommendations somewhat. So, what I'm going to go through now, let me get through here, I think we've already seen all of this, so this is the Workgroup charge, I think we went through all this at the last meeting, the process for reviewing the plan, the dates there, final recommendations today and let me get to the meat of it.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

That looks like our previous deck.

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

I know, this is not the right deck. Can we get the...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

...

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Yeah, Gretchen is this...

Gretchen Wyatt, MA – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

...

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

No this isn't it.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

...right?

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Yeah, this is the old one from the last meeting.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

In the printed package you have the updated one.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yeah, if you give us a minute we can pull up another one.

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

All right, sorry about that.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I don't have that.

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

It was distributed so I think if people have that we can probably start.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

That's the wrong one in the deck...

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

No, this is correct.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

No it's not.

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

No.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

There is one...

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

It's the right title.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah...

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Do you have it? Okay.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I have the...

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Okay, let me talk a little bit about the overall recommendations just to get started here while we get the right slide deck up. So, for those of you who weren't here at the last meeting we found that there was a lot of overlap between the two Workgroups, the Strategy and Innovation Group and the Consumer Workgroup.

So, overall, I think both groups thought that the plan needs to better align the goals and the objectives and the strategies with the vision and the principles. The group felt like the vision and the principles that are laid out in the very beginning of the plan make a lot of sense and they're appropriate but the pieces that follow after it aren't quite in line with it.

I do want to be clear that when our Workgroups met and through our discussions there was not any significant disagreement between the Consumer Workgroup and the Strategy and Innovation Workgroup which I think is an important point. Both groups kind of took two different pathways to review the material but we both ended up in the same place in terms of how the plan needed to be reframed and restructured a little bit.

Overall the framework that is used, the collect, share, use framework I think both groups felt like that was not the right emphasis. It emphasizes data rather than a person-centered health strategy. And we had a lot of robust discussion in our group, and I know Christine did as well, that the goal of this plan is not to create a big HIT infrastructure but the goal is to improve healthcare and I think we need to tweak the language a little bit in the plan to really have that come across in a clear way.

So, the overall goal or the theme is really to use digitized information to improve health and healthcare and that if we can change the language a little bit and emphasize the end goal not the means by which we do that it will go a long way.

I think we talked a lot about the need to really communicate the intent of this plan to the general public and to the industry so that it makes sense to people as they read through it and so the goals make sense and the strategies. So, we felt like reframing that a little bit would go a long way.

So specifically while some of the strategies and specifics, and metrics in there talk about data both groups agree that the overall focus of the plan should be on improving the health of individuals and communities.

Again, I think the language that we use is very important here it's going to drive all the conversation it's going to drive the actions of the industry so we need to be clear from the start. How are we doing on those slides?

Gretchen Wyatt, MA – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

It says they've uploaded, they've been uploaded twice...

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Okay, good, great. Well, I'm on slide three when you get there. So, in terms of the joint recommendations the first one we talked about was really about providing some clarity and that the plan's actions and strategies need to use unambiguous clear language to describe how the goals are going to be achieved. We need to add some definitions to the terms there to avoid vagueness and make sure nothing is misinterpreted.

A second key recommendation was really around transparency and that the federal agencies I think need to provide some sort of reporting on their progress, how they're doing towards these health improvement goals, ensuring that the industry and the stakeholders can monitor the progress as we go along.

The language on the slide doesn't quite exactly...what we we're talking about as a group. I think the focus is really on transparency and helping the public and the industry understand why we're doing this and where we are in the process in terms of doing it.

Oh, there we go, great, okay, all right. So, both Workgroups recommended that the plan reframe the focus to emphasize a person-centered health and wellness, to clearly align with other national health planning activities and leverage Health IT so that individuals, purchasers, payers can all partner together to identify and align to, and achieve health goals.

And I just want to make another point here at the bottom we actually talked a lot in our meeting last week about changing the language in the plan, instead of referring to patient goals referring to health goals because we think we really need to shift the focus towards health and away from I think the old paradigm a bit.

Other joint recommendations, the plan really needs to show how the federal government is going to support this new infrastructure that is person-centered. So shift the plans focus from talking about data to talking about how it's going to support communities and individuals to improve their health.

We need to talk about how the private sector and it needs to work with the private sector to help identify government data sources that could support innovation and improve public health goals, and this was really around the thought that the government is really on this whole trove of valuable data that could potentially be accessed to improve public health, individuals and communities and we need to figure out how we can access that data and use it in an efficient way.

Each Workgroup proposed separate methods, and we're going to talk a little bit about that, in terms of how to reinforce this focus on improved health and as I mentioned before we took two different paths but ended up in the same place somewhat.

The Strategy and Innovation Workgroup focused a lot on the fourth goal that's in the current plan. So, if you'll remember the current plan has this fourth goal that reference's advancing the well-being of individuals and communities. And our Workgroup really felt that should be the overarching focus of the entire strategic plan. That's what our intent is and that's what we're driving towards.

So, the framework could be restructured in the strategic plan underneath that umbrella goal to advance the well-being of individuals and communities. And I'm going to just skip through some of these other pieces here and get to the next part to describe that a little bit more.

So, in terms of reframing everything under that fourth goal what that would mean is the plan would be structured in a way where the overarching goal would be to improve the health and well-being of individuals and communities and then underneath that would be for, we're calling them aims to not confuse the language here, meaning the plan would be divided into four parts.

The first being aligning the Health IT goals with public health goals and targets, you know, finding out what are the national health goals that we're trying to achieve and let's drive towards that so really having something to center and cement the plan.

And the second aim would be, okay, we know what the goals are now let's identify what relevant federal information is available and what data sources could be helpful to achieving those national goals.

And then the third component is really around, you know, what can the federal government do to help make that relevant information usable to people and organizations to help impact health.

And then finally, you know, the last component of the plan would be developing policies to help facilitate the safe acquisition sharing and use of health data. So, it would really take a little bit of the focus more on everybody is driving towards improving health not driving towards creating a big infrastructure.

And now I'm going to turn it over to Christine to talk a little bit more about her pieces.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thanks. Thanks, Jen, so this will not be new to you guys this is stuff that we talked about last month. If you need a reminder, you liked it last month, and so I'll jump right in and say, so Jen's done a great job explaining how the Strategy and Innovation Workgroup and I think the Consumer Workgroup really agrees, that the plan needs to be kind of re-anchored in a health improvement goal, so improving the health of communities and individuals.

In addition though, I'm not touching anything and it's moving the slides, in addition, we talked about having a new goal and that is a goal that you see here and again we talked about this last month, so building a culture of individual provider and community partnership to achieve shared person-centered health and healthcare goals. This is a goal at the level of, you know, kind of the aims that we were just going through on the last slide so I just want to make it clear that we're down like at that level.

But as you guys recall this is really about creating that partnership between patients, families, healthcare team, as well as community supports really driving some alignment about goals that matter to the patient and to their families as opposed to just sort of what's the matter with the patient but by creating that alignment then we now have a conversation about the health goals that I want to achieve, what my clinician and my clinical team thinks, you know, about that pathway, how we can all come together in some agreement and if we can use that kind of a strategy to really align our efforts in patient and family engagement in quality measurement reporting and payment then we thought you could also create some nice parsimony in those areas by really focusing on what matters to both, you know, obviously the clinicians and patients, and families.

So, we also talked a lot about how we might then streamline some of the activities in the plan around these things so we can document those goals, measure, refine them over time, you know, report on progress against goals, you know, things like that.

And we said that this would be an umbrella goal for some of the other, you know, more tactical items in the plan like care planning or shared decision making, or patient generated health data that these are all really necessary elements of creating this culture of individual provider and community partnership.

So, more joint recommendations, both groups talked about establishing a more dynamic interactive learning health system, increasing the focus on using Health IT to improve health equity.

We also talked about improving patient, family and caregiver experience and that was a big piece that we felt was a little light in the plan as well as elevating consumer voices in supporting the transformation of our healthcare system to improve the health of individuals and communities.

And we also highlighted, I think both groups highlighted the need for more focus on a broader set of information that would support transformation. So things like social determinants of health in addition to the more traditional clinical data.

We have a lot of specific Workgroup recommendations and strategies that we've identified, you guys have letters that were provided to you first in e-mail and now in your packets that go through those recommendations, the ones from the Consumer Workgroup, and I think you guys as well, nothing has changed since you saw them last month but there is a lot more detail.

I'm going to do a really fast go through in, you know, 1.5 slides on some of the high points and then I think we're going to maybe have David say a few words and then we'll open it up for discussion.

So, let's see, what have I not covered? All right, so we made some recommendations around training and other methods that would improve not just health literacy but Health IT literacy, interestingly that's something you find in the interoperability roadmap so that's good news.

We also talked a lot, particularly in the Consumer Workgroup, around usability of patient health data from a consumer perspective and this whole notion that with view, download and transmit and Blue Button, and more and more mobile Apps coming online that consumers will be an increasing data source, that we will be aggregating health information from lots of different things. We're already hearing about patients who have 3, 4, 5 different patient portals so we're going to be able to download, hopefully, health information from those areas.

But we're also seeing patients and families going outside what we would describe as traditional healthcare sources to seek care whether that's, I'm not going to my primary provider but I'm going to the Minute Clinic down the street or, you know, I'm using Anthem's Live Health On Line and I'm doing a video visit for \$49.00, by the way which I've done, and I'm getting a whole, you know, healthcare summary out of that.

So, now I'm really getting a much more complete picture than any, you know, sort of one part of my care team and that is a huge issue that I think you're going to hear more about in the interoperability roadmap as well where we're really figuring out how do we make that easy for consumers to do but we also need to make it really easy for providers to act on that health information without having to sift through a bajillion bites of data.

So, we also described the need to better identify and understand the support that family caregivers need and to better connect providers, patients and families to community resources including long-term services and supports as well as behavioral health resources.

We've talked about a couple of different aspects of privacy that we wanted to suggest be bolstered in the strategic plan and those were particularly the technologies and devices that aren't covered under HIPAA like mobile Apps particularly as we see consumers aggregating more of their own health information today. As well as more work around sensitive health information.

The bullet is not really clear here in that it's not guidance on the policy framework because obviously HIPAA provides a lot of that policy guidance for managing sensitive health information. It's more again how do we make it easier for consumers to flag, you know, or segment their data. How do we make it easier for providers to respect their choices around sensitive health information?

We've talked about mobile access and a focus on person-centered outcomes and then also I think the Strategy and Innovation Workgroup did some good thinking around evaluating and harmonizing federal and state policies that impede research and innovation. So, David, do you want to close with anything?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Thanks. So, I know this is very daunting and abstract and with a lot of words that we use so I wanted to frame the "ask" to this committee for today where I think we are in our process.

The Workgroups are very highly aligned on a lot of the substance. There are a number of specific elements that are a little different but are friendly.

And now I think the Policy Committee needs to communicate to ONC and to the larger world what the emphasis is you think should be put on the strategic plan as it comes to it's a final redrafting.

The staff has been extremely supportive and gracious in taking a lot of our feedback and working with it and capturing it and now beginning the process of redrafting the strategic plan to reflect all this input you just heard about.

So, at this point it's really a matter of, you all helping the staff take all this input and shape it into something that reflects what the FACA committee wants to emphasize. So, I just thought I'd flag a few of the things that I think we've been surfacing and really test whether you all agree with these or not and want to capture them in a recommendation to the staff.

One is about the structure of the plan, you've heard today two different, slightly different approaches to that, one of which is the bridge goal that Christine described which puts a much stronger emphasis on a person-centered approach and the other is more of a total restructuring emphasizing health improvement as the framework, again, these are friendly ideas but they're a little bit different in emphasis.

Apart from the structure there are several specific themes I'd say. One is that the collect, share, use language and framework is perhaps now out of date and not the one to be using to guide a 10 year strategic or a 6 year strategic approach.

A second meta-idea is that separating providers, particularly the traditional Meaningful Use qualified providers, from the rest of the healthcare continuum is not the right approach to take in doing a strategic plan that we need to look at the entire continuum broadly and how to manage that. And that means looking at the person's entire health experience and the information to support that.

Third, we didn't mention as much this morning, but the link to value and value payment is very important as a driver of adoption of our technologies and optimizing only around patient care is not taking the complete picture. I think we heard that from Charles last time in our meeting here.

And then finally, the federal role in all of this, which is the point of this particular report, we're recommending that the role of the federal agencies is to help to find the pathway toward a new information environment but leaving a lot of room for innovation and variation helping to move us toward an IT infrastructure that can address these new opportunities to manage health and not per se focus only on building out the IT infrastructure of the traditional medical model but looking at the IT infrastructure more broadly.

The last thing I want to mention to everybody is we do have a responsibility in our committee to bring you back a proposed work plan for the Policy Committee to address some of these issues and I think in the next month or so we'll try to bring back, as we did initially at our last meeting, some of the ideas we'd like this committee to take up for more deeper work than we could do during this first review of the strategic plan. Thank you, all.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good, thank you. Now did you include in those four, you know, you were talking about this is a federal strategic plan the notion of wanting to come back and look at a national...

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Yeah, Paul, we had suggested that this might be something the Policy Committee wants to do later on this year or next. It's not part of our recommendation today.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Right, so that might be one of the things you bring back in the next...okay. Good, comments? David Bates?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yeah, on the first one, I got a little confused, could you restate that one briefly, the first of your four recommendations?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

On the collect, share, use or the structure of the report?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

The structure of the report.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Oh, why don't I let Christine restate that.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Sorry.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

No, that's okay, so, I think the real commonality is that the first recommendation is that it should be anchored around a goal that is a health improvement goal. So, the Consumer Workgroup talked about, you know, any health improvement goal frankly, but, you know, something like the triple aim or whatever and the Strategy and Innovation Workgroup looked at the fourth...existing goal number four and said, well, wait a minute that is a health improvement goal which is improve the health of individuals and communities. So, the recommendation is really to reframe and anchor the plan in that notion.

Separate from that the Consumer Workgroup wanted to also create somewhere underneath that, you know, framework level, aim we'll call it, a separate goal that is about creating that partnership, but that's not the re-anchoring piece. Does that make sense, David?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yeah, so I felt like this was very thoughtful and, you know, from my perspective anyway re-anchoring around an improvement goal such as the triple aim would make a lot of sense. Triple aim is so widely used it's an obvious one to endorse.

I felt like going...addressing the entire continuum also just makes clear sense, so does the link to value, so does the...changing the role in government to helping to define a pathway. So, those are my reactions.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks. Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Yes, so thank you and I really liked the way that you have kind of reframed it with the focus on, you know, patient-centered or person-centeredness and on health improvement and as I was...after your presentation looking at that list again I think the point that you are making which is to change the focus from, heavily on infrastructure and data to really the end goals is something that will be helpful.

My question though in terms of as you start looking at this is when you translate that plan into actions and, you know, actual implementation is there a risk that if you increase the level of like looking at advancement of health as a goal, you know, advancement of health and well-being of individuals, changing it from being a goal that will have strategies, objectives, you know, implementation to something that is overarching also leads to not having that focus in terms of actions where it almost goes into the background and the actions that are implemented are more than...the more micro steps rather than really addressing the macro because you have now...as it is laid out today at least advancing health and well-being is a separate goal and therefore there will be some accountability in terms of achieving those goals so we set up, you know, goals, targets, etcetera.

But if you raise it above the level of a goal and it is like a general statement then how do we make sure that this still remains in the actual implementation and is translated into those goals?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

One comment about that, we, in our last presentation were very appreciative of the draft of the strategic plan as we have it, which has a number of strategies that are pretty specific at the level of action you're talking about, should be retained. We're really trying to put a wrapper around that and I think when the staff does do some rework of the documents I would hope they would definitely keep the incremental practical improvement steps that are listed there but also shaped them and support them with these larger strategic changes.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

And I'll just add one quick thing. So, I completely agree I think David has done a really good job of framing that. We also have things like the interoperability roadmap that are really highly focused on this more technical aspect.

From a consumer perspective the challenge I think we run into with hooking something onto collect, share and use is...well so the Drudge report actually ran a story when the strategic plan was released that says, 35 federal agencies are coming together to collect, share and use your health information, that is not the message, you know, that we really want to send here.

So, we really want to orient the...the infrastructure must be solid but it also needs to be deployed in the same way that congress created Meaningful Use not meaningful adoption, but really deploy that infrastructure around what matters which is health improvement goals.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Okay, thank you.

Jennifer Covich Bordenick, MA – Chief Executive Officer – eHealth Initiative

Yeah, I just want to echo what you said there because I think if we can reframe it in terms of improving health and well-being then people are going to say, you know, 35 agencies are coming together to improve health and it makes a lot more sense to the public and the industry to do that.

And we don't...I just want to, you know, really emphasize the staff did a lot of hard work here and a lot of the pieces there should be retained. It's just a matter of reorganizing them and restructuring them in a way that it makes sense for the general public.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Karen?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

See who is on the phone first.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Terry Cullen.

Theresa Cullen, MD, MS – Director, Health Informatics – Veterans Health Administration

Hi, as one of the benefactors of all of your comments I'm deeply appreciative. I think that you...what you have noted is what most of the federal agencies have been in dialogue with ONC this real commitment to make sure that we are emphasizing either the triple aim or something like that that's really centered around healthcare outcomes.

I would just urge you to be generous with your understanding of how difficult it is to sometimes work in the federal space so that if you come back with very, very specific things that you want us to implement that you think about our ability to actually do that. I think the ONC staff has done an amazing job pulling the federal community together, letting us all have voices at the table and so I want to highly recommend the work they've done

And I want to appreciate your comments but I just want to temper them a little, when we talk for instance about...which I think is really true, portal fatigue, sometimes we actually have federal fatigue where it's just as difficult to try to incorporate many suggestions. So, the more pointed they can be the more helpful they can be, the more actionable they can be we welcome that. Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And FACA fatigue. Okay, Karen, would you like to say something?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Terry, this is Karen DeSalvo, thank you so much for the nod to the staff because staff not only at ONC but across the federal agencies did a tremendous job.

Here's my reflection back, first of all I just want to say thank you for the comments to the last iteration and this time again, I don't know if I've had a chance to be probably thanking you all for the thoughtful way especially shaping a couple of items that I want to spotlight.

And so, let me first say contextually that the strategic plan is designed to get us to what we used to call the triple aim and the three-part aim and now we're calling better care, smarter spending and healthier people.

The general idea is that it's about better care but something beyond that, it's about better health as well and that this requires an infrastructure that goes beyond the health care system and the set of providers that we see.

I think the framing suggestions that you make are excellent and I do believe that the elements are in there it's a matter of how we presented and framed it and we've gotten some great feedback about that.

But, I just want to underscore this notion that it was designed to be about that and it was designed to be, again about health beyond healthcare. How are we are creating a healthy space for folks including and a nod to social and other determinants.

As you all may remember we very deliberately had at the table and encouraged their participation and had separate meetings with the Administration for Children and Families, the Administration for Community Living groups that had not really in the past been a part of thinking about the Health IT framework, Department of Education, Department of Justice really did a lot of outreach and so that's...we're in sync with you all. I think it's...I hope it's a matter of language.

And I do want to just...something Christine was saying a little bit earlier and this reminds me of evolution, so Gretchen will remember, but we started this probably a year ago maybe a bit more and so much has evolved in the marketplace and in our own thinking at HHS and ONC in the past year and some of what Christine was talking about a person-centered architecture for data that there are other places that people are receiving care but also thinking through their health and that there are...there is an increasing need for that data to wrap around a person and for it not to be solely hosted by healthcare institutions and there are platforms and models evolving and I think even in the last 9-12 months there has been advancement in the marketplace.

So, we have more of that language and thinking in the interoperability roadmap, some of that is timing when we started the two projects so I think you're going to see some looping back as we reflect on what we've heard and learned and put in the interoperability roadmap that's going to go back into this strategic plan.

So...and maybe my closing comment is about how dynamic and exciting the marketplace is and so this is also a good lesson for us that there are things we want to shape and say that, sort of to Terry's point, but I think more generally we want to make sure that we're doing what we need to do to lead and set direction but also to leave enough space for the marketplace to evolve because it is increasingly consumer-centric and that is exactly where it needs to go with a nod and an eye to making sure that we're doing the most that we can to spend the dollars wisely and reinvest and where appropriate from the healthcare system and to other components of health. So, thank you guys.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Devin?

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

That was great to hear again and to read through the slides and the whole phrasing around goal four and kind of making it more consumer-centric makes sense to me. And I know Karen had talked about this in the past when she first came on and I see it listed here sort of usability is folded into there and the usability of the data in the big way and in the small way.

But I guess, you know, wearing my multiple hats and not all of them are white hats in the sense that, you know, my provider community is very...not so happy and, you know, as the data becomes more interoperable that should generally make their lives easier but the systems that go with them don't necessarily align with that and I like that we're aligning all the overall metrics and that helps me on the kind of build side when we design our overall system.

But the day-to-day experience, not just the usability, the front end user experience, but kind of what the data means for how they spend their time maybe I'm wrong but I just don't feel that in these recommendations kind of equal parity of saying, yeah the consumer experience will get better but being the provider for that experience may not and maybe it should theoretically as everything kind of gets more seamless, but I feel like sometimes we don't given enough attention to making...calling that out and I know, Paul knows this, when I talked about the provider experience in our Subgroup, but, you know, now having done this for a while I don't hear much improvement on the provider experience and I'm concerned about it.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I can say, at least in the Consumer Workgroup, we were coming at it obviously from a consumer point-of-view but it's part of what we were really trying to get at when we suggested creating this bridge goal that's about partnership because we talked specifically about...I talked more in our slides, I've spent more air time on the idea of the patient's experience in collecting and, you know, sharing their data with their provider, but, I also said, you know, we need to make it easier for the provider.

So, I mean, I think that combined with one thing that the Strategy and Innovation Workgroup said which was we're starting to move away from the construct of like this is just about the EHR. So, I think if we pull those together we could do a better job in our joint recommendations of highlighting...because I mean, I know that my Workgroup, the Consumer Workgroup does not disagree with you at all on that.

And, again, if we have that partnership then I want it easy for me and for my care team to really use and act upon and welcome that data into their role. So, I think we could probably highlight that a little bit better in our recommendations.

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

Yeah, I mean, I guess, in our conversation also it makes me think that there has to be tangible metrics of improving towards...just with the consumer experience, which I think you've done a great job advocating for, and because we've kind of built that out we're very clear, like every time, every question, how does that effect the consumer experience.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yes.

Devin M. Mann, MD, MS – Assistant Professor – Boston University School of Medicine; Attending Physician – Boston Medical Center

And I just don't feel that we give quite the same for the frontline provider experience.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I will say one more thing though I think it's the second goal, and I'll look at Gretchen, does have a whole bucket of stuff around usability for providers. So, we should, you know, we're doing sort of joint recommendation but if you think that those fall short that would be helpful to know as well, because there are a whole bunch of around usability specifically.

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Yeah, the other thing I wanted to add, Devin, is the calibration of what's the federal role in answering that question. So, there's an assumption, as Karen said, obviously the consumer marketplace is changing very rapidly and the other users marketplaces, the payers and others, the provider ironically, the provider tool marketplace is probably not changing as fast as some of the others.

So, whether there's an opportunity here, in the comments Christine just made, to send a signal which is reinforced through certification payment, something that supports innovation and improvement in the provider facing tools would be a really interesting thing to do. I think our general philosophy has been the federal role to set guardrails and pathways not to define functional requirements at the level of individual tools and products that the market will do that well if the overall goals and outcomes are properly set.

But, I think if you could help all us think about ways of the federal policy is supporting enhanced provider functionality that would be fantastic.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. Gretchen?

Gretchen Wyatt, MA – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Just a quick note to Devin's point, as Karen had mentioned a lot of goal two of course is the interoperability roadmap and while we were developing the strategic plan we knew that a lot more detail would come through the roadmap.

Now obviously the strategic plan comment period is closed but if you have specific issues that you think should be included because we are cross walking the pieces so closely, the roadmap until, what May 5th is that the last date that folks can comment, go ahead and go to healthit.gov and put in comments there. The sixth?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

It's the ISA that's out longer.

Gretchen Wyatt, MA – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

So, it's definitely another place where we can capture the information because we're sharing the comments back and forth, but if there are things that the Policy Committee should look at as far as the issues that we might want to look at in a work plan that's something that we should probably take into consideration as well.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, so I think there was fairly uniform or agreement with your four themes and a little bit of hedging on the bridge...a little bridging with the bridge versus the refrain, but an acknowledgement that we could take the body of work and just do a bit of packaging and preamble to make sure that the focus on improving health for individuals and communities.

What does the group feel about Devin's proposal about including a little bit more emphasis on the usability for providers? So, that's a mission to your final tweaks before going out to ONC.

Okay, so we do need a vote on this. I'll entertain a motion to approve?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I move that we approve the recommendations.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

This is Deven.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Great and seconded? Any further discussion? All in favor?

Multiple

Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you and any opposed or abstained? Good. Thank you for wonderful work. Thanks and then we're going to be open for public comment please before lunch.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While we wait for the operator to get ready to open the lines if there is anyone in the room that would like to make a public comment please come up to the table. As a reminder you have three minutes and please state your name and the organization that you are with and Alan if you could open up the lines?

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Well, why we wait for people to dial in if they're going to, we had originally said 12:15, so maybe we could do 1:00 o'clock we come back after lunch. Okay and it looks like we have no public comment.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Any comments then?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

No.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay...we already are...all right, so we'll adjourn for lunch and then resume at 1:00 o'clock, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So, Paul, whenever you're ready we're all set.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

All right, welcome back and in this next session what we're going to do is preview a little bit of the work that's going on with the various Workgroups and preparing their responses to the interoperability roadmap which is going to be delivered next month. So, the first group that's going is the Advance Health Models and Meaningful Use Workgroup that Joe Kimura and I and Chair. And next slide, please. And the charge...pardon me?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Are you going to go sit over there?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

No, Michelle said I can't.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

There is not enough room, we don't want you to be so tight, but I guess you could break it up but we thought, it's up to you Paul we could do everybody up there for 10 minutes.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

I think you should go sit over there.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And I can stare him down.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Better, Karen?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

We appreciate the opportunity to look directly at you to share this information with us.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. As I was saying, the charge to the Workgroup was to develop a repeatable process of prioritizing use cases. So we were given Appendix H which is a collection of use cases that were donated by the federal agencies and the public and there were 56 of them and so ONC asked us to come up with a process to prioritize that and identify the set of actors.

So just to overview the use case itself, so what's a use case, that's a job that's to be done by a set of actors interacting with each other within a defined boundary, so that's what a use case is. And it is also used to articulate as exemplars key problems to solve, key jobs that have to be done so that all of us in the public can understand what is the problem solved, what's trying to be accomplished and you can identify key functional requirements from that.

What would you do with those functional requirements? They'd be used to inform priorities development of technical standards, policies and implementation specifications. So that's the goal.

So, if you look at those use cases proposed...submitted use cases the 56 of them we figured that they would fall in this map that you see before us the axis are impact and readiness and you may find some low hanging fruit in the upper right corner where you have high impact and ready for a change. The market may have either solved it or if they haven't then the federal government could step in or government can step in and help facilitate movement towards that high impact direction.

Alternatively, you may have high impact things where the market is not ready for it, it could be a lack of standards, it could be a lack of willingness, etcetera and those create gaps from where we are to where we want to be and that would be another area where the government could step in and help push things along either with a carrot or with a stick.

So, we developed a process or this is our process for your comment that sort of mimics a grant review process let's say in NIH. So the first step is to figure out whether something is scientifically or technically valid, you look at the proposal itself, you look at the folks who are conducting the research, etcetera and that comes up with a score of saying, how scientifically valid is this proposal. That doesn't mean you to have a guaranteed shoe in, in terms of being, in our case, a high priority use case.

The next step to evaluate it is, how does it address the programmatic needs? HHS on behalf of the country has a set of programs that it is working on and how did these use cases fit with those programs.

The next step is to look at the operational readiness that helps us determine the timing of the high priority cases and finally you need to understand who the beneficiaries are.

So, at the end of this process we're looking for a process that ONC or HHS can use over and over again as it looks at programs and comes up with use cases to prioritize which ones are the first to work on for example.

So the first step, let me go into a little bit more detail is the impact and this is a must pass kind of step. So, we're looking at the triple aim that was mentioned earlier this morning, how does this use case address the triple aim.

So, we look at it and score this use case proposal for each of the triple aim elements on a scale from 1 to 3. So the max score would be 9. You have to pass this if you don't score well here then you don't go onto the next stage.

The next stage is, programmatic considerations that is there are number of programs in play right now, for example the National Quality Strategy has these six components, safety, patient experience, patient engagement, care coordination, prevention, community and affordability. How does the use case incorporate those high priority strategies as determined by the Secretary?

Another one is what was mentioned earlier and Karen is going to talk more about is the health delivery, the delivery system reform, the notion that we're going to be moving to 30% by the end of 2016 and 50% by the end of 2018 and alternative payment models is a big driver. How does the use case incorporate those milestones? How can you incorporate those milestones into this use case?

And finally, let's say the ONC interoperability roadmap has 3, 6 and 10 year goals can the use case be used, employed to help drive the plans in that roadmap. So, for each of these we're going to rate them 0 +1 and +2.

The next stage has to do with readiness. Here we're looking for some kind of assessment of how ready, what's the timeliness, how soon can we move toward the goals that are exemplified in a particular use case. We're looking at business and cultural environment, is there a business case for this use case to be advanced, are there technical impediments like lack of standards or you have to change the architecture of all the systems, what are the cost benefits for each stakeholder those certainly either get in the way of or enable moving towards the goal exemplified by use case or the policy environment we talked about privacy and security this morning. A lot of these factors can affect the readiness of the overall market to adopt or incorporate, or build up something...build up a particular use exemplified by the use case. And here we're scoring from 0 to +2 as well.

And finally I wanted to make sure that all the stakeholders are taken into account. The six you see there need to...we need to make sure that the compliment of use cases do cover all of those stakeholders.

Finally, we end up with our repeatable process that is part of our recommendation and the way we've applied it to Appendix H to show how well it works or not.

So just as an example what we've done so far is try to get through stage 1, the must pass step, so we took the 56 and we ended up scoring them so through a multi-building procedure we ended up with 17, so we reduced from 56 to 17 and got a third remaining.

And we looked at their score in terms of the triple aim. So you see before you one of the proposed use cases that's still amongst the 17 is that authorized providers, caregivers and population stakeholders, population health stakeholders have access to all the information they need in order to measure and manage population's health. It scored 8.86 out of a total of 9. So clearly this is a high impact proposed use case.

So, where we are is, as I've said we've distilled the 56, we've narrowed it down to 17, our next step is to take a third of those, so for a handful of them to consolidate some of the proposals into comprehensive use cases, which fulfill all the criteria, it is a use case, it's focused on interoperability and is representative of a number of domains that address a number of stakeholders.

Then we're going to take those five or seven let's say and then fill out the rest of the matrix so that we understand how it stacks up with readiness, the beneficiaries and the programmatic fit. And that's what we're in the process of doing and will end up with a handful of use cases we're going to present to you next month with our scoring system. And open to any questions before moving on?

David Kates – Director Interoperability – The Advisory Board Company

Any questions for Paul? Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thanks a lot. So, as we think about use cases and the criteria that you have laid down which seems very, very logical but one of the things that comes to mind is that when we think of the criteria like business case today or the policy environment, etcetera it is still thinking of the current system and how the current system operates and if we think of what will be use cases that will be disruptive in nature then just by being disruptive that means that there isn't necessarily a policy environment for that or there isn't a strong business case for them today.

So, how do we make sure that we are also testing use cases that can be disruptive that can change the way so we are not just strengthening the inefficiencies of the current system by only looking at use cases that work in the current system?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good question that's why we have this must pass up front. So, the impact, the triple aim impact is the defining gateway before it goes on down the path. So we would pick up things that are promoting health in ways that we wouldn't have seen when we just focus on healthcare for example.

So once it passes that gateway then the other factors are modifying factors, so the ones that you mentioned are in the realm of readiness and if there's a poor business case or there's a lack of standards that will certainly get in the way of the timing how quickly can we get from where we are to where we need to go but it will also call out where does the federal government, as an example, one of the actors, where can they play a role in overcoming some of the barriers. So, that's how we plan to use it and it's for that reason that we have the first gate only be the triple aim.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

This is really helpful, Paul, thank you it's really good. I had a question I was trying to think about how or whether this evaluation could help to prioritize high impact, high leverage kinds of use cases and that took me also to thinking about beneficiaries.

The way that I understood it, it sort of seemed like, you know, patients, consumers equal footing with providers everybody is kind of on equal footing and everybody is a one-to-one whereas I think there are some use cases that might benefit only a segment of one population, so, you know, only people with diabetes or only cardiologist, or whatever.

So, I'm trying to understand a little bit more about is that piece of it and then if there's a way that it might really identify high leverage pieces. I was thinking about view, download and transmit because that's such an interesting not a huge lift technologically but really potentially high impact so how can we get that through with a broad impact on many, many both providers and consumers. Does that make sense?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes, it does. I'd go back to the first gate which is the impact on the triple aim. I would say of any of these stakeholders the consumer/patient probably has the most priority there because the healthcare and affordability really goes to the individual consuming the care or relating to the care system.

When we talked about beneficiaries, that fourth step, it's not to say they're equally weighted we just want to make sure there's balance, for example we haven't left off researcher, so it's almost a check mark at the end of the process to make sure, do we have a balanced set of high priority use cases that would exercise the system to these exemplars. So, it wasn't meant to be co-equal.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Very good, thank you Paul I really appreciate the update and appreciate the work of the Workgroup. Christine I think you're next. We're getting a lot of your time today, thank you.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay, so interestingly there's an old adage in Washington and it says he who comes to meeting with the most pieces of paper wins and in my experience it is almost always true but in this case we, as a Consumer Workgroup, are not to that point, so I actually don't even have slides for you today so this is kind of exciting.

What we wanted to do was just to give you an early preview into how we are approaching the interoperability roadmap, some of the early issues that we've identified and welcome your feedback on those as well. I do have a large stack of actual paper in front of me so I'm hoping that kind of bodes well for our future.

So in terms of the process, where we are at, we actually started before the version one of the roadmap was released. We started by doing a briefing on open APIs. The Workgroups felt that we weren't fully up-to-speed on those issues and we wanted to understand them better given that there's been so much talk about them recently particularly in our Joint Policy and Standards Committee's meeting. So, we started there, that was a terrific briefing.

And then we've had one conference call since the roadmap was released and we've been assigned Section C section D. Section C is more consumer and Section D is more provider. So those are the comments that we're going to look at.

We've been asked to look not just from a consumer perspective but also from a provider perspective particularly with respect to Section D. We do have about four physicians on the Consumer Workgroup and I think we also have a nurse as well so we've got an interesting base there.

And we're doing two more calls including the first tomorrow to go through section by section so that's where we are at.

Our first kind of glance particularly looking at Section C, which is on consumers, we had a lot of robust discussion about the role of the consumer and harkening back to our conversation this morning looking at consumers as aggregators of data and how we're beginning to share that data, how we're beginning to make it usable for providers to act on that data that's a big construct and I think, Karen I was really happy to hear you say this morning that you guys...you're thinking it's evolved because the construct of the roadmap in this regard is really focused on asking consumers to demand their health information.

And the Workgroup felt like that didn't make a lot of sense anymore, that (a) that's a right we have under HIPAA and (b) it's not about demanding and sort of trying to force the, you know, providers to give us our data that construct hasn't really been effective in the past and I think the Workgroup is confident it's not going to really work going forward.

Much like we commented on the federal Health IT strategic plan this is really about partnership and how we at the same time are on two parallel and very connected tracks which is opening up access to data and giving consumers usable tools so that they can act on that information, but also creating a culture in the healthcare system that embraces that role for consumers that recognizes consumers as an essential source not just sort of a valuable source of data but really an essential source of data since I'm really one present at all my encounters, right, and that is probably moving beyond the fairly limited construct of patient generated health data where we were thinking of, even last year when we did some really good work on this, but we were thinking about, you know, wearables and data that I'm contributing as a consumer as opposed to data that I'm now actually pulling together that's coming out of the system but it's also coming from me and so it's a larger construct that I think we're looking at and so how we shift and incentivize and support the system in that kind of a construct is a key point that I think we will do a lot of work on.

To that end it makes us think about whether Section C and D should be as separate as they are because they don't reflect true partnership and there are pieces that live in one that are either redundant to the other which makes it both feel a little bit overwhelming for people and I think particularly for providers or there are pieces that are missing from one.

You know we have this explicit call for example for providers to be engaged in governing interoperability initiatives but we don't say the same thing explicitly in the consumer section. And we know that's not the intention, we know that doesn't make sense but it's again I think sort of an artifact of having these two separate sections that I'm not sure really in the end should actually be so separate.

They are very clearly actions that belong in the provider or the vendor sphere, no question, but again, how we really forge that partnership is going to be the question. I think you'll also hear from us in some other areas looking at the common, the core clinical data set, I think there are some comments we have around the data from a consumer perspective that has been proposed to live in that set.

We also have some comments around so now we have consumers, you know, coming into this role as data aggregators if you will we're going to see a lot of errors in the record that we know aren't right and so...and we had these discussions in the Meaningful Use Workgroup, you know, last year and the year before.

We have a right to request corrections and amendments but how do we make that technologically easy for me as a consumer to mark areas so that my care team and individuals can really see, oh, the consumer is saying this is not actually accurate. We're going to see a lot more of that and I'm not sure we paid quite enough attention there.

And then finally, there are a lot of things that I think we were happy to see in the interoperability roadmap that also reflected our comments in the federal strategic plan, so a larger emphasis on digital health literacy was one, a larger focus on care planning and so I think we will talk a little bit about how to make that a person-centered planning process that is more whole person oriented, so if you look at the work really fabulous work that's been done in the disabilities community, they don't call it care planning they call it a person-centered planning process because it's not just about my care it's about my health but it's also about connecting to community supports, etcetera.

So, how we can look at that as a use case, I think by the way there is some real interest in the Consumer Group at looking at the appendix of use cases and kind of flagging some that they think are high-priority but really looking at the planning process as an incredible opportunity to bring together a lot of the elements of the strategic plan with the interoperability roadmap in one place that has...is I think a high leverage high impact spot for both providers and consumers but also payers is a really promising area that the group has a lot of interest in.

And then really there's a lot of support and liking the fact that there are some partnership-based strategies in the roadmap that really are about recognizing the value of consumers as a data source but also at the same time again making that easier for providers to upload and ingest and act upon.

We'll make some comments of course on timing issues there are some things for example in the 6 year time window that call for providers to support view, download, transmit and consumer-facing Health IT initiatives like online scheduling or medication refills but a lot of that is happening in the market today and it is such a fundamental key toward improving digital health literacy and really engaging patients, families and caregivers in their own healthcare data that we felt like that such a gateway we need to have that, you know, a lot sooner to have some emphasis on that a lot sooner. So with that I'd be happy to take questions or hear your feedback.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thanks, Christine. David Lansky?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Thank you Christine, a lot of real interesting issues there. I wanted to kind of reflect that we've come a really long way in our thinking about the overall paradigm for health information and the things you're talking about are very exciting and very apt to the market we're in.

I'm also struck that we sometimes have a tendency to go from one fix solution to another fix solution and in fact the world is going to be very pluralistic for a long time. Some consumers at some point in their life of will be very active and strong managers of their data. Some will be very dependent or not interested or not capable. And each of us as an individual may migrate from one role to another depending on our own state of health and consciousness and whatever.

So it seems like we have to anticipate, rather than picturing a fixed architecture and fixed roles for provider or the consumer as the custodian or the owner, a more dynamic situation. And then the challenge for us is to think about the guardrails and ground rules that are strong enough to accommodate that fluidity but not prescriptive about how each of us has to be or telling consumers you have to play a certain role or you can't play a certain role and similarly to providers.

So, it raises the issue that was briefly mentioned this morning with Deven's comment about co-ownership of the record and somehow making a list of all the features and characteristics of this ecosystem whether it's the co-ownership or the patient identifier, or the role of security in the cloud, etcetera that we have to solve for in this new environment and it's a much more difficult environment than we had in EHR in an office and was relatively confined and we could talk about sharing...sending a Direct message from one EHR to another with a much simpler environment to plan for.

But I'm wondering if we should start thinking about the table of contents if you like of the rulebook that we have to begin to populate and I know governance is a topic we keep coming back to which is very important in this context of fluid data control but I think it's exactly where we need to go and what we have to solve for going forward.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I think that's very insightful. I agree completely on two fronts and one I would say that I think the roadmap does...because it has very specific call to action, you should do this on his timeframe, which is really what we need to be to be able to sink our teeth into. I think it has real potential to be the table of contents.

I do think that there is a great parsimony that's needed as well. And I think your suggestion that one source of parsimony could be in fact this sort of is this about...does this reflect the dynamic nature of roles and does it accommodate what will happen and change because I agree with you, you know, last year we were thinking about patient generated health data in this way and, you know, now we're like, what are you kidding me. So, I think that's going to continue to happen.

I would just say a couple of other things, one is I think again this notion of partnership does reflect that back-and-forth and more of that fluidity and so the more we can use that as a lens I think the better off we will be.

I also think we have to think about designing the system for our most challenging circumstances, so if we think about vulnerable populations and what their pathway is, if we make the system work for them I feel like it can work for everybody and so I think that's another lens through which we need to look at this and certainly the Consumer Workgroup was thinking that way as well.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Anyone else? Thank you, Christine.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay and then Chris Lehmann and Micky Tripathi Co-Chair of the Interoperability and HIE Workgroup.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Micky should be on the phone.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes, I'm here.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

All right, good afternoon, we'll be representing the discussions of the Interoperability and Health Information Exchange Workgroup. First I would, as usual, thank the ONC staff, Michele and Kory, for getting us organized and situated. As you know our roadmap sections that we were asked to comment on focus on the accurate identity matching and the reliable resource location.

So we had obviously the general questions that were given to us, you know, is this according to the overall goals of interoperability nationwide and how can we use this to work toward a learning health systems in the long-term. And we had some specific section questions in which way does the draft approach needs to be adjusted to address the industry needs and the current barriers.

So far where we are is we had our first discussions and meetings. We discussed overall what was really asked of us and tried to specify questions a little bit more by March 3rd our members were supposed to send us draft comments and that was really only pertaining to the patient matching sections and what I will present to you today are some preliminary findings from this and I suspect there will be more discussions and some change. And Micky if at any point you want to jump in and add something feel free.

So, this is where we are today presenting the first themes. So in general the working group recognized that there is an incredible importance in accurate identity matching and reliable resource location as the roadmap category, however, there was some concerns about the timeframe specifically.

There were a total of 36 critical items in those two categories alone 20 of which were in that 2015 to 2017 timeframe and overall the group felt that while there's a need to work on those issues and focus on further pushing these items that this is actually more...these items are more into development in the 2015 timeframe and not necessarily can be expected to be actually implement until later.

There were a number of comments reinforcing the fact that the roadmap should really pose a floor to interoperability and not ultimately a ceiling. That there is a desire to exceed what is in the roadmap but that what we are having here is a common denominator to serve as a basis and ceiling for this.

So, there were a lot of questions and this slide kind of beats on one topic. There were a lot of questions about the term "coordinated governance" the questions were raised, what the governance process really was supposed to constitute and supposed to deliver and to be what it's supposed to look like. Half of the critical action items were dependent on policy and operational functions that were supposed to be driven by coordinated governance, which as I said, was not well defined. So as a result of that there was really no ability by the Workgroup to comment on the levers and incentives because it was unclear and undefined at this point to the working group and I'm pretty sure there will be more information on that topic forward. I'm starting to realize that I probably need a new set of glasses because these slides are terribly far away.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Chris?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Yes.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Chris, this is Micky, so the only other point I would make to that is not, you know, we're certainly not trying to be overly critical or negative about the need for, you know, some type of governance and certainly for the reasons for putting that in there as an important, you know, sort of piece of the overall picture and an important driver of how we might, you know, foresee nationwide interoperability unfolding.

I think the real concern among the Workgroup members was just because it was undefined as one Workgroup member said, you know, I could wholeheartedly agree with some of these things under one definition of coordinated governance or wholeheartedly disagree with a number of these things depending on the definition of coordinated governance. So, I think that, you know, one of the things that we'll be doing is diving down into that in asking ONC for some more detail on that.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you, Micky. So, in our call last week we put some preliminary thoughts together on the accurate identity matching and the next couple of slides are pertaining to that.

First the thoughts were voiced that technical standards are necessary but not sufficient that there is a requirement for a combination for both technical standards and aligned business processes and strategies. There clearly was the notion that there is benefit to developing a minimum data set, minimum set of data for identifying and matching patients.

Certification could ensure that EHR technology is capable of capturing, storing and providing that minimum dataset, however, there was some thought in the group that it should not restrict approaches only to the set and that not every transaction might actually need the whole minimum set especially if data is frequently not available or there is insufficient quality.

There is the notion that the working group will make some recommendation of the minimum data set for the next meeting. Then there clearly was a lot of discussion about existing best practices.

So the work that was done on the standards and interoperability framework and then specific transaction areas, one topic that came up was prescription drug management systems that have developed technology to match patients and provide accurate identity so that we should look at some of these systems and share best practices and lessons learned.

And there was a discussion about the need for looking at locally driven data governance such as data sharing agreements that already exist and motivate the use of the minimum dataset and address technical issues requiring those so the notion of a lot of local variation and clinical and business practices that might be deviation from other areas and making a single national approach difficult, a discussion on data assurance, the quality of the data and the source of truth for the data were had as well, discussions on voluntary data elements that are highly dynamic and dependent on local capabilities also were brought up as potential challenges as well as clinical business and legal accountability, who is responsible for what, who ultimately takes responsibility for the match and says this is Patient X and I stand by this.

Further discussion included also that patient matching by itself actually might not be sufficient and Micky you might want to comment on that but the notion of developing record location services based on identity matching that makes the data available and allows people to identify not just the matching patient but where the data is stored and can be shared are things that are possibly very desirable and might be included in this overall plan. And Micky, do you want to add something to that?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

No. I would just, you know, say that this came out as an extension of the patient matching conversation. So I think the notion was that if we're just talking about, you know, like an EMPI enterprise, you know, patient matching like happens today, that that's one thing and that's great, but, you know, if we think about what the next service extension beyond that might be that seems to have some value because already there are a number of networks that are embarked on providing these kind of services.

The idea of record location following on that so that I could initiate a query for Christopher Lehmann let's say and know where his records are doesn't mean it brings the data together but the next step of being able to match the identities that exist at each of those entities and then be able to provide back to the inquirer under, you know, appropriate use and authorization of course where those records are might be you know something that ought to be called out in the roadmap as something that might be valuable. And it was just a gap that didn't appear in the roadmap. The roadmap talked about accurate identity matching and then talked about resource location but didn't talk about record location.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

It makes a big complex problem even bigger. So and then next steps include that we will finish the discussion on accurate identity matching, finalize comments then turn onto the reliable resource location, develop a consensus and have comments and then present back here at this committee.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Questions or comments from the committee? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Thank you Chris and Micky. I have one small comment and a couple of questions. My comment is Chris you said something about glasses, as an alternative I was going to recommend larger fonts and fewer words on the page would be another way to approach the same issue, this is just an observation from the software guy.

So the questions I have is under accurate identity matching your preliminary thoughts, you have this bullet Workgroup will make recommendation on minimum data set for next meeting and you talked a lot about certification but my question is haven't we already done that?

I mean it seems to me in the certification process we do have standards already set for all this demographic data and it exist in implementation guides for all kinds of interfaces so hasn't this already been done?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

So, I think a lot of the work is indeed, thank you for the question Paul, I think a lot of the work is already in a state where we can pull it together just for the patient identity matching.

What we are talking about here is just focus on the identity matching and I think reusing the work that has been done to look at minimum datasets, etcetera is obviously clearly something that will be valuable and useful. Micky do want to add something to that?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yeah, I would just say, I mean, the roadmap itself does identify...you know, speaks to the importance of a minimum dataset and does identify...for accurate identity matching and does propose a set, a minimum dataset for accurate identity matching. So, you know, we feel like we should comment on that and make a recommendation based on that whether all of those map to all of the structured demographic fields that are a part of certification I suspect that they probably do but we'll go through that exercise and point out any that don't.

Paul Egerman – Businessman/Software Entrepreneur

Terrific and thank you for that answer Micky because it seems to me we don't want to accidentally duplicate things. I mean, we've already defined date-of-birth for example and we don't need to do a new certification on it...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And if you do it's actually harmful because there is something else people have to attest to and there is a small probability of accidentally making it a little bit different than the last one and so that would be my observation there. And then my second question is on page eight you talk about voluntary data elements. I just didn't understand what that meant. I mean, what's a voluntary data element?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

So, in this case the discussion that was had in the group is that in addition to the minimum data set that people might choose to add additional data elements to help in the accuracy of their patient matching so that's voluntary outside the minimum set that's what it means.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yeah and just to add to that, the roadmap does have, you know, some...I forget exactly how was framed but there was some critical action steps related to how voluntary data elements beyond the minimum dataset might be treated so that's what's we're responding to.

Paul Egerman – Businessman/Software Entrepreneur

Okay, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you. Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you for the presentation. My question is related to identity matching and just the process by which for instance a traditional EMPI or RLS type services that, you know, HIEs kind of develop, how is the Workgroup taking input from some of the new innovations in this field for instance in the New Orleans and also in Chicago for a clinical data research network we have been working on these global patient IDs where the PHI does not leave the data warehouses of the health systems yet you can, you know, create a centralized kind of recognition system so that you can identify patients using some, you know, hash and other algorithms.

So are you relying mostly on members of the Workgroup for input on this or would you also be going outside the Workgroup to get input on some of the new innovations in responding to these questions?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

So I think that...thank you for the question the answer to your question to date we have only relied on the members of the Workgroup.

But I think your point is well taken that, you know, in order to have input on newer technologies maybe more elegant solutions, it's not an unreasonable thing obviously to look outside and one of the points that we had in there was that we need to look at people who have done this well like prescription drug monitoring and I think your example is a good one to include as well.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yeah, and right, and I would just add, remember this is addressing the roadmap, which is, you know, a high-level policy document essentially articulating a roadmap over the next 10 years so that's really the level of abstraction that we're at as well.

And then with the further caveat that we are a Workgroup of the Policy Committee so, you know, we would never expect to be diving down into evaluating different technological approaches to things but really looking at, from a policy perspective, how do we think about, you know, standards and technology.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Any other? All right, thank you Chris and Micky.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And finally we're going to hear from the Privacy and Security Workgroup it's nice to see Deven and Stan back up.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

We're going slide less for this presentation as well. I was told there would be no slides, mostly because again we're at the very early stages of our consideration of the roadmap, in fact we had one call with the Workgroup on the topic and we probably spent most of it just going over what was in the roadmap because most of them hadn't had a chance to read it yet, which means we have one call scheduled to try to get to the point of some recommendations, which means that Stan and I have to do some work to sort of provide a some straw recommendations for them to consider to the various questions that have specifically been asked in our particular categories of the roadmap.

And because the Workgroup really hasn't had a chance to give much feedback on that, I'm going to give you some indication of the directions we're heading and we'd love to get some feedback on that but we'll, you know, our next Workgroup call which is actually next Monday, we'll be able to vet these more thoroughly within the Workgroup.

So, we are going to...we have some very specific questions to answer in Sections G and H of the roadmap and I'm going to invert the order and you'll understand why in a second.

So Section H deals with consistent representation of authorization to access health information and this issue of authorization has come up before the Policy Committee before we took it on when we took on the issue of querying for patient records and what's sort of reasonable and sort of assuming that an entity who is asking you for a patient record actually has the authority to get that record.

And the authority comes from legal authority to get it, just for example it's a treatment relationship and a physician is asking for the information in order to treat the patient under HIPAA or there is a consent from the patient that says, you know, I want...the patient would like the data to come to this particular provider or be sent to this particular App. So, authorization is really a general term about sort of are you allowed to get this and under what circumstance.

Now Section G is actually about permissions from the subject of the data, the patient, to exchange the data which is just one category of authorization. So we are flipping our consideration of that because authorization to access the data is a bigger topic and permissions is just one piece of that but those are the two sort of general areas where a series of questions are asked and that's where we're going to focus.

One of the things that came up during the Policy Committee's first discussion of the roadmap and also came up on our Workgroup was some confusion about some of the phrasing in the interoperability roadmap around basic legal authorization to access a record versus what the roadmap calls basic choice which is like your "opt in" or your "opt out" not always instantiated as a matter of law but sometimes just about what a health information organization or health information exchange might provide as a different measure of trust for a patient, you know, your data won't be exchanged in this HIE or accessible through it unless you opt in or you opt out it's usually on that sort of very basic level of all in or all out versus more granular choice which is the type of choice that's provided that's much more narrow it's based on specific type of data. It's based on type of provider.

And one of the things that was very confusing for a lot of folks is that in some parts of the work plan it seemed to suggest that the direction where the roadmap was heading was towards basic choice, towards maybe even requiring basic choice and having some technological means to put that forward.

In one part of the work plan there's language that says, well, you know, the legal authority to exchange data is what you rely on if you don't have basic choice in place which suggests that the default is opt in or opt out and then you just rely on law when there's silence versus another way of looking at it would be well the legal framework applies and in some cases people do have some choices that are at this basic opt in and opt out level and when those choices are present how do we make sure that those choices get honored.

So it seems to be, at least preliminarily, an interest in having some overarching comments that ask ONC to be sort of very clear about the environment that their approaching and how much is the roadmap responding to existing circumstances versus signaling directional change from a policy stand-point.

We got a much greater degree of clarity from staff when we talked with them about this during one of our Workgroup calls in terms of sort of recognizing that existing law, HIPAA in particular, when you don't have any additional legal requirements or voluntarily added choices on top of that, allows exchange without necessarily having to get some sort of specific permission from the patient.

But certainly when you have a basic choice type of situation when it's offered to individuals ideally that would be offered in some way that has some standardization across the marketplace so that if you do have a basic choice being offered to someone it's able to be communicated and it's able to be recognized by systems on both points of the exchange where it's relevant.

And then certainly with respect to the more granular environment in the state law the idea that the state laws are very different in their wording but somewhat similar in their approach and is there a way to get some harmonization nationally to enable some standardization with respect to how those choices are represented in an exchange environment and that being a bit more clear in the next iteration of the roadmap would make...would be helpful in terms of sort of the direction that this is heading.

You know another possible statement that we might put before you as a recommendation in the future is to again...acknowledge the fact that policy debates about control over patient records and how much choice the patient should have are number one very contextual, number two, are ongoing and will probably continue to persist as technology evolves and as circumstances change and cultural changes that take place in terms of how much control people want to have over their data and we shouldn't be using the roadmap as a vehicle for policy change but to instead recognize a set of conditions that exist and how do we enable interoperability within that sphere while working, you know, where policy harmonization is desirable over some period of time we can lay down the groundwork for that. So those are really some overarching comments that we're sort of the continuing to discuss.

In terms of the issue of consistent representation of authorization now this is not consistent representation of consent necessarily but how do you know that the person asking you for a patient's data is in fact authorized to get it. And there, you know, are a lot of sort of specific questions that we've been asked here including questions about sort of role-based access. Does the requester even have the right role to be asking for the data and how do you know that the legal authority for the requester to get the data actually exists.

And on some level we had started to provide some answers to this as a committee in that query discussion that we had, oh, probably more than a year ago, about how do you know that a treatment relationship either exists or is going to exist and are there technological ways to present that in some systems, are there other assurances or mechanisms that a record holding provider who is considering whether or not to release or not that they can rely on in order to go ahead and release the information, can some of this be built into the technology so that those decisions are not necessarily made by a human but are appropriately vetted by the machine.

And I think one of the directions that we seem to be heading is in trying to understand a little bit more about what are the common obstacles out there that prevent the easy flow of information from point-to-point that are not about identity, right, let's say you have enough assurance that the person on the other end of that query is in fact Dr. Tang, but you don't know if Dr. Tang actually is treating this patient, you know, how do you...what kind of assurances are all right and in some respects it may be a matter of law and getting some clarity from regulators around what is the sort of acceptable set of behaviors to engage in in order to trust and rely that whether it's an attestation, whether it's an HIE formal agreement that nobody's allowed to ask for the information unless it's for a certain purpose, is there one-size-fits-all, is there more than one way to demonstrate this authentication and what are the common roadblocks that come up can we categorize those in a way that we could say to the regulators who are potentially in a position to provide more guidance out there so that people know what they should do in order to not be on the wrong side of the law, what are the circumstances where we need some more clarity?

So that's sort of one area that we're going in, you know, clearly with state law as well, it's not just a federal regulatory clarification it's helpful also to have state law clarity and particularly where there is an issue of consent which we'll get to in just a minute.

On the role-based access question, this is definitely one that has some of us scratching our heads because typically, the function of assigning roles to be able to access information in a system are internal to an organization and essentially an exchange today where it's happening we don't ask the disclosing provider to determine whether the query that's coming in is coming from an individual person who is in the right role to be able to access the information, they are organization to organizational handshakes and we count on those organizations to have appropriate role-based access mechanisms in place to make sure that the information gets routed to the right people and to the people who have the right to see that information.

So, you know, at this stage I know absent additional input from all of you and the stage of the Workgroup we sort of wonder whether the concerns about role-based access at an interoperability among organizations level is a red herring concern as long as we have laws that require organizations to be able to set rule-based access controls which we do.

So, then on the permissions, consistent representation of permissions recognizing that there are different legal requirements across the states but there's a strong desire to have some consistent way of persisting an individual's permission to collect and share data.

You know we are...Stan and I have put before the group a general agreement with asking the states or convening the states and getting the states together to see if there's a way to harmonize the content of these laws so that there is a way to build in some standardization with respect to how permissions get both collected and stored and then appropriately transmitted so that where you do have a legal requirement to collect an individual's authorization or consent to share data, you've done so and it's in a way that can be recognized across multiple systems because there could be multiple jurisdictions where these permissions are required.

But that also gets to the issue of persistence of consent and it's another one where I'm looking forward to further Workgroup conversation on this. So persistence means that the consent sort of follows the data, right, across entity to entity to entity, across state lines and with the exception of the federal substance abuse rules, Part 2, which do actually persist with the data if you're a substance abuse treatment provider covered by Part 2 and you're sharing substance abuse treatment information that's identifiable to the patient, you need to get that patient's authorization and that's good for one transfer.

Then where the data subsequently goes, if it wants...if the receiving provider wants to re-disclose it they have to also get the patient's authorization and so on, and so on, and so on, and on down the line. So the need for that authorization persists across multiple entities and we've had a discussion with the Policy Committee on this in our data segmentation for privacy work and lots of good suggestions came out about, you know, is there room to tweak the policies so that patients could have a consent at the front end that went across multiple treating providers and that's really going to be up to the Substance Abuse and Mental Health Services Administration to broker.

But absent a situation where the legal authority persists to require consent, persists with the data, most of the time the need to persist that consent depends on whether the recipient provider is going to further need consent in order to either act on or re-disclose that information. Otherwise, you've sort of got consent attached to data it goes across to another provider who may not have a legal obligation to get further consent when they re-disclose it.

So, the fact that this consent persists does that then put the receiving provider on notice that they, even without the legal obligation, have to abide by what's in the consent? And then if you have persistent consents does the absence of it suggest that you don't have the legal authority to share it.

So I think persistence, given the legal environment that we are facing with the patchwork of laws consent required in some circumstances, consent not required in others, creates I think a lot of confusion around what the role of persisting consents is with, you know, sort of repeated sharing of data downstream as opposed to can we cover the ability to get data from point A to point B in a regime where it can't move without consent and we can't make guarantees to a patient about what that means for downstream or subsequent use and it's going to depend on what the legal regime is in the hands of the recipient provider, that's essentially what it says in your HIPAA notice of privacy practices, which is that wherever this data is shared we can't guarantee that the same, you know, condition...we have rules that we have to abide by, we being, you know, if you're a covered entity, but once this data is shared, you know, how your data is handled by that subsequent entity may be sort of up to a different set of standards and rules.

So, I think that is...those are the sets of sort of considerations that we are weighing and we're trying very hard to sort of stick to the specific questions that we were asked because we're a little bit worried if we don't we'll run out of time to even address those but hopefully there will be a set of recommendations that the Policy Committee...that fits within sort of other issues that some of the other working groups are working on so it will be helpful. Stan did I leave anything out?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

No, I was following along as you were talking and you nailed it.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good, thank you very much. Karen?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

So, I want to thank Deven and Stan and their team for today and in advance, I didn't have a chance to thank you all for your presentation earlier.

A lot of thoughtful comments during the time that you presented about the strategic plan some key barriers that we face in the country in privacy and security and I appreciate also in that space of y'all thinking a lot more about the security and I would encourage you to do that in this document as well.

And maybe just make a couple caveats, one thing before I forget, I did want this committee to know that Erica Galvez is listening, she's in Chicago and I've been e-mailing with her to make sure there's nothing that she wanted me to raise and she feels that folks have been covering things well.

Just a comment about context and we do think that there's opportunity for more precision in this section and so we're looking forward to having the chance to work with you guys on that and Lucia, as I think you all know, is away today.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

So, she's...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I think she's listening.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

She maybe on the phone also...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

She's on the phone.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

I don't know why she should be on vacation, but she's a dedicated public servant. So, it's a great frame and I think moving forward it will be great to have some additional feedback, always learning from our history but remembering that the world is changing fast.

Here's just a comment for all the Workgroups, including this one, you mentioned it when you started the conversation Deven which is to say we live in a legal and regulatory framework that is today and we have a fair amount of discussion in thought of ONC and the federal government about what if the world changes and y'all were touching on this earlier about big data, etcetera.

But the world, if it does change, is going to be some time and so as we're thinking about the next three years to get data unlocked what are the conditions in which we are functioning right now and though we all I think have a sense of a broader vision where health is more than getting people to a doctor or keeping them from a doctor however you might phrase it that there's a lot of need right now to move healthcare data so considering that environment and that charge with an eye on two other things or related things.

One is what does happen as a world continues to evolve not just technologically but from a policy and payment and other stand-points. So, is what we're laying out today going to prepare us for a world in which there is a person-centered data model one in which a person really does control their data in ways that Christine was so well describing earlier today and what happens if things do evolve and you mentioned some of the policy areas that have been under scrutiny like the substance abuse sharing of data, etcetera.

And so there are some, you know, I think that there is a desire on our part for you all to comment on the 3 year timeline so that we are clear about what we can and should get done by when, but also if you have time to think about if the world were to evolve these kind of things would get easier or, you know, this might help shape a future of privacy and security that would make more sense.

And I'm thinking of a couple areas that we're interested in working like the harmonization of state laws you mentioned 42 CFR and maybe some of the other opportunities around some better consent models.

So, a little dreaming is what I'm asking, be practical, we all need to be practical but a little bit of dreaming because you all have spent a lot of time thinking about it and that would be very helpful. Thank you.

Deven McGraw, JD, MPH, LL.M. – Partner – Manatt, Phelps & Phillips, LLP

Thank you very much. I also want to say that we've been very well supported by staff in this endeavor it's been enormously helpful. So, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Chris?

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Thank you, this was again a fascinating presentation and my question actually to you is going back to the gnarly problem of establishing treatment relationships and role-based access. At a previous employer, we had an electronic health record that allowed people to look at the audit trail and one day I discovered a pediatric attending had looked at my medical record and obviously that raised a flag for me and resulted in an investigation and my question to you is, have...and it goes along with what Karen says, you know, make the patient the center of the data model but also the patient is somewhat of a steward of the data.

Have you thought about the potential of allowing audit trails to be seen by patients as a way and means to establish treatment relationships. Now at that point somebody is going to fall down in the well but nonetheless you can at least close this problem for the future to come.

So the ability of using audit trails and crowdsourcing of patients as one means of addressing the patient provider relationship is something I would love to see you think about.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay, thank you, that's helpful. There is actually a question about...it's actually about accounting of disclosures Paul if you remember that one.

Paul Egerman – Businessman/Software Entrepreneur

Yes I do.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

But that's helpful, Christoph, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Great, thank you. Troy?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Thank you, Paul. This isn't actually directed for you Deven, it's...Karen you triggered a thought in structuring the way the Workgroup should be managing, you know, the conversations and such and looking not so so much at what where at now but where we would hope to be.

One of the things that came up and I'm in the Interoperability Workgroup, patient matching, you know, it comes up over and over, and over again. Now we know that the basic demographics name, age, sex, where they used to live, where they live now, I mean, those are ways to verify the patient identity.

But in every healthcare environment we use a medical record number as the first source for patient matching and of course we use some secondary form of identification to validate that yes indeed I entered the number, this is the demographics, this is the patient on the screen now they're giving me a second form of identification now we've done true patient matching.

We began to discuss that aspect of it, having that national health ID but we were told to refrain from having those discussions and so I need clarity from somewhere, someone in this group that says, the reason we were told to refrain from it and not discuss that is because according to the laws and regulations HHS cannot talk about that and that because the FACAs are funding through HHS we were not allowed to talk about it either. So I'm just curious can anyone enlighten me?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So, every year for the past I think it's 14 years or more I don't remember exactly when it started...

Paul Eggerman – Businessman/Software Entrepreneur

In 1996.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Okay, so 19 years, Paul's been around even longer than me. Congress has...there is a requirement in HIPAA that HHS promulgate a unique patient identifier and then every year since 1996 in the appropriations bills there is a specific provision that prohibits the department from using funds, because it's an appropriations bill, to create a unique patient identifier. So there are some restrictions on what HHS can do in this space. And, you know, there are different interpretations as far as how far that limitation goes.

I personally don't believe that it prevents us from talking about the value of a unique patient identifier, because it's about creating a unique patient identifier, but there are some restrictions and so that's what you're hearing is that there are some limitations on how we can spend funds and that we cannot spend funds to create a unique patient ID as was required under HIPAA.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

One point of clarification Jodi, are they prevented from discussing it in the Workgroup and making a recommendation not us...is that the same as us working on creating one?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Well, we do, we support it, so if it was in...if the discussion was to recommend that we create a patient identifier I would say "yes" if it's to discuss the merits of a unique patient identifier which can be created by somebody else or how that might impact matching and that kind of thing I think that there is probably some room and we can come...if you'd like us to take a back I will, we will get a more specific opinion on any limitations that you all know what the line is, but I don't think it precludes any conversation but it does preclude us from creating a unique patient ID and I would assume that if there are recommendations to advise us to do that this could be problematic but...I think...

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

I think it would be more of a recommendation, you know, understanding the constraints that HHS is under and the ONC, it would be more of a recommendation that this is what is necessary to really reap the benefits of all the work that has taken place over the last 10, 15 years in terms of EHRs, adoption and interoperability and when you look at the aim statements really how we need to do it, this is one solid way of making sure that we do proper patient matching and identification in the realms of care.

So it would just be a recommendation that that's what we need not really a directive that says HHS needs to do this but at least get it on the table for a point of discussion and then allow the powers to be to work that through.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So we have history here Troy. We and Paul may remember, we took up the issue of accuracy in matching patients to their records of which we considered, you know, what does having a consistently represented identifier for patients what value does that bring so a whole set, there were hearings that the Tiger Team hosted in the Policy Committee issued consensus recommendations on how to improve patient matching.

I suspect that before we would go down the road of thinking what more we would do on this issue that we would recirculate what we've already said so that the newer members of the group can get up to speed on it and we can consider whether we're saying, you know, that's what we thought then but this group thinks differently or you know it was a whole body of work where we looked into, you know, what would be the value of having one, what is the cause of inaccuracy in matching, what promotes greater accuracy.

And on top of that ONC did a bunch of work on this issue as well fairly recently and made some recommendations. So, it's not untrodden territory, having said that it's an issue that just keeps...I feel like every meeting I go to on exchange it comes up again and again, and again so I'm not suggesting that it would be...I think Jodi's answer was spot on...the issue of a consistently represented identifier and its value in matching I don't think is off the table for us to talk about. It would be good to get clarification.

Paul Egerman – Businessman/Software Entrepreneur

Yes.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

It would be helpful to sort of have it build on what's come before.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, in fact as you said, I think it is a very good idea for that material to be given to this Workgroup because it's like one of the reason why I'd asked the question of Micky and Chris because I thought they were repeating some of the stuff that had already been done.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, we can do that.

Paul Egerman – Businessman/Software Entrepreneur

So, I think they could benefit from looking at some of that information.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, we'd be happy to distribute that again.

Paul Egerman – Businessman/Software Entrepreneur

We did look at it in a fair amount of detail.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And that reminds me too to remind all of us that this roadmap is a nationwide roadmap not an ONC roadmap. So, if there are actions that we think need to be taken and they couldn't be taken for some reason or another by ONC or even by HHS, or the federal government they're not off the table if it's a critical path item that we need to address I think this group were counting on helping us understand that.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good, thank you. Thank you, Deven and Stan. Oh, sorry, go ahead.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

It's not actually for you guys, it's more of a logistics question for ONC and I guess a little bit for the committee.

So, one of the things I think we're going to struggle with is the level of detail at which the Workgroup is going to operate and the recommendations we make and so I think we could use some guidance. It's a balance I think between what Terry Cullen said earlier, which is be practical, be specific, give me something I can use an act on and don't get too far into the weeds because the Policy Committee is often not really interested in all those weeds.

So if you guys have a sense of kind of the level of detail that you want feedback from the Workgroups that would be really helpful. I know the comments that we're getting, at least on the consumer side, are pretty detailed and so we just need to figure out what's useful to you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thanks for that question. We can work with the staff on that maybe I'll try to give an example and that will help us think through what that might look like. We actually had one today when talking about RLS but if you think that having APIs as a source of access to data for consumers I think y'all mentioned that earlier.

I wouldn't necessarily expect this Workgroup to define exactly, you know, whether that should be FHIR and when that should be matured and by which standards body, etcetera, but to say that this would be good and what kinds of data generally should be made available would be helpful compared with some of the more detailed standards.

And I think some sense of the realistic expectation of the healthcare marketplace and consumers for whether those would be things that would be useful in the shorter run versus the longer run and I'm specifically saying other healthcare because that's kind of the shorter time zone but then, is that a platform to go later. I hope that's helpful.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah, it's really helpful and I'll just ask you about one other example which is, you know, more of an approach, I think there are some areas where the plan would benefit from parsimony and you guys have asked for that too.

So, you know, is it...do you need us to say, look we think you can create parsimony by focusing here and that means you can remove, you know, C.2.4 through 9 or do you just want us to say focus here and anything else that doesn't look like this can go away and you'll figure it out. Do you understand what I'm saying?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Yes, sort of, I think that you're getting to this issues of is there...which was raised earlier if there are 36 critical action items and 20 of them are in the first three years, which are the most impactful. I'm going to talk about that in just a minute...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Not the "which" are most impactful but the exercise that we've been doing at HHS. So, I think, to be frank with you, it would be helpful if y'all could think about using whatever evaluation metric these are the things that we think would make the biggest difference in the marketplace.

I mean quite honestly it's the way we thought about the roadmap itself. Is what do we think are the major... what do you think would make the biggest difference, well we think it's the fact that we need to standardize standards because there are so many it makes it hard for people to work from a baseline and to collect once and reuse them in multiple ways for multiple purposes, it makes it...it creates less room for there to be innovation and the usability and the user interface because you're so worried about, you know, which of the standards you're going to make.

We thought that the right incentives to point to those standards and advance the adoption use of those whether that was through programs like Meaningful Use or beyond would be necessary to line up and the marketplace would have a big role to play in that.

And the third was that we needed to have a trusted environment where data was...I can't resist saying it, being collected, shared and used so that, you know, people had an understanding about all the nuances therein particularly around privacy and security but also, you know, understanding who is making decisions about data, who is at the table and how do we iterate that and expand it and how do we have a financial model that makes data available and makes it flow over time and do such with equity. So it was those three areas.

And then within it we've been working to figure out what we think are the most impactful...it would be sort of interesting to line that up with y'all, because we cannot do everything. We have to figure how we can get most of the way there with...meaning get there with...excuse me with a set of levers that are going to get us the most punch.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay and finally, we're going to hear from Karen giving us a briefing on the delivery system reform, she called it an exercise and we call it an initiative/effort, but this is really, really important and I'm not sure that the public understands how...this announcement was by Secretary on January 26th.

I think the if/when sort of question that uncertainty like with hybrids causes the market to sort of pause and that even if you want to act you don't. And so the Secretary answering the if/when question was really, really helpful I think to a lot of folks.

And I think the timeline that was set out the 30% in 2016 and 50% in 2018 is achievable, ambitious but achievable. And so this is an extraordinarily important effort and Karen has agreed to brief the committee because I think it does a lot to the pull side that we've always talked about, by Stage 3 we should be pulling towards the use of these systems not just been pushed into using them in the earlier stages of, for example Meaningful Use, but anyway, thank you Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you Paul, this is my first time sitting over here actually. Y'all look good. All right I asked if I could take some time to brief on this Paul thought it would be good for you all to have an update and so here I am.

This has been many months of work on the part of a really great team at Health and Human Services under some really strong leadership of Secretary Burwell about how to get to a delivery system that was better care, smarter spending and healthier people one in which we could build upon the successes that we have had particularly in the last five years related to what we have learned from the investments in the marketplace and in healthcare systems from the Center for Medicare and Medicaid innovation and what we have been seeing work in the private sector with new payment models and new delivery models and we can now have available with respect to the availability of information.

And maybe if you remember nothing else that I said I'm going to tell you kind of three big things and then we'll walk through these slides and I'll take questions and those are it is critical for you all to understand that we recognize that it's going to take at least these three things working together to advance better care for people in this country and better health ultimately so it's not just payment reform, it's not only better care models that we can innovate and expand upon and it's not just having the information available but those things are all intertwined.

It's also important for you to recognize that this is a conversation about mainstreaming. This is a conversation not about demonstrations or a grant program but a way that we make fundamental change in the ways that we are advancing care delivery in this country so that it is setting expectations and a clear pathway for providers and consumers going forward about what the world's going to look like and not be a grant program that is going to end or be something that we do on the side, all right so those are my three things, it all goes together and mainstreaming. And let me walk through the slides now.

So in essence, the three focus areas that we really wanted to focus on was where ways that we would change the way that we pay providers to change the incentives, allow for care to evolve and innovate, change the way we deliver care not in special models but in a more systematic fashion across the country and see that we could distribute information so it was available when and where it mattered most for people.

These three critical path areas we actually believe that we have the most need to emphasize the way we pay providers through the incentives space because we are one out of three dollars that are going out the door in this country or coming in the door depending on where are because we have a real opportunity to learn from what we have already done in the last few years with some new payment model testing and really because we've been asked by a lot of private payers and states to lead.

We've been asked to be more declarative about the direction that we're going and so we have spent quite a lot of time thinking about how we can promote value-based payment systems and what we would call alternative payment models but also linking all payments to value in some fashion and I'll get into our announcements in that area.

I do want this group to know though that though we are pretty focused on the Medicare fee-for-service system we have been thinking through how we can leverage the other opportunities we have at HHS whether that's through the work with our qualified health plans on the marketplace, whether that's through our work with states in Medicaid or even things like our Medicare Advantage Program and we're not finished there we know also that we have an opportunity with our partners in the VA, the DoD and the federal employee health benefits program as they purchase care through their various mechanisms to think about how we understand where the world is with alternative payment and value-based payment models and how we can advance that charge to give some certainty to the market about where things are doing and by when.

In the delivering care space we want to make sure we recognize that this is about, you know, coordinated care, better access to care, care that is more consumer centric and consumer focused, more convenient and that really doesn't necessarily have to be invented many people have invented that and they're living that every day it's just not ubiquitous and it's not the typical main way that folks are getting care. So this is really about encouraging this kind of service and being able to take it to scale.

It's also about not only being able to improve individual health but really thinking at the population health level and making sure that the skills and tools, and opportunities there to manage in that way and really doing everything we can to see that access to care is not hindered by any of our rules or structures but that this is getting to a place where once you have your insurance that you can get access to care in ways that are going to make sense for you culturally, linguistically, geographically, etcetera.

In the information space this has been of course about seeing that we're continuing to bring electronic health information to the point of care and allow it to be meaningfully used, certainly for Meaningful Use providers but as much as we can to start to consider ways that our efforts through things like the SIM state grant programs can advance adoption of electronic health information, health records for the rest of the care continuum to begin to move that data through interoperability, unlock it so that it can be used for small data, big data and long data to create a transparent marketplace where cost and quality information is available and makes sense to consumers, to providers, to payers, to business, to others who need that to make better decisions and do it in such way that it actually can help inform good decisions and then finally, to work in a space of better support for consumer and clinician decision-making, evidence-based decision-making at the point of care and at the point of self-management.

I want to just walk through a few of the higher level recent announcements that we've had. I just would tell this committee, and those listening, to notice that there is going to be an ongoing cadence of announcements around delivery system reform. The work plan that we've laid out does have some big impactful areas but where it makes sense we have been linking other announcements to delivery system reform and so you'll see that in the language of our announcements, press releases, blogs, rulemaking, etcetera.

Last fall we actually had our first big announcement related to delivering care and that was the transforming clinical practice initiative which is designed to support 150,000 clinicians, largely doctors, but other frontline providers to allow for them to adopt and adapt to alternative payment models.

This is an 800 million dollar investment to give hands on support through a series of technical infrastructures so that it wasn't that you were trying to figure it out yourself, but actually if there are best practices from which to learn or if there are ways that we could support and enhance the transition to alternative payment models or to more coordinated care we would be available to do.

These are...right now we're in the midst of sort of looking at people who have expressed interest in the program I won't go through this slide, but in the next few months we'll have the opportunity to talk about which of the providers we're going to be able to assist to help advance their care practices.

We got quite a lot of attention, and I think rightly so, for this work in announcing goals around payment reform. This is the centerpiece of what will be an ongoing conversation about how we can move towards linking payments to not just quality but really moving to alternative payment models.

What we said is that by 2018 50% of Medicare fee-for-service will be in alternative payment models and that working backwards by 2016 30% will be in alternative payment models.

For context, in 2011 we had no payments in alternative payment models and today we're at about 20%. So, we're working in that direction and we feel that we have a very clear pathway ahead to get there through payment mechanisms like accountable care organizations, patient-centered medical homes, bundled payments.

We have a related goal which is to see that we are linking by 2018 90% of our fee-for-service payments to quality or value and by 2016 85% to quality or value, we're actually around 80% today. So we're getting close to that number.

Part of this slide where it says categories two through four is a reminder to point you all to a paper in JAMA that Dr. Patrick Conway and others wrote which describes the four categories one being fee-for-service, two being linked to quality, three and four being alternative payment models but the fourth category being one in which there is...you're lifted off, if you will, of the fee-for-service payment chassis and is really a population-based payment the three and four with some shared risk.

Another point about that is it's not a continuum you don't have to move from 1 to 2, to 3, to 4, there are certainly organizations that have jumped from 1 to 4 that would be less likely than jumping from say 2 to 4 but we don't want people to think that you must move across that continuum it's really just a way to describe payment.

These are internal goals for us at HHS but we have very clearly said that we need the private sector and Medicaid to come along, we need this because we need doctors, hospitals, the provider community to have some certainty about what's the business model in which they're going to work in the future.

That invitation for them to participate has translated into us creating a learning and action network, we'll have our first public meeting of this, first meeting of it March 25th, which is just coming up here in Washington at the White House. There will be some in person but then it will also be available for webinar and we're just starting to send out the notices and invitations so we can share that with the committee if there's interest.

This is...the learning and action network is a table that we're assuming that will help us first of all get some alignment with private payers, Medicaid in particular those two other major payer buckets to think about what is an alternative payment model to ascribed to our categories and then to work through some of the important technical issues whether that's...what are the right quality measures, how do we get to place that we don't have 1000 quality measures but some things that really matter and how can we align that providers across the various payers, how we handle risk adjustment, what is the attribution expectations just to give you all some examples.

Also within this space will be our opportunity to think about how these value-based payment models can help advance another important part of our work here to advance delivery system reform which is to see that we unlock data and make it available so that it can be used for payment reform, for population health improvement, for individual care decisions and for consumer self-management and decisions.

We released the same week that we announced the payment goals, the interoperability roadmap as a key portion of advancing the information stream of work around the delivery system reform effort. As you likely notice in the document there's a lot of pointing back to the fact that we need to have, for example, a supportive business, clinical and regulatory environment and one in which the public and private payers are advancing interoperability in a variety of ways, and we need to have a clear set of standards so that we are collecting things once and not having to multiple collect but can really reuse.

I mean you guys know this, if you want to take value-based payment to scale or alternative payment models to scale you can't be doing that on paper charts, you know, we're going to have to have a way that we can have this as an automated part of the workflow.

We don't want to crush the clinical experience we want to make it seamless but we also need to have data so that we know if we're getting better and so that the dashboard is measurable in a systematic way not only for a person over time but for communities and for larger populations.

So my last slide is really about sort of next steps and what you can do, before I get to that I just want to go reiterate what I said at the outset, please remember that this is about fulfilling this expectation that people should have access to affordable quality care that means we need to...we believe we need to then change the way we're paying for care that is the business model so that we can have the kind of delivery model or care model that people want to practice and that the data shows consumers and patients enjoy. And we need to have a data model that can support that in seamless way and frankly to Health IT platform that can help us innovate care delivery on top of it and make care that much more accessible.

We are absolutely asking for organizations, for states, for private payers to set their own goals for payment and where they would like to get and what they think they could accommodate and how quickly.

We want to certainly be able to spotlight care innovation models and understand what the data is telling us about what works and what doesn't work. This is an area of care delivery where I have a lot of personal experience and I know sometimes that I think people know this every day in their own experience that very often unfettered by concerns for example around fee-for-service and volume driven models, really wonderful team-based care can evolve and it's a lot more person-centered than the kinds of care that we often have to experience in this country and it's really what the Secretary wants everyone to be able to have is that kind of coordinated, secure, safe, accessible experience that really makes them feel a part of their care and not of where.

We are, as I said, launching the healthcare payment learning and action network March 25th and that will be, as I said, some in person but available also through a webcast for the morning sessions and we expect to be some commitments, etcetera from partners in the private sector and beyond.

And then for our purposes in this committee and for this constituency of folks it's really helpful to continue to get feedback about the roadmap and about the standards advisory.

It would be...I would not be doing the Secretary a service if I didn't emphasize to you all how important this is to her that we get this, what she calls the dictionary, right the basics, the fundamentals about the standards and how we're defining the data elements that we think will really matter to advanced better care for people to help them be more engaged to see that their information is there when and where it matters to them and that we are unlocking this data in a way that it's not trapped and unavailable for whoever needs access to it.

So this is...we have to get this piece right because it's a really important part of the puzzle and we have to do it...I'm sorry to tell you expeditiously not only because she's expecting it, but because the country is expecting it, I say this so much but it really is urgent business and so I appreciate y'all being willing to work on hard and fast timelines.

We need to be able to show some results so we can continue mainstreaming and taking these things to scale. We can keep building on this over time and that is probably my final comment which is if you...of all the important elements of this delivery system reform effort the fact that we've identified our critical pathways, that with action plans to work on them that are getting more and more defined longitudinally we really want this to be in partnership with the states and the private sector and we want this to be something that is durable beyond our time in this administration.

This needs to give some certainty to the marketplace meaning the healthcare marketplace that things are going in a certain direction that people can count on it that they can build their business and delivery model and data models in such a way that this is going to really get us to some more stability of a place that we're going so that's the reason we've set our sights well beyond when we're likely to be here. Thank you and I'll stop there and be happy to take in the questions.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you, Karen. David Bates?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Thanks, Karen. We were obviously really excited about Secretary Burwell's announcement. Can you say more about what makes you confident that this is an achievable goal because it seems like a stretch to many of us?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you for the question and, you know, we have a roadmap around the payment reform that spells out for us what needs to happen by when within our portfolio of responsibilities at HHS particularly related to the Medicare fee-for-service that looking at accountable care organizations, the patient-centered medical home type primary care payments and bundled payments where we are in the cycle of what we've learned from the Innovation Center and what is working and the interest in an opportunity to expand ACO models but other models it seems that it doesn't seem, we believe that we have a clear pathway to get there and I think if you weren't certain it could be evidenced by the fact that we've gone from 0 to 20 in a couple of years and we're on a pathway to get to 30.

She was very clear with us that she wanted to know that we would have a way to get there and that this would be not an empty promise but a real pathway to the future and working this through with the private sector and the states is going to be able to layer on top of that the revenue for providers such that it's not just a Medicare revenue but more beyond that.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

The more you can be transparent about pathway is down the road...

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Sure.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

The easier it will be for us to kind of make the leap. In our own organization we talk about this all the time and there is still a lot of people who want to hang back and I would like to see us move forward but it’s hard.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

I understand and we can get into some more specificity upcoming and maybe what would be helpful is as we are making announcements just to make sure I spotlight that for the group, I think you understand there is so much that we can say, but we will be...that’s part of the reason to point back to this fact that, well this rule has come out and its delivery system reform but we have some language for example in the rules around our qualified health plan right now that is asking them about how much of their payments are in alternative payment models.

You’re going to start seeing some private prayers and Medicaid programs coming forward as an additional add-on so that will be add on to what we’re doing going forward but it’s a great point about cataloging it David. I don’t know if that was on your mind too, but we should find a repository where we can let folks know what all is beginning to lineup from a payment stand-point and fall into these kinds of buckets so that it’s more clear to the outside world.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

I think the pointer system...just like I think it was the same day that you put out the interoperability roadmap you had a reference to the goal but if it isn’t called out then we won’t build, build, build in our own organization to just educate them on see it’s really happening and these are all the steps that are coming into place.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

That’s really helpful.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Anjum?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you, Karen and this is obviously fantastic in terms of a plan that is really thinking of the delivery system transformation and thank you for your own leadership and you making a lot of this happen.

But our experience from, you know, beacon communities and other such programs where we are thinking of system transformation especially focused on population health improvement, etcetera, shows that there is still a need for a shared IT infrastructure for making a lot of this happen.

But at the same time, you know, if you think of shared IT infrastructures like information exchanges that are community information exchanges there is still a big question mark in terms of sustainability of a lot of those programs. We just completed a study recently, a national study, we looked at 60 HIEs that were fully operational and most of them are struggling financially but also they are not collecting some of the measures that will eventually make the business case for that. So, there is still a gap in terms of time.

So, as you think of the timeline of making this happen at the same time the investments that have been made in, you know, community shared infrastructure or that will be made in the community shared infrastructure still is a question because if I recall correctly even in the practice transformation funding there is some restriction in terms of what can be spent on just ITs infrastructure it's 10% or something, it's a low number. So, does that...in your planning does that seem to be something that the Policy Committee would generally have to address nationally?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

I believe it's one of the central questions that we have to address and its part of the circular conversation that we have when we get into the governance discussion, how are we going to...it's one thing to say that we should, it's another thing to ask how.

There are some models that are more sustainable, some of them have a public utility flavor, some of them are leaning also on private payers as a mechanism not to pay for the infrastructure but in some cases for example to pay the providers to participate and that gets to data trust and use.

So, as we're working on the governance model that includes the sustainability in this learning and action network will be also an ongoing conversation with the private payer states and others who are going to participate in these Workgroups, but this stream of discussion about...if we are going to have this infrastructure so that data can move so that we can reduce redundancy and waste also have an opportunity for shared measures and metrics and the kinds of quality reporting and the transparency that will be necessary that the funding has to come from someplace and I think the long-term model can't be grants it's got to be something that is more part of the...work of business.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

David Lansky?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Well, Karen I'm sure you can imagine for purchasers that I work with this is music to our ears it's really wonderful stuff, very strong signal, as you said, one out of three dollars of purchasing dollars are federal and the remainder are coming from other private purchasers and state purchasers.

So it raises for me the opportunity that we have to...as we come back to the use case issue and the roadmap and other places, give fresh attention to the purchaser requirements as part of those use cases to the extent as it is true of public dollars you have the opportunity through HHS to drive a lot of this transformation through incentives and signals of various kinds and we can align that with private sector incentives and signals but we need this robust information infrastructure to support the value assessment which is then used for payment and we have a long way to go to get there. So I hope we can take this impulse, this new agenda to come back around to the work we're doing here and looking at the purchaser requirements as high-value in supporting that infrastructure.

The second thing I want to say that was signaled by other people I think and to David's point, there's going to...probably like your...from category one to category four, level one, level four payment models, this may not all be incremental and comfortable to achieve this goal and do it as rapidly as you and the Secretary would like will be disruptive, uncomfortable and require boldness and that may mean, and I take this fairly simple example, but one that's on my mind, patient reported outcome measures and functional outcome measures we've been talking about 20 years, we've made very, very little progress at achieving implementation of those at scale to achieve a mainstream opportunity to pay people who achieve good outcomes.

That might require a really bold step to say we are definitely going in this direction we're going to assert an expectation that were going to measure and report on quality in that way for certain categories of service and disease, that will be uncomfortable for a lot of people and they'll say it's too hard, it's too fast as we've seen with even Meaningful Use.

So, I just want to say on behalf of the private sector I think there is a great impatience and willingness to be more aggressive about those bold objectives and we could find ways to have that conversation to move quickly in that direction.

And the last point is I think the quality measurement piece you've mentioned a couple times, we gave a lot of attention to that in this committee for the first three or four years and we've pretty much passed it off and we may want to think about does this is committee need to look again at quality measurement strategy in light of this initiative.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

There's a lot of great things in what you just said there David. I might respond to a couple. One is about the discomfort as you move to alternative payment models and it depends on the organization and exactly which payment model or what are the many folks are engaged in. I'm keenly aware that more certainty will be better because then people can really make longer-term plans, people being organizations.

On the other hand there's going to be a lot of tough ones inside of organizations about the dollars that are coming in and some harder decisions about whether there's less money for more work or more work for the same money or how we're going to define work, that will be helped somewhat by the TCP/IP grants so really a lot of this is going to have to be worked out inside of organizations and the rapidity of the payment changes may or may not come crashing into it, you know, it's an end of one but our experience in this in New Orleans was new payment model we evolved pretty quickly to team-based care in medical homes and then pretty quickly evolved when it was taken away.

Actually if you talk to just about any patient-centered medical home demonstration in the country they would have a similar experience is that it's easy to move into a new care delivery model when your business model changes now with certain big organizations you have to ensure money.

I just want to say something too though about...so we recognize that we haven't solved it, we want to sort out what's the best way to help and support is what I want to say and maybe I should emphasize this piece too, David, was that I said to some of the group earlier it's really important for the provider voice, the physician voice, the nurse voice others to be heard in this because if we just do a payer voice or purchaser voice we're going to really miss how this feels the down line logistics of it and we don't want that to happen.

With respect to the rapidity of change, we also are paying attention to not leaving folks behind. And there is the risk that small organizations, rural organizations, safety net providers may not be included in new models for whatever reason and so it's an area of attention for us and one that we certainly don't want to lose sight of because this is about every American not just about those that are living in communities where they already have ACOs.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, thanks. Christine?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Thank you, this was really helpful. Karen, I had a question, I guess I was surprised to hear you say that today 80% of payment is tied to value. I was really, really surprised with that. Can you talk a little bit more about like...

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Yeah and fee-for-service, what that means? I'm thinking particularly of ambulatory care where a lot of the consumers experience things and I'm thinking, really, because they're really behaving like fee-for-service.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

So, think about the Meaningful Use program which is technically tied to quality or things that folks do or PQRS or some of the value-based payment programs. So there are in hospital payments mostly all are linked in some way to outcomes in performance and they're a huge part of the payment continuum. The same thing with providers not all of them but individual professionals linked, so it's still fee-for-service but there's a quality modifier generally in some sort.

So, you're right as long as you're in that category two it's still a fee-for-service model, it's just got nuance to it because you're having to demonstrate that you're able to measure and report on quality in some fashion and there's generally some sort of a reward or a penalty based upon the results of those findings.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Right, so is it part of the vision or where is it part of the vision to shift the fee-for-service payment more towards outcomes because I think that's what a lot of us are hoping for and counting on and I get it, but I think, you know, particularly in an ambulatory environment PQRs reporting only...and there isn't quite the public transparency around that data as there is in some hospital compare for example and it's a challenge and so it's still not quite paying for things like care coordination, right, where, you know, and care planning. I mean, we've the new care management fee, but is that part of the vision is shifting more towards outcomes and not just reporting on things that have value and some of it is sort of questionable value but more like high-value outcomes?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

I'm going to say yes with a caveat.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

So, I'll channel Patrick Conway right now as best I can which is to say that yes we need to move to measuring outcomes, yes we need to not only have macro alignment of the measures and more parsimony in what we're selecting to mark improvements, but we need to have micro alignment back to your point and there needs to be eClinical quality measurement and they need to be not sort from the paper world. So those three things are happening.

A definition of what are the right measures, lots of input coming from that, Institute of Medicine, National Quality Forum tables that are being set it will be a part of learning and action network, what is the set of things that are going to make the most sense for the care space, what are the outcomes-based ones that really matter, attention, keeping us straight about the fact that it's not just what matters to the payers or the purchasers, the health system but to the people who we're there to serve.

And then the piece about, you know, lining all that up so that you're not the San Diego Native American Health Center, you know, reporting on GPRA and UDS, and Meaningful Use and PQRs...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Right, sure.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And everything else and you can't keep up with it. And then figuring out how it's just abstracted that is going to take a little time, that's the caveat piece that I just I think is a reality. As fast as we all want to move and it's important as that is it's probably sequential for some of those things to happen.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Questions comments? I just wanted to echo David Bates and David Lansky a bit. You asked for the providers to help support this and I think from the provider setting we would love to and I think one of the things that David mentioned is the unwavering certainty in the messaging and the constant tide back would be really helpful both in the public and the private sector because that certainly drives a lot of change.

And then to echo what David Lansky was saying it's not necessarily just the eQM it's really the PROs the things that would turn people's heads in a different direction that's the kind of pull that we need. I think a lot of organizations are having to make their own quality measures just to sort of try to point...so the more reinforcement and the consistent message and the prevalent and predominant message along with the real goal that we all shoot for, for our dashboards would be really helpful, but, I mean, we're all appreciative of the stakes that have been laid in the ground in terms of timing it's been very helpful. Thanks for the update, Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you. Thank you, all.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay I think we're ready for public comment, please.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Paul. If there's anybody in the room that would like to make a public comment please come up to the table and Alan can you please open the lines?

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While we wait for public comment our next meeting is April 7th and it will be here in person and we'll get a report out in more detail on the interoperability roadmap. And we have no public comment.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, well, thank you everyone for attending and participating this month and I think Deven said we're going to have cherry blossoms for the next meeting. So, thank you.

Deven McGraw, JD, MPH, LL.M. – Partner – Manatt, Phelps & Phillips, LLP

I wouldn't hold my breath because you never know with those things, but it would be nice.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

We should have pushed it back a little bit.

Public Comment Received During the Meeting

1. It would be interesting to know what vendor functionality the hospitals are using for specific measures. For example, what vendor are critical access hospitals using that are successfully sending a Summary of Care and View, Download and Transmit. It is apparent that these vendors are doing something correctly and that should be shared.
2. Can she please go over the EP Stage 2 attestation numbers again? How many EPs have attested to Stage 2 , how many used the flex rule, how many are being penalized.
3. Is there anyone at this meeting that is an actual EP provider "front line" and practicing in the current HIT environment? Seems like everyone at this meeting is backslapping and congratulatory and do not ask hard questions.
4. Why is the HIT vendor not in the stakeholder list?

Meeting Attendance						
Name	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14	11/04/14
Alicia Staley	X				X	
Anjum Khurshid	X	X	X	X	X	
Aury Nagy					X	
Charles Kennedy		X	X	X		
Chesley Richards	X			X		
Christine Bechtel	X	X	X	X	X	
Christoph U. Lehmann	X			X		
David Kotz	X	X	X	X		
David Lansky	X	X	X	X	X	
David W Bates	X	X	X			
Deven McGraw	X	X	X	X	X	
Devin Mann	X	X	X	X	X	
Gayle B. Harrell	X	X	X	X	X	
Karen Desalvo	X	X	X	X	X	
Kim Schofield		X	X	X	X	
Madhulika Agarwal						
Marc Probst	X	X	X	X	X	
Neal Patterson		X	X		X	
Patrick Conway						
Paul Egerman	X	X	X	X		
Paul Tang	X	X	X	X	X	
Scott Gottlieb		X	X			
Thomas W. Greig	X			X		
Troy Seagondollar	X	X	X	X	X	
Total Attendees	17	17	17	17	14	0